HEALTH FOOD MANUFACTURERS' ASSOCIATION

CODE OF ADVERTISING PRACTICE

Updated October 2019

Buckinghamshire&Surrey trading standards

PRIMARY AUTHORITY ADVICE

Buckinghamshire and Surrey Trading Standards have assessed the HFMA 'Code of Advertising Practice' who have demonstrated that their activities are organised in such a way as to ensure that it provides a high level of quality in its compliance services which include the labelling and advertising of food supplements, foods and cosmetic products in the UK.

If HFMA members follow this Primary Authority Advice, we are of the opinion that their quality systems in relation to the 'Code of Advertising Practice' would be appropriate for maintaining compliance with regards to labelling and advertising of food supplements, foods and cosmetic products in the UK and therefore should be respected by local authority officers within trading standards.

Buckinghamshire & Surrey Trading Standards have not assessed the part of the Code of Advertising Practice that covers medicinal and homeopathic products and further 'advertising controls covered by specific bodies ASA, UK Advertising Codes, UK Code of Non-broadcasting advertising & UK Code of Broadcast advertising.

Buckinghamshire and Surrey Trading Standards will not support enforcement authorities within England & Wales who pursue enforcement action relating to the aspects of the 'Code of Advertising Practice' that we have approved.

Buckinghamshire County Council

SURREY

HFMA Code of Advertising Practice
October 2019 Edition

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INTRODUCTION

The Health Food Manufacturers' Association (HFMA), founded in 1965, is the authoritative and responsible voice for the UK natural products industry and promotes, protects and defends the general interests of members of the industry and promotes high standards of product manufacture and presentation to ensure consumer safety, responsible and informative communications and compliance with applicable legislation. We represent around 125 manufacturers and suppliers of specialist health products, notably food supplements, herbal products, natural remedies, sports nutrition products, natural cosmetics and health foods.

This Code, administered by HMFA CLEAR CHECK® accredited compliance service[1], was established as a focus for industry self-regulation in terms of product advertising and promotional standards. The underlying principle of the Code is for labelling and advertising to be presented in a considered, fair, legal and truthful manner.

Compliance with this Code of Advertising Practice, in spirit as well as in principle, is a condition of HFMA membership. With the exception of broadcast advertising, members are required to submit product labels and advertising to the public for pre-vetting by a CLEAR CHECK™ Code Administrator, as follows:

- labelling and advertising materials for food supplements
- labelling and advertising materials for 'functional foods' (foods associated with health claims)
- labelling and advertising materials for foods for specific groups
- labelling and advertising materials for cosmetic products
- advertising materials for licensed medicinal products (includes those with marketing authorisations, registered traditional herbal medicines, homeopathics, products with licences of right)

The principles of the Code apply to all advertisements, including those directed to the trade and health professional, and, whilst pre-vetting of these materials is not mandatory, it is strongly recommended that they also be submitted.

In the case that copy has been vetted and agreed by an alternative association or regulatory body, evidence of this must be provided. Evidence of MHRA authorisation is required for medicinal products.

Submitted copy is treated as confidential and is not disclosed to anyone outside CLEAR CHECK™ without prior permission.

The Code Administrators provide comprehensive advice on all aspects of materials that fall within the scope of the Code, including the labelling and advertising of food supplements, foods and cosmetics, and the advertising of medicinal products in the UK. The focus of the service is on assisting members to present their products within the established legal framework and industry

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[1]Surrey and Buckinghamshire Trading Standards have assessed HFMA 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". Contact HFMA CLEAR CHECK® for more details.

codes and guidelines. General guidance on classification and determining suitable claims for products outside the scope of the Code may also be provided on request.

For the purposes of the Code, the term ‘advertising’ means the making of a representation in any form in connection with a trade, business or profession in order to promote the supply of goods or services and includes:

- magazine and newspaper advertising (text and illustrations)
- leaflets, brochures and direct mailings & other electronic or printed material
- advertorials
- posters
- point of sale materials
- television and radio commercials
- product-related websites
- on-line advertisements
- video and audio tapes/discs
- press releases
- films and other recordings
- verbal representations by commercially interested parties
- on-line marketing communications (e.g. social media content) which falls under the control of the marketing company

There are many other areas for which the manufacturer or distributor is legally responsible, related to, for example, product safety and manufacturing practices that are not covered by the Code. Companies should make sure they are conversant with applicable legislation, and clearly understand their responsibilities in this regard. A company is responsible for ensuring that all applicable legal requirements are complied with.

To complement the Code and assist members, various guidance notes, including for example on the labelling of food supplements, have been compiled; these are available to members via the HFMA website.

REGULATORY CONSIDERATIONS

The labelling and advertising of health products is covered by general legal provisions, as well as specific European and national legislation appropriate to the product category. In addition, printed media and broadcast advertising is controlled by various statutory and advisory bodies. Manufacturers, suppliers, advertisers and their agents are responsible for acquainting themselves with and conforming to the legal requirements in force at any time.

A brief summary of the regulatory requirements related to the labelling and advertising of relevant legislative categories is provided below. For further help with determining which regulations may apply contact the CLEAR CHECK™ office.

Foods & Food Supplements

The principal regulations that apply to the presentation (which includes labelling and advertising) of all foods, including food supplements and 'functional foods', to the UK market are The General Food Law Regulation (EC No. 178/2002), The Food Safety Act 1990, The Food Safety and Hygiene (England) Regulations 2013, The General Food Regulations 2004 and The Food Information Regulations 2014 (which establish and enforce EU Regulation No. 1169/2011 on the provision of food information to consumers).

Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (General Food Law Regulation) is directly applicable EU legislation. The Regulation defines a food as '*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*.
The Regulation also sets out what is not considered to be a food, which includes medicinal products.

The Food Safety Act makes it an offence to falsely describe or present a food or sell food which is not of the nature or substance or quality demanded by the purchaser; The General Food Law Regulation requires that the labelling, advertising and presentation (which includes the setting in which the food is displayed) of the food should not mislead the consumer.

The Food Safety and Hygiene (England) Regulations provides for the enforcement of certain provisions of Regulation 178/2002 and for the food hygiene legislation.

The General Food Regulations provide the enforcement of certain provisions of Regulation 178/2002. It also amends the Food Safety Act 1990 to bring it in line with Regulation 178/2002.

The EU Food Information to Consumers Regulation (EU FIC) sets out the labelling information which must be provided to the consumer and how that information must be presented. The advertising of food products is also covered by the regulations.

The EU FIC makes it an overarching obligation of a food business operator to comply with all relevant EU and national food labelling requirements and to check that those requirements are met.
The food business operator (FBO) under whose name the food is marketed is primarily responsible for the food information and for checking its accuracy, however, every FBO in the supply chain

must also take responsibility for ensuring the information is accurate and must not supply food which they know or presume to be non-compliant.

The EU FIC prohibits references to the prevention, treatment or curing of disease in labelling or advertising.

Food information must be accurate, clear and easy to understand and must not be misleading, particularly;

- As to the characteristics of the food; relating to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production;
- By attributing to the food properties or effects which it does not possess;
- By suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specially emphasising the presence or absence of certain ingredients and/or nutrients;

General labelling requirements:

- Name of the food [name required by law – prescribed or customary or descriptive name]
- List of ingredients
- Indication of allergenic ingredients or processing aids, or those derived from allergens (the name of the allergen must be emphasised within the ingredients list)
- The quantity of certain ingredients or categories of ingredients (QUID)
- The net quantity of the food (l, cl, ml, kg, g as appropriate; for the UK market food supplements in tablet/capsule form may be sold by number)
- The date of minimum durability
- Any special storage conditions and/or conditions of use
- Name or business name and address of the UK or EU food business operator
- The country of origin or place of provenance (not required in all circumstances – consult regulation)
- Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
- For beverages containing more than 1.2% by volume of alcohol, the actual alcoholic strength by volume
- A nutrition declaration (for foods this must follow the format prescribed by EU Regulation 1169/2011; for food supplements the declaration must comply with the requirements of the Food Supplements Regulations.) A few exceptions apply, e.g. food from small local manufacturers, table top sweeteners, chewing gums – contact CLEAR CHECK for more information.
- A batch/lot number

Additional labelling particulars are required in certain circumstances, for example for products containing sweeteners, those with added caffeine.

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

The name (name required by law) and quantity declaration must be provided in the same field of vision.

For products presented to the UK market labelling information must be provided in English, however details may also be provided in additional languages on a voluntary basis (where space permits).

Food Supplements

Food supplement labelling and advertising is principally governed by the EU FIC Regulation and The Food Supplements (England) Regulations 2003 (FSR); the latter implement the Food Supplements Directive (No. 2002/46/EC; FSD).

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 or powders designed to be taken in measured small quantities*.

In parallel with the labelling requirements of the EU FIC Regulation, the Food Supplements Regulations require the following mandatory particulars:

- The prescribed name, Food Supplement
- 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.
- 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 the product stored out of the reach of young children
- The amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product
- The latter information shall –
    - Be given in numerical form
    - For vitamins and minerals, given using the relevant unit specified in the accompanying schedule to the Regulations
    - Be the amount per portion of the product as recommended for daily consumption
    - Be an average amount based on the manufacturer's analysis of the product
    - Include a declaration of the percentage nutrient reference value (% NRV) for those vitamins and minerals for which reference intake values have been established

Additional cautions/warnings may be required; e.g. herb contra-indications; cautions relating to iron, vitamin A & vitamin K; DH agreed advisory statements triggered by high levels of certain nutrients. **The provision of the last two sets of label cautions is mandatory for HFMA members.**

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.

Under the requirements of the FSD, minimum and maximum levels for vitamins and minerals will be set at some stage; **until such a time as these are agreed members should adhere to the HFMA guidelines on recommended upper levels for supplementation**.

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).

Fortified Foods

Where vitamins and minerals are added to foods EC Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods applies.
The Regulation applies to ordinary foods to which vitamins and minerals have been voluntarily added, for example breakfast cereals, energy bars, and sports nutrition foods.

The Regulation:

- defines the purposes for which addition of vitamins and minerals is allowed
- lists permitted vitamins and minerals and their source substances which may be added
- sets criteria for the establishment of maximum and minimum levels of vitamins and minerals *(this will be carried out in conjunction with those to be established for food supplements)*
- lays down the requirement for the establishment where necessary of purity criteria for the vitamin and mineral substances
- lays down specific labelling requirements, including compulsory nutrition labelling
- prohibits the addition of vitamins and minerals to fresh produce and alcoholic drinks
- lays down criteria for the control of other substances - by way of prohibition or restriction (for example by limiting levels) or by placing 'under scrutiny'*

  **The Regulation introduces the possibility to put under scrutiny and, if necessary, to restrict the use of substances added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption as part of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.*

The provisions regarding the addition of vitamins and minerals do not apply to food supplements or foods for specific groups; however, the provisions relating to the control of other substances **do** apply to these categories.

Foods for Specific Groups

Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (Food for Specific Groups Regulation - FSG), which repealed EC Directive 2009/39/EC (Foods for particular nutritional uses, PARNUT), came into force on 20th July 2016.

The Regulation provides a new framework establishing general provisions for the following categories of foods, which are considered as essential for certain vulnerable groups of the population:

- Infant and follow-on formula
- Processed-cereal based food and other baby food
- Food for special medical purpose
- Total diet replacement for weight control.

The Regulation abolishes the concept of 'dietetic' food and establishes a single Union list of substances that can be added to these foods including minerals and vitamins.

From 20 July 2016, young-child formulae and food intended for sportspeople are exclusively covered by horizontal rules of EU food law. The rules on gluten-free foods & very low gluten foods are transferred to EU FIC Regulation, whilst meal replacement products intended to replace one or two meals in the daily diet and presented as contributing to weight loss or maintaining weight after weight loss (i.e. not those intended to replace the total daily diet) are now regulated under Regulation (EC) No 1924/2006 on Nutrition and Health claims.

Most vitamin/mineral supplements, conventional foods bearing a nutrition claim such as 'low-salt', 'reduced-salt' or 'low-fat', and conventional foods containing added vitamins or minerals are not considered as falling under the remit of FSG.

In regards to labelling, presentation and advertising the general provisions of the EU FIC Regulation apply; however, specific compositional and information requirements have been implemented through Delegated Acts for infant formula and follow-on formula (applicable from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, which apply from 22 February 2021), food for special medical purposes (applicable from 22 February 2019) and for total diet replacement for weight control (applicable from 27 October 2022). The Delegated Act for processed-cereal based food and other baby food has not been finalised yet; thus, rules remain under Directive 2006/125/EC until they are adopted.

Various FSG foods must be first notified to the competent authority before placing on the UK market.

Further legislation relating to foods and food supplements

Nutrition and Health Claims made on foods Regulation (NHCR)

Regulation No 1924/2006 applies to all nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.
Commercial communications includes all forms of labelling and promotion material, such as catalogues that make claims for products, advertising, consumer leaflets and product websites. Product names, brand names and trademarks which may be construed as nutrition or health claims fall within the scope of the Regulation.
The Regulation applies without prejudice to all foodstuffs including drinks, food supplements and foods for particular nutritional uses.

Only authorised health and nutrition claims are permitted; the EU Register of Claims lists all authorised and non-authorised claims and the conditions of use which apply.
Health claims should only be made for the nutrient, substance, food or food category for which they have been authorised and not for the food product that contains them.

Certain types of claims are prohibited by the Regulations.

When a health claim is made the labelling, or if no labelling exists, the presentation and advertising must include:

- A statement indicating the importance of a varied and balanced diet and a healthy lifestyle
- The quantity of the food and the pattern of consumption required to obtain the claimed beneficial effect
- Where appropriate a statement addressed to persons who should avoid using the food

- An appropriate warning where there may be a health risk if the product is consumed to excess

Plus

- Nutrition labelling for a food must be presented in conformity with the mandatory nutrition declaration under EU FIC Regulation (No 1169/2011)
  Where the claim relates to a substance that cannot be included in prescribed nutrition labelling the indication of the amount of the substance to which the claim relates must be clearly separated from but in the same field of vision as the nutrition information

- Nutrition labelling for a food supplement must follow the manner laid down by the Food Supplements Regulations

The wording of authorised claims is not prescribed and the regulation does allow for a degree of flexibility of wording provided any alternative wording conveys to the consumer the same meaning as the wording of the authorised claim.

The Novel Foods Regulations 2018

Implementing Regulation (EU) 2015/2283

The EU Regulation repeals and replaces Regulations (EC) 258/97 and (EC) 1852/2001, which were in force until 31 December 2017.

Foods and food ingredients new to the EU require pre-market approval.

A novel food or food ingredient is a food/ingredient not consumed to a significant degree in the European Union prior to 15 May 1997 and that falls under at least one of the following categories –

- Food with a new or intentionally modified molecular structure (where that structure was not used as, or in, a food in the Union before 15 May 1997)
- foods consisting of, isolated from or produced from micro-organisms, fungi or algae
- food consisting of, isolated from or produced from material of mineral origin
- food consisting of, isolated from or produced from plants or their parts, except where the food has a history of safe food use in Union and is consisting of, isolated from or produced from a plant variety of the same species obtained by traditional propagating practices which have been used for food production in the Union before 15 May 1997; or, non-traditional propagating practices which have not been used for food production in the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances
- food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production in the Union before 15 May 1997 and the food from those animals has a history of safe use within the Union
- food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae
- food resulting from a food production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances
- food consisting of engineered nanomaterials (as defined in the Regulation)
- vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation 1925/2006 or Regulation 609/2013, where a production process not used for

food production in the Union before 15 May 1997 has been applied; or they contain or consist of engineered nanomaterials
- food used exclusively in food supplements in the Union before 15 May 1997, where it is intended to be used in foods other than food supplements

Authorisations are generic as opposed to the applicant-specific authorisations under the old Novel Food regime. Any food business operator can therefore place an authorised Novel Food on the European Union market, provided the authorised conditions of use, labelling requirements, and specifications are respected.

Individual authorisation of a novel food can be granted when based on newly developed scientific evidence and proprietary data, and is limited in time to five years.

A centralised authorisation procedure managed by the European Commission applies.

Safety reviews are centralised and conducted by the European Food Safety Authority.

Authorised novel foods are included in a Union list. Once a novel food is added to the Union list, then it is automatically considered as being authorised and it can be placed in the European Union market.

Traditional foods from countries outside the EU, which are considered novel foods in the EU, can be notified under a simplified procedure, which assesses the safety of the traditional food taking account of evidence of a history of consumption in the third country, and lack of safety concerns raised by the EU countries or EFSA.

The Organic Product Regulations 2009

These Regulations implement into the UK the EU framework of organic standards, which include:

- Regulation (EC) No. 834/2007 on organic production and labelling of organic products
- Regulation (EC) No. 889/2008 laying down detailed rules for the implementation of Regulation (EC) No. 834/2007 with regard to organic production labelling and control
- Regulation (EC) No 1235/2008 laying down detailed rules as regards the arrangements for imports of organic products from third countries

Food business operators in the EU who produce, prepare, store, import from a non-EU country, export to a non-EU country or market organic products must register with a control body in the member state in which they are situated and comply with the control system for organic production.

There are special labelling provisions for organically produced foods including details of the organic content and inclusion of the code number of the relevant control body.

The Genetically Modified Foods Regulations 2004 and The Genetically Modified Organisms (Traceability & Labelling) Regulations 2004

These implement, respectively, EC Regulations 1829/2003 and 1830/2003

Particular labelling requirements apply where a food contains or consists of a GMO or is produced from a GMO, regardless of the presence/absence of novel DNA or protein; their presence has to be highlighted on product packaging. The labelling rule does not apply to ingredients produced with GM technology (e.g. a vitamin produced with a GM enzyme).

Specific 'vertical' food regulations

For certain foods, such as cocoa, chocolate, honey, fruit juices and jams, specific regulations covering all aspects of their production, and which may include labelling requirements, apply.

Medicines

The Medicines and Healthcare Products Regulatory Agency (MHRA), an executive agency sponsored by the Department of Health, is the authority responsible for the regulation of medicinal products in the UK, including classification and product licensing.

The regulatory requirements for labelling and advertising of medicinal products are dependent on the type of authorisation granted, as outlined below.

Marketing Authorisation (MA), previously known as Product Licence (PL)

Products with marketing authorisations (full product licences) are controlled principally by the Human Medicines Regulations 2012. Claims are limited to those within the terms of the marketing authorisation.

Traditional Herbal Registration (THR)

This form of authorisation applies to herbal medicines that are to be used to relieve the symptoms of/treat minor health conditions where medical supervision is not required (e.g. colds) and where the plausibility of effect is based on a documented history of traditional use rather than clinical evidence.
Claims are limited to those of the registration and must make clear they are based upon traditional use.

Homoeopathic Certificates of Registration (HR) [Simplified scheme]

These registrations are issued in accordance with the simplified scheme allowed under The Human Medicines Regulations 2012
The simplified scheme does not allow therapeutic indications.

Homeopathic National Rules Marketing Authorisations (NR)

Under this scheme, regulated by the Human Medicines Regulations 2012, it is possible to claim that the product is used within the homeopathic tradition for the relief or treatment of minor symptoms or conditions that do not require the supervision of a doctor.

Product Licence of Right (PLR)

Product licences of right were issued to medicinal products on the market at the time the Medicines Act 1968 was implemented in 1971. A small number of products, including some homeopathic products have retained product licences of right.
These products do not fall within the scope of the Human Medicines Regulations 2012 but remain subject to the provisions of the Medicines (Labelling) Regulations 1976, the Medicines (Advertising of medicinal products) (No. 2) Regulations 1975 and the Medicines (Labelling and Advertising to the Public)Regulations 1978. Product indications are limited to those within the terms of the licence.

The packaging and patient information leaflet of licensed medicinal products must be submitted to and approved by the MHRA prior to use. This requirement does not extend to advertising, which is, in the main, controlled under a long-established system of self-regulation.

Cosmetic Products

Cosmetic products are regulated by EC Regulation 1223/2009, implemented in the UK by the Cosmetic Products Enforcement Regulations 2013.

The Regulation defines a cosmetic product as '*any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membrane of the oral cavity with a view to exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours*'.

The following mandatory labelling particulars are required:

- Name and address of responsible person
- County of origin for products imported into the EU
- Nominal content (weight/volume)
- Date of minimum durability (with applicable symbol) or for products with a minimum durability of more than 30 months the 'period after opening' symbol with time frame indication
- Any required cautions
- Batch number or means of lot identification
- Function of product, if not obvious from the presentation
- List of ingredients, using INCI names, under heading 'Ingredients'

Where there is both outer and inner packaging, all of the above, apart from the ingredients list must be provided on both the product container (inner package) and the outer packaging; the ingredients list can be omitted from the inner container label.

EC Regulation 1223/2009 requires the designation, in the EU, of a responsible person for every cosmetic product placed on the EU market.
The responsible person must take responsibility for ensuring that the cosmetic products they place on the market comply with the requirements of the Regulation.

Prior to placing a cosmetic product on the market, the responsible person must first notify the Commission via the electronic notification portal.

The Regulation does not include any specific requirements relating to the advertising of cosmetic products; however, claims made for a cosmetic product are required to comply with the common criteria for the justification of claims that have been established by the Commission.
Claims made in advertising are subject to the general consumer advertising requirements.

Special Note: Aromatherapy Products
Formulated aromatherapy products with a cosmetic function are subject to the Cosmetic Products Regulations described in the previous section.
Pure essential oils not presented for medicinal or cosmetic use, fall within the scope of the General Product Safety Regulations 2005.

Consumer Protection legislation

Various pieces of legislation are in place designed to protect the rights of consumers, including The Consumer Protection from Unfair Trading Regulations 2008 (CPRs) [which implement the Unfair Commercial Practices Directive, 2005/29/EC]. These regulations control unfair practices used by traders when dealing with consumers and create criminal offences for traders that breach them.

The Regulations prohibit;

- 31 specific practices which are always considered unfair – such as claiming false endorsement or authorisation; misleading availability; misleading effect (which includes false claims that a product has curative properties)
- Misleading actions and omissions that cause or are likely to cause the consumer to take an alternative decision - such as deceiving the consumer by the provision of false information; creating confusion with competitors products; omission of material information; providing material information in an unclear, unintelligible and ambiguous manner
- Aggressive practices

The CPRs are amended by the Consumer Protection (Amendment) Regulations 2014, which introduce the right of the consumer to claim for redress when misleading actions or aggressive practices by businesses have been found to have occurred and to have caused them harm.

[Advertising to businesses is covered by the Business Protection from Misleading Marketing Regulations 2008. Advertising must be accurate and honest and not make misleading comparisons with competitors, for example by using a competitor's logo or trademark, or something very similar; comparing your product with a competitor's product that is not the same.]

BORDERLINE ISSUES

The regulatory environment for specialist health products is complex. A particularly difficult area is product classification - products with health properties often fall into the grey area between licensed medicines and other product categories and hence are commonly known as 'borderline products'.

Under the current regulatory regime products must be sold under one classification only, e.g. as a food, medicine or cosmetic. The legal classification impacts heavily on the advertising and promotion of the product, particularly in relation to the nature of the claims that may be made.

The area of borderline issues deals with determining which aspects of formulation and presentation are acceptable for foods or cosmetics (and other categories such as medical devices and biocides) and which will cause the product to 'cross the line' into the realm of medicinal products.

The following are examples of factors that can have an impact on determining whether a product should be marketed as a food, cosmetic or medicinal product:

- Effect/mode of action on the body
- Site of application (only relevant to the cosmetic/medicines borderline)
- Direct and implied claims on product and in advertising
- The properties of and history of use of the ingredients
- The form of the product e.g. pharmaceutical form such as tablets and capsules, or 'food' form
- Manufacturer's intended purpose for the product
- Target audience
- The presence of essentially similar licensed products on the market

The overall impression of the product's presentation is an important consideration including the impression that is likely to be gained by the 'averagely well-informed consumer'.

The Medical Products Directive (No. 2001/83/EC) states that in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a medicinal product and within the definition of a product covered by other Community legislation, medicinal legislation takes precedence.

A medicinal product is defined as:
Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;
Or,
Any substance or combination of substances which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Only one limb of the definition need apply for a product to be considered a medicinal product. This means that the presentation of a product alone is sufficient, regardless of the formulation or whether the product is capable of fulfilling a therapeutic action, to determine status. The reference to the modification of a physiological function in the second limb can be interpreted as applying to a very broad range of actions on the body.

The term 'disease' is generally interpreted in the Human Medicines Regulations 2012 as including ‘any injury, ailment or adverse condition, whether of body or mind’. Thus, any adverse physical or psychological condition could be considered as falling within the broad definition of disease, including for example, stress, anxiety and jet lag.

The MHRA’s policy and practice on borderline products is explained in their publication Guidance Note 8 – ‘A guide to what is a medicinal product’ (Examples of words and phrases that would generally be understood as indicating medicinal use are listed in an appendix to this document).

The MHRA has also produced guidance documents on ‘Borderlines between medical devices and medicinal products’ and ‘Borderlines with medical devices’.

The European Commission has produced a number of documents to assist the application of EU legislation in borderline cases, for example, a ‘Manual on the scope of application of the Cosmetics Regulation’ (April 2018), a guidance document on the demarcation between cosmetic products and medicinal products legislation, and, guidance on the borderline between medical devices and medicines (MEDDEV 2.1/3 rev.3).

RESPONSIBILTIES, ENFORCEMENT and CONTROLS

Medicines Law

Borderline determinations

The Borderline Section of the Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for determining whether a given product that is not already appropriately authorised as a medicinal product is indeed a medicinal product and consequently subject to the formal licensing procedures.
The majority of cases are brought to the MHRA's attention from competitors, from local authorities, other regulatory bodies, trade associations and members of the public.

Determinations are considered on a case-by-case basis taking into account all relevant factors including precedents from case law determined by both the ECJ and domestic courts.

In many cases the borderline section will work with a company to resolve a particular issue without the need to resort to formal procedures however where applicable, the statutory procedures laid down by The Human Medicines Regulations 2012 for the issuing of determinations will be followed. The statutory procedure for the determination process includes the provision of applying for referral to an Independent Review Panel to hear written and oral representations against provisional determinations.

Final determinations issued by the borderline section are published on the MHRA website.
Failure to comply with the outcome of the determination procedure is a criminal offence.

Medicines advertising

The control of medicines advertising is based on a long-established system of self-regulation, supported by the statutory powers of the MHRA.
Medicines legislation makes it the responsibility of 'any person' who promotes a medicine, including the licence holder, a private individual or any third party such as a journalist, publisher or public relations agency, to ensure compliance with the legislation.

The MHRA has the powder to require sight of advertisements in advance of publication. The MHRA also carries out monitoring of medicines advertising and investigates complaints from any source (including healthcare professionals, public). These roles are carried out by the MHRA Advertising Standards Unit.
Advertising can also be investigated by other organisations, such as the Advertising Standards Authority and Association of the British Pharmaceutical Industry (the latter in regards to advertising for prescribed medicines).
The decisions made by the MHRA on adverts reported to have breached legislation are published monthly on the MHRA website.

The MHRA can also resort to formal statutory procedures either in the form of notices issued at any stage during the investigation or through enforcement and prosecution.
Where determination notices are issued, the advertiser may make written representations to an Independent Review Panel for consideration.
Failure to comply with the outcome of the determination procedure is a criminal offence.

Food Law

The Department for Environment, Food and Rural Affairs (Defra) is responsible for food labelling legislation in England that is principally not about food safety; Defra also co-ordinates food labelling policy across government.
The Food Standards Agency (FSA) is responsible for food safety, and for working with enforcement authorities to make sure food law is applied throughout the food chain.
The Department of Health and Social Care (DHSC) is responsible for nutrition information policy.
For Northern Ireland, all domestic labelling and standards legislation is the responsibility of the FSA.
In Wales, responsibility for general labelling requirements rests with the FSA and responsibility for nutrition labelling lies with the Welsh Assembly Government.
Responsibilities in Scotland lie with Food Standards Scotland (FSS).

The enforcement of regulations on food standards, safety and hygiene is primarily the responsibility of local authorities trading standards departments (or their equivalent).

The Food Information Regulations 2014 introduce improvement notices (except in Scotland), which can be applied where there is a failure to comply with legislative requirements, however non-compliance with the allergen labelling rules remains a criminal offence.
It is an offence to fail to comply with an improvement notice.

For food safety offences the courts may impose a fine or in certain instances a period of imprisonment.

Cosmetics Law

The Office of Product Safety and Standards, part of the Department for Business, Energy & Industrial Strategy is responsible for product liability and safety law, including the implementation of legislation relating to cosmetic products.
Local Authority Trading Standards (and their equivalents) are responsible for enforcing the legislation.

It is an offence to supply a cosmetic product that may cause damage to health, or that contains restricted or prohibited substances, or that is incorrectly labelled. It is also an offence not to undertake certain safety assessments and to compile technical documentation.

Further Advertising Controls

As well as the controls imposed by specific areas of legislation relating to food, medicines or cosmetics, other legislation is relevant to the advertising of such products, including The Consumer Protection from Unfair Trading Regulations, The Broadcasting Acts and Communications Act.

Consumer Protection Regulations

The CPRs are enforced by the Competition Markets Authority or Trading Standards (and equivalents in Northern Ireland and Scotland).
A breach of the Consumer Protection from Unfair Trading Regulations 2008 is a criminal offence.
The maximum penalty on conviction is an unlimited fine and two years' imprisonment.
Enforcers may take civil enforcement action in respect of a breach of the CPRs under Part 8 of the Enterprise Act 2002. This can be done by applying to a court for an enforcement order and a breach of any order could lead to up to two years' imprisonment and an unlimited fine.

UK Advertising Codes

The Codes set the standards for the advertising self-regulatory system which is based on an agreement between advertisers, agencies and media owners. The Codes lay down the rules to follow.

The Committees of Advertising Practice (CAP) write and maintain the Codes, which are administered and enforced by the Advertising Standards Authority (ASA).
The ASA investigates complaints and can take steps to remove or have amended any ads that are considered in breach of the rules. Where complaints require formal resolution, rulings are published weekly on the ASA website.

CAP regularly monitors ads on TV, radio, the internet and in national and local media and can follow up ASA rulings to ensure compliance. CAP can take action against advertisers that continue to place ads that repeatedly break the Code or seemingly refuse to work with the self-regulatory system, which can include the advertiser being required to seek CAP advice before publishing future ads for a specified period. CAP also provides advice and guidance on how to create advertisements that comply with the rules.

UK Code of Non-broadcast advertising
The Code applies to non-broadcast marketing communications which includes a wide spectrum of materials (e.g. newspaper ads, catalogues, posters, cinema ads, online ads in paid for space, sales promotions, advertorials, ads & marketing communications on a traders own website).
The Code does not apply to some forms of advertising including claims in marketing communications in media addressed only to medical, dental, veterinary or allied professionals that relate to those practitioners' expertise; live oral communications; point of sale displays.

Besides general rules on advertising, the Codes includes specific rules on particular sectors including medicines, foods, food supplements, health-related and beauty products, weight control and slimming.

UK Code of Broadcast advertising
The Code applies to all advertisements (including teleshopping, content on self-promotional television channels, television text and interactive television advertisements) and programme sponsorship credits on radio and television services licensed by Ofcom.
Rules specific to certain sectors such as medicines, foods, food supplements, beauty products are incorporated within the Code.

Broadcasters must ensure that all advertisements are cleared before broadcast.
Special category radio advertisements, which includes those relating to foods, food supplements, medicines, health and beauty products and treatments, must be cleared centrally by RACC (Radio centre).
Television advertisements are required to be reviewed by Clearcast.

HFMA CLEAR CHECK® will, upon request, provide preliminary advice on advertising copy before the materials are forwarded to the appropriate clearance centre.

PROCEDURE FOR HFMA CLEAR CHECK® REVIEW OF MATERIAL

Submission of material

Submissions of labelling and advertising material for review should include, as appropriate/applicable:

- A copy of the material including visuals (which may be in outline form)
- Details of approval of the relevant material from another UK self-regulatory body, certification body, MHRA or trading standards office, if applicable
- A full quantified list of all ingredients if the product is not licensed
- In the case of advertisements, an indication of where the advertisement is to appear or how it is to be distributed or presented
- For medicinal products, a copy of the relevant parts of the product licence/registration. Any subsequent variation/s made by the licensing authority must also be notified
- Any other information that impacts on labelling which would not otherwise be known, for example, the presence of irradiated ingredients in foods, novel food status

Substantiating evidence for claims must be supplied for consideration upon request by a Code Administrator.

Process and scope of review

The material submitted is reviewed by a Code Administrator for compliance with the principles of this Code of Advertising Practice, with reference to:

- the relevant labelling or advertising regulations
- the terms of the marketing authorisation or product licence/registration, where applicable
- government and industry guidelines
- other relevant codes of practice

Advice on any required/recommended alterations is then provided. Where available, the Code Administrator will provide guidelines and checklists on subjects relevant to the material submitted. In the case of issues not clearly defined in the regulations, current industry practice and the current approach of the authorities are taken into account to determine the suitability of a proposal.

Note that the following areas are not routinely considered as part of the review:

- accuracy and efficacy of formulation, except in relation to appropriateness of claims
- the safety of ingredients and finished product
- the accuracy of declared quantities in final product
- the accuracy of GM status claims and other negative-presence claims
- the determination of novel ingredient/food status
- the content of any referenced websites, publications or similar [separate review of these materials can be carried out]

Agreement and the review stamp

When agreement has been reached on suitable copy, the copy is returned stamped with a reference number.

The review stamp conveys compliance with the principles of the HFMA Code of Advertising Practice and is provided based on current scientific opinion and current regulatory and industry practice.

Until a body of case law has been built up to form the basis of an authoritative statement, advice on the law and application of the regulations can be given as informed opinion only.

The review stamp does not constitute an endorsement or approval of the product or services offered, nor should it be regarded as a guarantee of the legality of the product. It remains the responsibility of the manufacturer/supplier/importer to ensure that the product placed on the market meets its claims.

Appeals

In the event that agreement cannot be reached with the Code Administrator, an appeal may be made to the Advertising Committee, with whom ultimate responsibility for interpretation of the Code rests.
Appeals applications should be directed to the HFMA Executive Director at Head Office, with notice given to the Code Administrator concerned. Strict confidence is maintained throughout the proceedings.

Resubmission

Copy should be resubmitted for review every two years if it is still in use. At times, changes in the law, codes of practice or interpretation may necessitate an earlier review.

CHARGES

An hourly consultation rate is applied to all HFMA CLEAR CHECK® services, billed in 15 minutes increments. Telephone discussions and product-related meetings of longer than ten minutes duration (5 minutes for non-members of the HFMA) are chargeable at the hourly rate.

Details of the current fee structure may be obtained by contacting the HFMA office. Any changes made are notified by the HFMA Secretariat.

Invoices are issued monthly for payment within 30 days of the invoice date.

HFMA CODE of ADVERTISING PRACTICE

PRINCIPLES OF THE CODE

1. General

1.1 The Code is applied in spirit, which means that the intention behind the principles as well as the exact wording is taken into account. It is not enough that there is an interpretation of the presentation of material that meets the requirements of the Code; no reasonable interpretation should contravene it.

1.2 Information provided should not be misleading, for example by the inclusion of false or exaggerated information. Misleading information in one part of an advertisement is unacceptable even if it is modified or contradicted in another part, including illustrations.

1.3 Information should not deceive the consumer, even if the information is factually correct, for example by the omission of material details, or exert undue influence, causing the consumer to take a different action.

1.4 Information should not claim or infer that a product has particular characteristics or functions which it does not in fact possess.

1.5 Labelling and advertising materials should be easy to understand and clearly legible.

1.6 All descriptions, claims and comparisons which relate to any objectively ascertainable facts must be capable of substantiation.

1.7 Material must be prepared taking the perception of the receiver into account. The impression obtained from a quick glance is considered along with that obtained from a detailed reading. Images, illustrations, sounds, shapes, the wording chosen and the use of emphasis are examples of the factors considered to determine the overall impression gained from the material.

1.8 Advertising should be set out taking account of the principles relating to taste and decency, should not be offensive and should not exploit the lack of knowledge or experience of the reader (e.g. by use of complicated scientific terminology).

1.9 Unsolicited questions from journalists, health practitioners, the trade or members of the public may be replied to truthfully and fully, either verbally or by a personal letter. However, responses to solicited enquiries are considered extensions of advertisements and the usual restrictions apply, including the prohibition on medicinal claims for unlicensed products. Solicited enquiries include those resulting from telephone help-lines or ‘further information’ offers on labels or in advertisements.

1.10 No labelling or advertisement should encourage or condone, directly or indirectly, the indiscriminate, unnecessary or excessive use of the product in question.

1.11 Advertisements must be clearly distinguishable from editorial matter, for example by labelling as an advertising feature or advertorial.

1.12 Advertisements for products must not be placed or accepted on the basis that they are to be positioned in juxtaposition to editorial matter which suggests that the products are suitable for purposes for which they may not be advertised.

1.13 No advertisement shall denigrate or attack unfairly any other products, goods, individuals, competitors or services.

1.14 No advertisement shall denigrate orthodox medicine or orthodox drugs.

1.15 Advertising shall not suggest that normal good health can be affected by not taking the product.

1.16 Advertising shall not suggest that the effects of taking a product are guaranteed.

1.17 Advertising should not be directly targeted at children or induce children to ask their parents or other adults to purchase the advertised product for them.

1.18 Advertisements should not falsely represent the business as a consumer (for example; a company website carrying comments supposedly from consumers but which have been drafted by employees of the business).

1.19 Information provided in labelling and advertising must not claim or imply copy has received approval or endorsement by the HFMA.

1.20 Advertising should not bring the health products industry into disrepute.

2. Claims and Comparisons

2.1 Unlicensed products, including food supplements, must not be presented for medicinal use in labelling, advertising or promotion. This prohibition also applies to advertisements addressed to the trade. Words, phrases or visuals must not claim or imply the treatment, cure or prevention of any ailment, illness or disease.

2.2 Exaggerated claims, direct or implied, are not acceptable. Words such as 'magic', 'mystical', 'miracle' or 'wonderdrug' should not be used.

2.3 Negative claims, that is claims that a product does not contain a given ingredient, should only be used in cases where the ingredient mentioned is likely to be found in similar products and should not be given in a manner which gives the impression that the ingredient is generally unsafe or harmful.

2.4 Slogans and abbreviated claims which, because of brevity or for any other reason, are capable of misinterpretation shall be used only in association with copy that clearly indicates their meaning.

2.5 No advertisement shall, by statement or implication, suggest that a product contains some unknown active principle.

2.6 Advertisements should not suggest that the safety or efficacy of a product is due to the fact that it is ‘natural’.

2.7 Care should be taken in the use of the word 'natural' or similar terms, used unqualified to describe a product or its ingredients. Made, or derived, from natural sources, may be the more appropriate description. In advertisements for products which combine ingredients from natural sources with synthetic ingredients, the term 'natural' must be used only in reference to those constituents to which it applies.

2.8 Advertisements should not imply that a product is wholly or mainly of a herbal nature unless the active ingredients consist wholly or mainly of parts of plants.

2.9 A product described as 'unique' should have properties or active ingredients which set it apart from others in the market.

2.10 A product may not use the word 'new' for more than one year following introduction to the market. To justify such a description the advertiser must be able to demonstrate the existence of real novelty in effect or formulation or presentation.

2.11 Medicinal and food supplement products may be described as palatable or nice to eat, provided this is purely to inform the consumer and not couched in terms which might encourage excessive or unnecessary use of the product.

2.12 No claims that the taking of a product is unaccompanied by side effects may be made. This does not prohibit claims that a product does not cause specified side effects (such claims must be backed by robust and suitable evidence). Claims should also take account of any side effects of the non-active ingredients.

2.13 No claim shall be made based on the fact that a product is legally available without a prescription.

2.14 All comparisons shall be balanced, fair and supportable. Comparisons shall not unfairly denigrate or discredit a competitor product, ingredient or treatment. Superiority claims must be supported by direct comparative tests or similar and where applicable make it clear the aspect of the product or marketers performance that is being claimed to be superior.

2.15 Comparisons with identifiable competitors should be between products meeting the same need or intended for the same purpose and should be based on objective criteria (one or more material, relevant, verifiable and representative feature, e.g. price, market share, quality) and be presented in a manner which does not mislead. Consumers must have access to the information on which the comparison is made.

2.16 Comparisons that do not identify the product which is being compared, such as comparisons between a marketers own products should be clear, fair and not misleading.

2.17 Subjective claims should be clearly set out as representing the views of the individual or business.

2.18 Advertising should not describe a product as ‘free’ or similar if the consumer has to pay anything other than the unavoidable cost of responding to the offer and the collection or delivery of the product.

2.19 Green/environmental claims must be clear, accurate, relevant and not misleading and presented in a manner which indicates if the claim applies to the complete product, a component of the product or to the packaging.

3. Endorsements, Testimonials and Recommendations*

3.1 An advertisement for a food or food supplement product should not suggest that the product is recommended by a member of the medical, dental, pharmaceutical or related professions. Illustrations of any person who might appear to be a doctor, dentist, pharmacist, nurse or member of any related profession are not permitted.

3.2 Recommendations or endorsements of food products by national associations of medical, nutrition or dietetic professionals and health-related charities may be permissible where relevant national rules apply.

3.3 Recommendations from medical, para-medical or scientific specialists on a cosmetic ingredient or product or a general message on hygiene or beauty are acceptable, provided they are established on the basis of adequate and appropriate evidence.

3.4 Any material in testimonials which is contrary to this Code must not be used.

3.5 Marketers must hold documentary evidence that a testimonial or endorsement is genuine and retain contact details of the person who provided it. Permission for use of the testimonial must be obtained.

3.6 Copies of testimonials must be made available if the Code Administrator requires them.

3.7 Testimonials and copies of press articles may not be used to make claims for a product which the advertiser himself may not make.

3.8 Testimonials should represent the genuine views of the user. If the testimonial is shortened, care should be taken that the original meaning is not changed in any way.

3.9 The writers of testimonials may not be identified as members of any of the health care professions.

3.10 Use of symbols or logos must not imply that a product has achieved the required relevant third-party endorsement when it is not the case

[***Medicines Law prohibits the inclusion of testimonials or other promotional material in labelling and package leaflets of medicinal products]***

4. Promotional Activities for Unlicensed Products

4.1 Any material that accompanies or is available in association with unlicensed products, in any commercial setting, should not make claims which are not permitted for the product or its components [for example; a book written by a 3rd party which discusses lifestyle choices relating to disease risk reduction but which is placed next to commercial product; the

availability of clinical scientific papers on a commercial website marketing food supplements]

4.2 If the labelling or advertisement for a product also mentions or offers for sale printed or electronic material (e.g. a book, disc or similar), or includes an internet address or quick response code, the content of the relating information will be treated as an extension of the advertisement and subject to the same rules.

4.3 Printed or electronic material making generic claims may not be placed in a commercial environment in juxtaposition to (or in association with) a product for which the claims made by the accompanying copy could not be made.

4.4 Seminars held to describe the medicinal properties of generic substances must not refer to or depict products and this includes product displays, product give-aways and the presence of catalogues or other advertisements for products. The advertisements for the seminar may not mention or depict products.

4.5 Articles, brochures, hand-outs etc. by companies describing the medicinal properties of generic substances, must not mention or be associated in any way with products.

4.6 Products that are not medicines should not be grouped together with medicines under any general indication such as 'Herbal Remedies' which could give the impression that they are medicines. This applies in all retail situations, including on commercial websites.

5. Principles Specific to Foods and Food Supplements

The principles detailed in sections 1-4 of the Code also apply to marketing communications relating to food supplements

5.1 Any fancy name used in addition to the legal name must not make a prohibited or misleading claim for the product.

5.2 Trade-marked/brand names that can be construed as a nutrition or health claim may be used if authorised or accompanied by a relevant authorised claim. However, products bearing trademarks or brand names which do comply with applicable legislation but which existed before 1st January 2005 may benefit from a defined transition period (to 19th January 2022) after which time the appropriate legislative requirements will apply.

5.3 Terms such as 'natural', 'fresh' and 'pure' should be used in accordance with guidelines issued by the UK competent authorities from time to time.

5.4 Industry agreed warnings for food supplements containing certain ingredients, including vitamin A, vitamin K and iron, are to be applied as appropriate.

5.5 Advisory statements as agreed with the UK competent authority for food supplements containing high levels of certain vitamins and minerals are to be applied as appropriate.

5.6 Only permitted nutrition claims and authorised health claims may be made, in accordance with applicable legislation or in line with any guidelines issued by the UK competent authorities.

5.7 Health claims should only be made for the nutrient, substance, food or food category for which they have been authorised and not for the food product or food supplement that contains them.

5.8 A degree of flexibility of the wording of health claims is allowed, provided that its aim it to help consumer understanding, taking into account factors such as linguistic and cultural variations in the target population. Where alternative wording is used it should convey to the consumer the same meaning as that of the authorised claim.

5.9 General and non-specific health claims, such as 'supports well-being', 'hair care' can be made but only where accompanied by a relevant authorised health claim.

5.10 Where a health claim is made the product label, or if none the product advertising, must make clear the importance of a balanced and varied diet and healthy lifestyle.

5.11 Claims should not imply that normal foods cannot provide a healthy diet or that there is widespread vitamin or mineral deficiency.

5.12 Advertisements and labelling for food supplements should avoid any suggestion that supplements can take the place of a well-balanced diet.

5.13 Food supplements may be presented to safeguard nutrient levels in the diet but advertisements should not suggest that it is necessary for ordinary healthy adults to supplement their diet.

5.14 The labelling, presentation and advertising of food supplements shall not state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

5.15 Health claims must not make reference to the rate or amount of weight loss.

5.16 Health claims which make reference to recommendations of individual doctors or health professionals and associations other than national associations of medical, nutrition or dietetic professionals and health-related charities to which national rules apply, are prohibited.

5.17 Claims which compare the nutritional content of a food supplement with a food (e.g. Supplement X provides as much vitamin C as 4 oranges) are not permitted.

6. Principles Specific to Cosmetic Products

The principles detailed in sections 1-4 of the Code also apply to marketing communications relating to cosmetic products

6.1 The cosmetic function of the product, unless obvious from the presentation or advertising copy, must be clearly stated.

6.2 Claims made in the presentation and advertising of a cosmetic product (e.g. labelling, name, trademark, text, graphics and visuals) should not state or imply that the product has functions or characteristics which it does not possess.

6.3 Medicinal claims should not be made for a cosmetic product, however, claiming a secondary preventative purpose for a cosmetic product may be feasible in certain circumstances; the use of such claims will require to be assessed on a case-by-case basis.

6.4 Claims that no animal tests have been carried out are only permitted if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished cosmetic product, or its prototype, or any of the ingredients the product contains, or used any ingredients that have been tested on animals by others for the purposes of developing new cosmetic products.

6.5 Claims, either direct or implied, for a cosmetic product must conform to the list of common criteria developed by the European Commission: legal compliance, truthfulness, evidence support, honesty, fairness and informed decision-making, and associated best practice guidance for claim substantiation evidence.

6.6 The responsible person for a cosmetic product is obliged to ensure claims are justifiable.

6.7 Words such as 'cosmeceutical', which makes a pharmaceutical implication, should be avoided.

6.8 Claims regarding the efficacy of sunscreen products are required to take account of the recommended principles adopted by the European Commission.

7. Principles Specific to Medicinal Products

The principles in sections 1-3 of the Code should also be taken into account

7.1 General Principles on Advertising and Promotion to the Public

7.1.1 Advertisements which offer to treat cancer, or to prescribe a remedy for its treatment, or to give advice relating to treatment are prohibited.

7.1.2 Advertising to the public for a prescription only medicine (POM) is not permitted.

7.1.3 Advertising must be set out in such a way to make it clear that the message is an advertisement and that the product is a medicinal product.

7.1.4 Claims made in advertisements must be consistent with the product's Summary of Product Characteristics and must not promote a medicine for uses outside the scope of the therapeutic indications listed on the approved SPC or data sheet. This includes claims relating to the clinical effect of the product as well as claims relating to speed, mode and duration of action etc.

7.1.5 Advertisements should not refer to any medicine as 'essential'.

7.1.6 An advertisement for a medicinal product should not contain a suggestion that it is recommended by a member of the medical or allied health professions, by scientists, or by persons who are none of these but who, because of their celebrity could encourage the consumption of medicinal products.

7.1.7 No advertisement should suggest that a medicinal product is a foodstuff, cosmetic or other consumer product. It is acceptable to indicate that a product is palatable but the advertising shall make it clear the product is a medicine.

7.1.8 An advertisement for a medicinal product should not suggest the effects of taking a medicine are better than, or equivalent to, those of another treatment or medicinal product, if it is possible to identify the brands being compared.

7.1.9 Advertising shall not contain any offer to diagnose, prescribe or treat by correspondence, telephone, facsimile or electronic communication.

7.1.10 Advertisements should not suggest that health can be enhanced by taking the medicinal product or that health could be affected by not taking the product.

7.1.11 Advertising should not state or suggest that the effects of taking a medicinal product are guaranteed.

7.1.12 Advertisements should not encourage unnecessary, indiscriminate or excessive use of any medicine.

7.1.13 Advertising shall not contain improper, alarming or misleading claims of a recovery.

7.1.14 Advertising should not suggest that a product does not have any side-effect or that its safety or efficacy is due to the fact it is 'natural'. It is acceptable to indicate the absence of a specific side effect if that effect is common amongst other, similar products.

7.1.15 Advertising shall not in any way tend to induce unjustified concern that the reader is suffering from any illness, ailment or disease, or that without treatment they may so suffer or suffer more severely.

7.1.16 Advertising shall not contain any material which gives the impression that a medical consultation or surgical operation is unnecessary. It shall not discourage those who see it or hear it from seeking medical advice.

7.1.17 Advertising shall not be directed exclusively or principally at children (under 16's).

7.1.18 No advertisement for a medicinal product should contain material which might, by a description or detailed presentation of a case history, lead to erroneous self diagnosis.

7.1.19 Advertisements should not imply, directly or indirectly, that the normal incidents of the human condition, such as fatigue or irritability, require continuous treatment by medicines.

7.1.20 Advertisements should not use, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body, or parts thereof.

7.1.21 Care should be exercised to ensure that advertisements do not cause lay persons to be confused by the use of medical or invented terminology or other information unsuitable for the lay public.

7.1.22 In the case of promotional aids to the public, without claims, which serve solely as a reminder (e.g. t-shirts, pens, mugs) then only the brand name need be listed i.e. the general information for advertising is not required.

7.1.23 Medicines shall not be promoted to the public with the offer to refund money to dissatisfied users.

7.1.24 Supply of samples of medicinal products for promotional purposes, by the licence or registration holder and anyone acting on their behalf (e.g. distributors), by pharmacies, retailers or similar forms of commercial undertaking and those acting with their consent or on their behalf, to any member of the public, is prohibited. This includes the provision of vouchers/coupons to enable the consumer to obtain product for free or at an unreasonably low cost.

7.1.25 Advertisements should not state that a product has been approved or endorsed by the MHRA or Department of Health or any other relevant body. Advertisers may state that a medicinal product is licensed or authorised.

7.2 Essential information in consumer advertising

Consumer advertising for medicinal products must incorporate the following. This does not apply to products with Product Licences of Right (PLRs), Homeopathic products registered under the Simplified Scheme, or materials without promotional claims (i.e. those just bearing the brand or product name):

a) The name of the product.

b) Information necessary for correct use of the medicinal product, i.e. the product indications, or at least one indication for use, consistent with the SPC plus any additional information specifically required for the product.

c) The name of the active ingredient (if the product contains only one active ingredient). Provision of a pack shot which is sufficiently large enough for the active ingredient to be clearly legible fulfils the requirement. If the product name includes the name of the active there is no need to list the active ingredient separately.

d) A clear and legible instruction to 'always read the label' if the label carries full consumer information. If information is instead provided on an in-pack leaflet, advertising copy must direct the consumer to 'always read the leaflet'.

Essential information must be clearly legible, placed prominently, be in a print size in proportion to the rest of the copy and placed horizontally.

7.3 Additional principles specific to Traditional Herbal Medicines (THMs)

7.3.1 Advertisements for THMs must make it clear that the product is a traditional herbal medicine.

7.3.2 All advertisements for THMs must include the following statement:
'Traditional herbal medicinal product for use in *[specify one or more indications for the product consistent with the terms of the registration*] exclusively based on long standing use as a traditional remedy.' [When placed in the body of the advertisement rather than as a footnote this text meets with the requirement to include an indication of use of the product]

7.3.3 Advertising for THMs must reflect the approved indication, accurately and in its entirety, for the product and not mislead the consumer as to the benefits that can be obtained from using the product.

7.3.4 Claims must be clearly set out in the context that the indication is based exclusively on longstanding use [e.g. traditionally used as a remedy for xx; long history of use as a traditional remedy for xx]

7.3.5 Advertising for THMs must not mislead consumers regarding the strength of supporting evidence for the therapeutic benefits of the product. Claims such as 'effective for' or 'clinically/scientifically proven', 'relieves xx' are unacceptable.

7.3.6 Advertising must not state or imply that a THM has been granted a marketing authorisation or that the benefits of the THM are comparable with those of a medicine which has a marketing authorisation. It is acceptable to state that a THM is a registered or authorised traditional herbal medicine.

7.3.7 Claims that a herbal medicinal product is 'organic' may only be made for products that have been certified by an approved Certification Body as meeting organic standards applicable to the production of herbal medicines.

7.4 Additional principles for Homeopathic Medicines registered under the Simplified Scheme or authorised under National Rules Scheme

7.4.1 **Homeopathic products registered under the Simplified Scheme**

(a) The content of advertising is limited to the information that is permitted for inclusion on the product label [Ref: Schedule 28, Human Medicines Regulations 2012]
No other information can be included.

(b) Mention of any specific therapeutic indication is not permitted.

7.4.2 **Homeopathic products authorised under the National Rules Scheme**

(a) Advertising may include the homeopathic use.

(b) Claims must be consistent with the authorised indication and clearly state that the product is *a homeopathic medicinal product used within the UK homeopathic tradition for* xx [the stated indication].

(c) Claims should be set out in the context of traditional use.

(d) Advertising must not imply that the efficacy of a product is based on clinical data or that efficacy has been demonstrated. Claims such as 'effective for', 'works to relieve' is not acceptable.

7.5 Principles for Medicines, including homeopathic medicines with Product Licences of Right

7.5.1 Products with PLRs may only be advertised to the consumer in accordance with the provisions of the Medicines (Labelling and Advertising to the Public) Regulations 1978 (SI 1978/41).

7.5.2 The promotion of a product for any disease listed in the relevant schedules to the regulations is not permitted, except where specific requirements are complied with.

7.5.3 Advertising must not include any reference to the Commission on Human Medicines, the Advisory Board on the Registration of Homeopathic Products, the MHRA or the Licensing Authority.

ANNEX I

CONTACT DETAILS

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Department for Environment, Food & Rural Affairs (DEFRA)
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Tel: 03459 33 55 77 (Help line)
E-mail: defra.helpline@defra.gsi.gov.uk
Website: www.gov.uk/government/organisations/department-for-environment-food-rural-affairs

Department of Health & Social Care
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Website: https://www.gov.uk/government/organisations/department-of-health-and-social-care

Food Standards Agency (FSA)
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Website: www.food.gov.uk
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FSA in Wales:
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FSA in Northern Ireland:
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Food Standards Scotland
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Medicines and Healthcare Products Regulatory Agency (MHRA)
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Website: www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

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Website: www.radiocentre.org

ANNEX II

ACCESS TO INFORMATION & USEFUL WEBLINKS

CAP Codes of Advertising Practice
https://www.asa.org.uk/codes-and-rulings/advertising-codes.html

MHRA guidance note 8 and other borderline products guidance
https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device

MHRA Blue Guide (Medicines Advertising)
https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines

European Cosmetic products borderline documents
http://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products/index_en.htm

European Medical devices borderline documents
https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

European Commission health & nutrition claims webpage
http://ec.europa.eu/food/safety/labelling_nutrition/claims/index_en.htm

European Commission Register of Claims
http://ec.europa.eu/nuhclaims/

European Food Safety Authority
http://www.efsa.europa.eu

EFSA health claims guidance documents
http://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance

DHSC guidance on implementation of EC Regulation Nutrition & 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

DHSC guidance on principles of flexibility of wording of authorised health claims
https://www.gov.uk/government/publications/update-on-flexibility-of-wording-for-health-claims

DHSC Nutrition Legislation Information sheet
https://www.gov.uk/government/publications/nutrition-legislation-information-sources

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

European Commission Food Supplements
https://ec.europa.eu/food/safety/labelling_nutrition/supplements_en

European Commission Food Information to Consumers Regulation
https://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation_en

Food Standards Agency Food Additives legislation guidance to compliance
http://www.food.gov.uk/business-industry/manufacturers/additives-supps-guidance/foodadlegguid

European Commission Food Improvement Agents (e.g. Food Additives)
https://ec.europa.eu/food/safety/food_improvement_agents_en

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

Food Standards Agency General Food Law guidance
http://www.food.gov.uk/enforcement/regulation/foodlaw

GOV.UK, Food Safety – responsibilities
https://www.gov.uk/food-safety-your-responsibilities/food-safety

European Commission Medicinal products for human use webpage
http://ec.europa.eu/health/human-use/index_en.htm

EU Novel food
https://ec.europa.eu/food/safety/novel_food_en

Import controls/restrictions
http://www.food.gov.uk/business-industry/imports

Department of Business Innovation & Skills (BIS) consumer safety (e.g. cosmetics, general products)
https://www.gov.uk/guidance/product-safety-for-businesses-a-to-z-of-industry-guidance

Business Companion website (Trading Standards, overviews of legislation)
https://www.businesscompanion.info/

ANNEX III

Food Supplements – Mandatory vitamin & mineral cautions

The provision of the following is mandatory for HFMA members

Vitamin A
The following warning notice should appear on the labels of all supplements providing more than 800µg of preformed Vitamin A (as retinol, i.e. not as beta-carotene) daily:
'This product contains Vitamin A. Do not take if you are pregnant or likely to become pregnant except of the advice of a doctor or ante-natal clinic'

Vitamin K
Products providing more than 100µg of Vitamin K in the daily intake should carry the following warning:
'If you are taking anti-coagulants (blood thinners) do not take this product except on the advice of a doctor.'

Iron
For supplements where the total iron content of the package is equal to or in excess of 200mg, the following warning should be given:
'This product contains iron, which, if taken in excess, may be harmful to very young children. Keep out of sight and reach.'

Vitamins and Minerals provided in excess of EVM recommended level
The EVM (UK Expert Group on Vitamins and Minerals) recommendations of 2003 indicated potential safety issues with long term intakes of a limited number of vitamins and minerals [Vitamins C & B6, Nicotinic acid, Iron, Calcium, Magnesium, Zinc, Manganese, Phosphorus, Beta-carotene] when provided at above certain levels.

To enable the continued presence of applicable supplements on the UK market HFMA has agreed the use of **advisory statements** to be applied to labels of those products where the recommended daily intake provides in excess of the EVM level.

Label advisory statements and re-formulations in response to EVM findings, May 2004

Nutrient	**Threshold to trigger statement** (recommended daily amount)	**Label advisory statement/reformulation**
Vitamin C	> 1000 mg	'[This amount of Vitamin C]* may cause mild stomach upset in sensitive individuals'
Iron	> 20 mg	'[This amount of Iron]* may cause mild stomach upset in sensitive individuals'
Calcium	> 1500 mg	'[This amount of Calcium]* may cause mild stomach upset in sensitive individuals'
Magnesium	> 400 mg	'[This amount of Magnesium]* may cause mild stomach upset in sensitive individuals'
Beta-carotene	1) >7 mg 2) See footnote[1]	1) Encourage reformulation to ≤ 7 mg/day 2) Label statement: '[Beta-carotene]* should not be taken by heavy smokers'

Nicotinic acid	> 20 mg	1) Encourage reformulation to nicotinamide 2) If nicotinic acid is used, label statement: '[This amount of Nicotinic acid]* may cause skin flushes in sensitive individuals'
Zinc	> 25 mg	Label statement: 'Long term intake [of this amount of zinc]* may lead to anaemia'
Manganese	See footnote[2]	Label statement: 'Long term intake [of this amount of manganese]* may lead to muscle pain and fatigue'
Phosphorus	> 250 mg	Label statement: '[This amount of Phosphorus]* may cause mild stomach upsets in sensitive individuals'
Vitamin B6	> 10 mg > 100 mg	Label statement: 'Long term intakes [of this amount of vitamin B6]* may lead to mild tingling and numbness' Encourage reformulation to lower daily amount

Notes on Table

* For single nutrient products, the words in square brackets may be deleted.

[1] Government officials considered that the labels of all food supplements containing beta-carotene should carry the advisory statement '[Beta-carotene]* should not be taken by heavy smokers.' Industry considered that this should only be on products recommending a daily amount > 7mg. This footnote is for information only.

[2] Government officials considered that the labels of all food supplements recommending a daily amount greater than 0.5mg manganese should carry this advisory statement. Industry considered that this statement could only be justified on products recommending a daily amount greater than 4mg. This footnote is for information only.

Notes

a) No vitamins are completely stable and they deteriorate at different rates. Amounts of vitamins are added to food supplements during manufacture to compensate for losses during shelf life. For very labile nutrients, such as vitamin C, the threshold values above refer to the declared amount and manufacturers will strive to use only the necessary quantities in the products to ensure 100 per cent of the declared value at the end of shelf-life.

b) All sources of nutrients in a product should be taken into account when declaring the quantities of nutrients and deciding if the trigger level for an advisory statement has been exceeded.

c) These advisory statements are based on current evidence and are subject to change in the light of new evidence and advice.

The Department of Health & Social Care has published a guidance document [Label advisory statements and suggested reformulations] to reflect this agreement
https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs

Final EVM report, published in 2003
http://cot.food.gov.uk/cotreports/cotjointreps/evmreport/

ANNEX IV

UK LEGISLATION

Since legal requirements are continually evolving it is impossible to give a definitive list.
Here below are some that should be considered:

Statutory Instruments numbers quoted for the more recent regulations/amendment regulations are generally those applying to England. Similar legislation will apply to Scotland, Wales and Northern Ireland.
An increasing amount of UK Regulations refer to provisions laid down by EC Directives and Regulations and act as tools to implement the EU requirements and lay down enforcement provisions, rather than repeat the specific requirements within the Statutory Instrument.

Foods
The Food Safety Act 1990, and as amended

The General Food Regulations 2004, No 3279 as amended

The Food Information Regulations 2014 No 1855

The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 No 1631, as amended 2010 No 1886

The Food Supplements (England) Regulations 2003 No 1387, as amended 2007 No 330

The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009 No 3251

The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 No 2210

The Nutrition and Health Claims (England) Regulations 2007 No 2080, as amended 2010 No 1768

The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 No 688 as amended 2017 No 62, 2019 No 44

The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009 No 3051, as amended 2011 No 1043 & as amended by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 No 688, 2017 No 62

The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 No 2182, as amended by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (as amended)

The Medical Food (England) Regulations 2000 No 845, as amended 2007 no 3521, 2011 No 3012, & as amended by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (as amended)

The Novel Foods (England) Regulations 2018 No 154

The Genetically Modified Food (England) Regulations 2004 No 2335, as amended

The Genetically Modified Organisms (Traceability & Labelling) (England) Regulations 2004 No 2412, as amended

The Kava-kava in Food (England) Regulations 2002 No 3169, and as amended 2004 No 455

The Tryptophan in Food (England) Regulations 2005 No 2630

The Food Irradiation (England) Regulations 2009 No 1584, as amended 2010 No 2312

The Organic Products Regulations 2009 No 842, as amended 2010 No 1902, 2015 No 1669

The Food (Lot Marking) Regulations 1996 No 1502

Other Areas of Legislation Affecting Food

There are many other pieces of legislation relating to foods including those in the areas of hygiene, marketing standards, environment protection, feeding stuffs, contamination, packaging, BSE/TSE, importation, animal by-products. For example:

The Food Safety and Hygiene (England) Regulations 2013, No 2996, as amended 2014 No 2885, 2016 No 868

The Official Feed & Food Controls (England) Regulations 2009 No 3255, as amended 2011 No 136

The Official Feed and Food Controls (England) and the Food Safety & Hygiene (England) (Amendment) Regulations 2014 No 2748

The Materials and Articles in Contact with Food (England) Regulations 2012 No 2619

The Contaminants in Food (England) Regulations 2013 No 2196

The Trade in Animals and Related Products Regulations 2011 No 1197

Medicines

The Human Medicines Regulations 2012 No 1916 as amended 2013, No 1855 & 2593, 2014 No 490 & 1878, 2015 No 323, 903, 1503, 2016 No 186, 2017 No 715, 2018 no 199, 2019 No 62

The Medicines Act 1968 as amended [partly revoked by The Human Medicines Regulations 2012]

The Medicines (Advertising of Medicinal Products) Regulations 1975 No 298 and No 2 Regulations No 1326 [relates to products with Product Licences of Right only]

The Medicines (Labelling) Regulations 1976 No 1726, plus amendments [applicable to PLRs only]

The Medicines (Leaflets) Regulations 1977 No 1055, as amended [applicable to PLRs only]

The Medicines (Labelling and Advertising to the Public) Regulations 1978 No 41, as amended [applicable to PLRs only]

The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 No 2750 [majority of requirements revoked by The Human Medicines Regulations 2012]

The Medicinal Products (Herbal Remedies) (Amendment) Regulations 2011, No 915

The Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order 2001 No 1841

The Medicines for Human Use (Kava-kava) (Prohibition) Order 2002 No 3170

The Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008 No 548

The Medicines (Products for Human Use) (Fees) Regulations 2016 No 190

Weights and Measures Requirements

Weights and Measures Act 1985, as amended

The Weights and Measures (Packaged Goods) Regulations 2006 No 659, as amended

The Weights & Measures (Food) (Amendment) Regulations 2014 No 2975

The Weights and Measures (Specified Quantities) (Pre-packed products) Regulations 2009 No 663

The Units of Measurement Regulations 1986 No 1082, 1994 No 2867, 1995 No 1804, 2001 No 55, 2009 No 3046

The Weights and Measures (Quantity Marking and Abbreviations of Units) Regulations 1987 No 1538, and as amended

The Weights and Measures (Miscellaneous Foods) Order 1988 No 2040, as amended

The Weights and Measures (Metrication Amendments) Regulations 2009 No 3045

The Weights and Measures (Cosmetic Products) Order 1994 No 1884

Other relevant/miscellaneous statutes include:

Consumer Protection Act 1987, as amended

Consumer Rights Act 2015 & Consumer Rights (Enforcement & Amendment) Order 2016, No 1259

Trade Description Act 1968 [mostly replaced by the Consumer Protection from Unfair Trading Regulations]

The Consumers Contracts (Information, Cancellation and Additional Charges) Regulations 2013, No 3134, as amended 2015 No 1629

The Consumer Protection from Unfair Trading Regulations 2008 No 1277

The Consumer Protection (Amendment) Regulations 2014 No 870

The Business Protection from Misleading Marketing Regulations 2008 No 1276 as amended 2013 No 2701

The General Product Safety Regulations 2005 No 1803

The Cosmetic Products Enforcement Regulations 2013 No 1478

The REACH Enforcement Regulations 2008 No 2852, as amended

The Biocidal Products and Chemicals (Appointment of Authorities & Enforcement) Regulations 2013 No 1506

The Prices Act 1974 including: The Price Marking Order 2004 No 102

The Medical Devices Regulations 2002 No 618, as amended 2003 No 1697, 2007 No 400, 2008 No 2936, 2012 No 1426, 2013 No 2327, 2017 No 207

The Transmissible Spongiform Encephalopathies (England) Regulations 2018 No 731

The Producer Responsibility Obligations (Packaging Waste) Regulations 2007 No 871, as amended 2016 No 241

The Packaging (Essential Requirements) Regulations 2015, SI 1640

The Psychoactive Substances Act 2016 (Chapter 2)

Copy of UK legislation can be accessed via: http://www.legislation.gov.uk/

Food Standards Agency Food & Feed Law Guide
https://www.food.gov.uk/sites/default/files/media/document/foodandfeedlawguide.pdf

ANNEX V

EU LEGISLATION

Those listed represent a selection only
These principally represent the primary directive/regulation; for the majority amendments have been issued at a later date

Food

Regulation 178/2002	General principles and requirements for food law
Regulation 1169/2011	Provision of Food Information to Consumers
Implementing Regulation 828/2014	Provision of information to consumers on the absence or reduced presence of gluten in food
Implementing Regulation 2018/775	Country of origin of primary ingredient (applies from 1 April 2020)
Directive 2002/46	Food Supplements
Regulation 1924/2006	Nutrition and Health Claims Regulation (NHCR)
Regulation 432/2012	Establishing list of permitted health claims other than those referring to reduction of disease risk and to children's development and health
Implementing Decision 2013/63	Guidelines for implementing Article 10 of Regulation 1924/2006
Regulation 2019/343	Generic descriptors derogation under NHCR
Regulation 1332/2008	Food Enzymes
Regulation 1333/2008	Food Additives
Regulation 1334/2008	Food Flavourings
Regulation 1129/2011	Annex II to Regulation 1333/2008 establishing a Union list of food additives
Regulation 1130/2011	Annex III to Regulation 1333/2008 establishing a Union list of food additives for use in food additives, food enzymes, food flavourings and nutrients
Regulation 872/2012	List of approved flavouring substances (Annex 1 to Regulation 1334/2008)
Regulation 873/2012	Transitional measure in regards to the list of flavourings
Regulation 231/2012	Specifications for food additives listed in Annexes II and III to Regulation 1333/2008

Regulation 1925/2006	Addition of Vitamins, Minerals and Other Substances
Regulation 307/2012	Establishing implementing rules for the application of Article 8 of Regulation 1925/2006 [substances under scrutiny/for restriction]
Regulation 609/2013	Specific Foods Groups Regulation (on food intended for infants & young children, food for special medical purposes, and total diet replacement for weight control)
Delegated Regulation 2016/128	Supplementing Regulation 609/2013 re compositional & information requirements for foods for special medical purposes [applies from 22.02.2019, except in respect to FSMP for infants for which applies from 22.02.2020]
Regulation 2015/2283	Novel Foods
Regulation 2017/2470	Establishing Union list of novel foods
Regulation 2017/2468	Traditional foods from third countries requirements
Regulation 2018/456	Procedural steps to determine novel food status
Regulation 1829/2003	Regulation on GM Food and Feed (incl. labelling of finished product)
Regulation 1830/2003	Traceability and labelling of GMOs
Regulation 834/2007	Organic production and labelling of organic products
Regulation 889/2008	Rules for implementation of Regulation 834/2007
Regulation 710/2009	Rules on organic aquaculture animal & seaweed production
Regulation 1235/2008	Arrangements for imports of organic products from third countries
Directive 2009/32	Extraction solvents in production of foods/food ingredients
Directive 2011/91	Lot marking
Regulation 852/2004	Hygiene of foodstuffs
Regulation 882/2004 & Regulation 2017/625	Official controls on food and feed law compliance Replacing Regulation 882/2004; transition arrangements apply – main application date 14 December 2019
Regulation 2073/2005	Microbiological criteria for foodstuffs
Regulation 396/2005 & Regulation 2018/62	Pesticides [setting maximum residue levels] Replacing Annex I to Regulation 396/2005
Regulation 1881/2006	Contaminants [maximum levels in certain foods]
Regulation 931/2011	Traceability requirements under Regulation 178/2002 for food of animal origin

Regulation 1935/2004	Materials & articles intended to come into contact with foods
Regulation 282/2008	Recycled plastics & articles intended to come into contact with foods
Regulation 10/2011	Plastic materials & articles intended to come into contact with foods

Medicines

Directive 2001/83	Community Code relating to medicinal products for human use
Directive 2004/27	Amendment to Directive 2001/83
Directive 2003/94	Good Manufacturing Practice Principles and Guidelines
Directive 92/25	Good Distribution Practices
Delegated Regulation 1252/2014	GMP for active substances
Delegated Regulation 2016/161	Rules for safety features appearing on packaging of medicines
Directive 2004/24	Traditional Herbal Medicinal Products
Decision 2008/911	Establishing a list of herbal substances, preparations and combinations for use in traditional herbal medicinal products
Regulation 726/2004	Pharmacovigilance rules & establishment of European Medicines Agency
Regulation 1235/2010	Amending Regulation 726/2004
Directive 2010/84	Amending Directive 2001/83 as regards pharmacovigilance
Regulation 1027/2012	Amending Regulation 726/2004 as regards pharmacovigilance
Directive 2011/62	Falsified Medicines Directive [amending Directive 2001/83; Including requirements relating to Active Pharmaceutical Ingredients (API's)]

General

Directive 2011/83	Consumer Rights
Directive 2005/29	Unfair Commercial Practices
Directive 2006/114	Misleading and comparative advertising
Directive 2001/95	General Product Safety

Regulation 528/2012	Biocidal products
Regulation 1907/2006	REACH [Registration, Evaluation, Authorisation and Restriction of Chemicals]
Regulation 764/2008	Mutual Recognition Principles [relating to movement of goods between Member States] To be replaced by Regulation 2019/515 from 19 April 2020
Directive 93/42	Medical Devices (repealed from 5.04.2017 by Regulation 2017/745 which will fully enter into force on 26.05.2020)
Directive 94/62	Packaging and packaging waste
Regulation 1272/2008	Classification, labelling & packaging of substances & mixtures

Cosmetics

Regulation 1223/2009	Cosmetic products
Regulation 655/2013	Establishing common criteria for the justification of claims in relation to cosmetic products
Regulation 2019/701	Establishing a glossary of common ingredient names for use in the labelling of cosmetic products

European Legislation can be accessed via: http://eur-lex.europa.eu/en/index.htm
In some instances, a 'consolidated' version of applicable legislation is available.

HFMA Code of Advertising Practice
October 2019 Edition

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