Food Supplements: How to ensure Compliance of Food Supplements under UK Law

In order to **manufacture, process, distribute, use, sell or import food supplements** in the United Kingdom ("UK"), a manufacturer, importer or distributor of food supplements must be compliant under the law, writes Dr Rosanna Cooper. In this article we explore the regulation of food supplements in the UK.

1. Introduction

The industry sector for food supplements is wide and varied spanning across the whole of Great Britain ('GB'), which means that the **manufacture, process, distribution, use, sale or import** of food supplements are subject to national law:.

> From 1 January, EU Regulations and tertiary legislation relating to nutrition have been retained under the powers contained within the European Union (Withdrawal) Act 2018 as UK law. That EU legislation is subsequently amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020.
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> The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 transferred responsibilities from EU organisations involved in the risk assessment and risk management processes covered by nutrition legislation to bodies in Great Britain (GB)

2. The regulation of the sale of food supplements

Food supplements are sold 'in dose' form as pills, tablets, capsules or liquids and may be used to balance certain **nutritional deficiencies** or maintain an adequate intake of certain nutrients. The Annexes of the **EU Food Supplements Directive 2002/46 ("The Directive")** as amended have been adopted into UK laws and along with other Regulations made in each part of the UK, they aim to ensure safe use of food supplements:

> **1.6 Foods supplements within the EU from 1 January 2021**
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> Food supplements are regulated by Regulations made in each part of the UK (The Food Supplements (England) Regulations 2003 in England; Food Supplements Regulations (Northern Ireland) 2003; The Food Supplements (Scotland) Regulations 2003; The Food Supplements (Wales) Regulations 2003). These Regulations cross refer to the Annex of retained Directive 2002/46/EC, which sets out rules for vitamins and minerals used in food supplements. The Directive contains a list of permitted vitamins and minerals in Annex 1. The permitted forms of those vitamins and minerals is listed in Annex 2.
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> The Directive contains a power for the EC to update the lists in the Annexes, to set purity criteria, and to set maximum and minimum amounts for vitamins and minerals that may be used in food supplements.
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> **1.7 Changes to supplements from 1 January 2021**
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> Minor changes have been made to the regulatory framework that governs food supplements by inserting the lists of vitamins and minerals that may be used in the manufacture of food supplements, contained as an Annex to retained Directive 2002/46/EC, into the Nutrition

(Amendment etc) (EU Exit) Regulations 2019 as Schedules to ensure that they continue to have affect in GB. This guidance sets out how GB system works when accounting for those changes.

The remainder of this UK guidance on food supplements remains relevant and useful,

1.12 Modifying Annex of the Directive 2002/46/EC in the European Union and Northern Ireland

From 1 January 2021 Great Britain has its own list of Vitamins and Minerals for use in Food Supplements and modification processes.

Food business operators wishing to add vitamins and minerals to food supplements in the EU or Northern Ireland following from 1 January 2021 must continue to comply with the un-amended requirements of Annex of the Directive 2002/46/EC and/or Food Supplements Regulations (Northern Ireland) 2003.

We recommend that food business operators who wish for the addition of vitamins and minerals and their sources to be included in the Annex of the Directive 2002/46/EC, which applies to the EU and Northern Ireland, from 1 January 2021 refer to the extensive Food supplements, specifically administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods.

The **Directive** as amended regulates **the composition and labelling of food supplements**, including their vitamins and minerals content, as well as the manufacture, import and sale of food supplements.

The Directive specifies:

- Which **vitamins and minerals** can be used in the preparation of food supplements;
- The **units of measurement** to be used;
- The **labelling requirements**;
- The **presentations** that are allowed for food supplements; and
- The **advertising** that is allowed for food supplements.

3. Vitamins and minerals for use in food supplements

The UK has adopted the Annex to the Directive in connection with which vitamins and minerals, and vitamin and mineral substances, that may be used in the manufacture of food supplements and included the list as schedules to Nutrition (Amendment etc) (EU Exit) Regulations 2019:

1.8 Schedules of vitamins and minerals for use in food supplements

Details of vitamins and minerals, and vitamin and mineral substances, that may be used in the manufacture of food supplements were contained as an Annex to Directive 2002/46/EC. These lists have now been inserted into the Nutrition (Amendment etc) (EU Exit) Regulations 2019 as Schedules to ensure that they continue to have effect in GB.

Schedule 1: Vitamins and minerals which may be used in the manufacture of food supplements

Schedule 2: Vitamin and mineral substances which may be used in the manufacture of food supplements

Supplementary information: schedule 1

The Annexes to retained Directive 2002/46/EC are inserted as schedules into the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 with the footnotes to the Annex omitted. This is because the footnotes set out recommendations rather than legal requirements, consequently they have been included here for reference.

Folic acid (µg)

Folic acid is the term included in Annex I of retained Commission Directive 2008/100/EC of 28 October 2008 amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions for nutrition labelling purposes and covers all forms of folates.

Supplementary information: schedule 2

The Annexes to retained Directive 2002/46/EC are inserted as schedules into the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 with the footnotes to the Annex omitted. This is because the footnotes set out recommendations rather than legal requirements, consequently they have been included here for reference.

Vitamin E: (f) Mixed Tocopherols

alpha-tocopherol \< 20 %, beta-tocopherol \< 10 %, gamma-tocopherol 50-70 % and delta-tocopherol 10-30 %.

Vitamin E: (g) Tocotrienol Tocopherol

Typical levels of individual tocopherols and tocotrienols:

115 mg/g alpha-tocopherol (101 mg/g minimum)

5 mg/g beta-tocopherol (\< 1 mg/g minimum)

45 mg/g gamma-tocopherol (25 mg/g minimum)

12 mg/g delta-tocopherol (3 mg/g minimum)

67 mg/g alpha-tocotrienol (30 mg/g minimum)

\< 1 mg/g beta-tocotrienol (\< 1 mg/g minimum)

82 mg/g gamma-tocotrienol (45 mg/g minimum)

5 mg/g delta-tocotrienol (\< 1 mg/g minimum)

Vitamin K: (b) Menaquinone

Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

Vitamin C: (c) Calcium-L-ascorbate

May contain up to 2 % of threonate.

Mineral: Selenium Enriched Yeast

Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2,5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85 % of the total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine shall not exceed 10 % of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1 % of total extracted selenium.

Mineral: Silicic Acid In the form of gel.

1.9 Modifying schedules

The Nutrition (Amendment etc) (EU Exit) Regulations 2019 provides for the appropriate GB authorities to make regulations to amend the schedules, set the purity criteria as well as maximum and minimum amounts of vitamins and minerals that may be added to food supplements.

Food business operators, or other interested parties, that wish for vitamin and mineral substances to be considered for inclusion in the Schedules to the Nutrition (Amendment etc) (EU Exit) Regulations 2019 may submit a scientific dossier concerning the safety and bioavailability of the individual substance for consideration for use in the GB market by the appropriate UK authorities to the DHSC mailbox (which centrally coordinates dossiers for all 3 GB nations).

The UK government and devolved administrations in Wales and Scotland therefore recommend that, until further notice, scientific dossiers supporting the addition of a vitamin or mineral to the Schedules continue to be completed in line with administrative guidance produced by the European Commission and submitted to the DHSC mailbox (which centrally coordinates dossiers).

Food supplement operators need to know the process to determine which **vitamins and minerals** may be used in food supplements as well as the legal requirement for the maximum and minimum levels of vitamins and minerals that food supplements should contain.

Food supplements sold to the ultimate consumer must be pre-packed. The ‘ultimate consumer” is defined as:

> “any person who purchases otherwise than:
> a) for the purpose of resale;
> b) for the purposes of a catering establishment; or
> c) for the purposes of a manufacturing business”.

A “food supplement shall be regarded as “pre-packed”, if:

> *a)* it is ready for sale to the ultimate consumer or to a catering establishment, and
> *b)* it is put into packaging before being offered for sale in such a way that the food supplement cannot be altered without opening or changing the packaging”.

4. Definition of food supplements

Food supplements are **defined** as:

> Foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological function, alone or in combination, marketed in dose form, namely forms such as capsules,

pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities

"..dose form means a form 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 unit quantities".

The term 'to supplement' may be interpreted as 'taken in addition to' the diet.

Food supplements may only contain the allowable **vitamins and mineral salts** laid down in Annex I of the Directive, and the **vitamin and mineral formulations (singly or in combination)**, as listed in Annex II. To date there are 13 vitamins with 45 allowable sources and 17 minerals with a total of 136 allowable sources.

The **purity criteria** of food supplements will eventually be established by the UK Government, none have been set as yet. As no criteria have been laid down by the UK Government, generally acceptable **purity criteria** recommended by international bodies may be used such as the Joint FAO/WHO Committee on Food Additives (JECFA) and the European Pharmacopoeia.

The Appropriate Authorities will **evaluate different vitamins and mineral substances** for inclusion in the lists. A **scientific dossier** will have to be submitted to the Appropriate Authorities by companies wishing to market new substances to be evaluated in relation to the **safety and bioavailability** of the individual substances:

1.4 Lists and registers

Where the Regulations require a list or register to be established, each Appropriate Authority must produce and maintain a list or register.

Decisions made by the appropriate authorities as set out above, will result in the GB lists and registers needing to be updated periodically.

For convenience and clarity, GB lists and registers, which consolidate all lists produced and maintained by the appropriate authorities, are available on GOV.UK for food business operators and other interested parties.

Businesses may submit applications or dossiers in support of these lists being amended for consideration for use on the GB market to DHSC mailboxes, unless stated otherwise in this guidance. DHSC will centrally coordinate applications.

5. The working of the Appropriate Authorities

The Appropriate Authorities produces opinions used by the UK to:

- Evaluate proposals for the addition of vitamins and minerals to the schedules;
- Evaluate nutrition and health claims;
- Assess how to establish maximum limits for vitamins and minerals in food supplements and fortified foods;
- Provide opinions on substances other than vitamins and minerals;
- Work in close collaboration with national authorities.

Labelling and packaging of food supplements

The **manufacturer of food supplements** is responsible for labelling of such products, not the raw material supplier.

The words “food supplement” must appear on the label and can appear alone or with other words such as “**Food Supplement – containing vitamins and minerals**”. Manufacturers should use the more descriptive option wherever possible.

We have set out below some of the items that have to be included in the **labelling** of all food supplements:

- A declaration to the **effect that the supplement** is not a substitute for a varied diet;
- A **warning** to the effect that the product should be **stored out of the reach of young children**.

The labelling of food supplements must **not** contain any statement:

- Attributing to the product properties of **preventing, treating or curing a human disease**;
- Stating or implying that a **balanced and varied diet** cannot provide appropriate quantities of nutrients in general.

Furthermore, the names of the categories of any vitamins or minerals or other substances with nutritional or physiological effect which characterises the products or an indication or the nature of those vitamins or minerals or other substances be included in the labelling **do not have to be in the same field of vision as the term "food supplement**". Practically, it may be useful for consumers to have them placed together.

The labelling requirements apply to all food supplements including those containing vitamins or minerals. There are no exemptions under the Directive for the labelling of small packages.

6. Food Supplements UK Requirements

The legislation stipulates that:

> No person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the name under which it is sold is "food supplement". Without prejudice to the Food Labelling Regulations 1996, no person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless it is marked or labelled with the following particulars
>
> *(a)* the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;
> *(b)* the portion of the product recommended for daily consumption;
> *(c)* a warning not to exceed the stated recommended daily dose;
> *(d)* a statement to the effect that food supplements should not be used as a substitute for a varied diet;
> *(e)* a statement to the effect that the product should be stored out of the reach of young children; and
> *(f)* the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.

It is recommended for instance:

- To have a warning against exceeding the recommended daily "intake";
- To state on the labels that food supplements should not be used as a substitute for a varied diet;

7. Nutrition Labelling

In the case of vitamins and minerals, the name of the category of any vitamins or minerals or other substances with a nutritional or physiological effect which characterises the products or an indication of the nature of those vitamins or minerals or other substances **must** be accompanied by the **percentage of the relevant Recommended Daily Allowance (RDA).**

8. Nutrition and Health Claims

All health claims must comply with the requirements of UK laws on nutrition and health claims made on food ("Regulation"). This Regulation applies to claims made in any commercial communication, including on labels, leaflets, packaging, websites and advertising.

This Regulation stipulates that all nutrition and health claims have to be authorised at the EU level to be used in labelling and packaging. A nutrition claim states, suggests or implies that a food has beneficial nutritional properties, such as "low fat" or "high in fibre". A health claim states, suggests or implies that health benefits can result from consuming a given food, such as "helps build strong bones" or "maintains healthy cholesterol levels". The Regulation also controls general references to overall health and well-being, such as "healthy" or "superfood".

9. Medicinal Claims

Any food supplement that has a **medicinal effect or makes a medicinal claim** (to **prevent, treat or cure any disease or medical condition**) must have a marketing authorisation. In the UK, the Medicines and Healthcare Products Regulatory Agency ("MHRA") will grant this marketing authorisation.

If you are selling or intend to sell food supplements in the EU, you must ensure that your supplements are compliant.

It is worth noting that certain **herbal substances** may be classified as medicines requiring marketing authorisations.

10. Advertising and sale

The **labelling, presentation or advertising** of a food supplement must not include any mention, express or implied, that "a balanced and varied diet cannot provide appropriate quantities of nutrients in general".

When the marking or labelling of any food supplement is sold to the **ultimate consumer** or sold **ready for delivery to a catering establishment** in **pre-packed form**, the labelling particulars must be:

- On the **packaging**; or
- On a **label attached to the packaging**; or
- On a **label which is clearly visible through the packaging**.

In the case where the sale is not to the ultimate consumer, these particulars may be included on the commercial documents relating to the food supplements.

11. Imports and Exports

It is the responsibility of the manufacturer, importer or distributor to ensure that their products comply with UK laws. In addition, advice on complying with the appropriate legislation for the labelling and sale of individual products can be obtained from us.

12. Conclusion

There are a number of legislation that must be complied with in the manufacture, sale, promotion, marketing, distribution and advertising of food supplements.

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