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Guidance

Great Britain register on the addition of vitamins and minerals and of certain other substances to foods

Updated 12 January 2021

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This Great Britain Register on the addition of vitamins and minerals and of certain other substances to foods ('the GB VMS Register') has been established as laid down by Article 9 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, as amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019.

The appropriate authorities are conferred with the task of establishing, publishing and maintaining this GB VMS Register. The GB VMS Register is updated as necessary.

The register has only informative purposes and does not replace legal acts.

1. Section A: vitamins and minerals that may be added to foods

List of the vitamins and minerals which may be added to foods as listed in Annex I of Regulation (EC) No 1925/2006, as amended.

No 1925/2006, as amended. **1.1 Vitamins**

| Vitamin D |
|------------------|
| Vitamin E |
| Vitamin K |
| Vitamin B1 |
| Vitamin B2 |
| Niacin |
| Pantothenic acid |
| Vitamin B6 |
| Folic acid |
| Vitamin B12 |
| |

1.2 Minerals

Calcium

Biotin

Vitamin C

Vitamin A

Vitamin A

Magnesium

Iron

| at Britain register on the addition of vitamins and mineral | | |
|---|--|--|
| Copper | | |
| lodine | | |
| Zinc | | |
| Manganese | | |
| Sodium | | |
| Potassium | | |
| Selenium | | |
| Chromium | | |
| Molybdenum | | |
| Fluoride | | |
| Chloride | | |
| Phosphorus | | |
| Boron | | |

2. Section B: vitamin formulations and mineral substances that may be added to foods

List of vitamin formulations and mineral substances which may be added to foods as listed in Annex of Regulation (EC) No 1924/2006, as amended.

2.1 Vitamin formulations

| Vitamin A | Niacin |
|-------------------|----------------|
| retinol | nicotinic acid |
| retinyl acetate | nicotinamide |
| retinyl palmitate | |
| beta-carotene | |

| Vitamin D | Pantothenic acid |
|-----------------|-------------------------|
| cholecalciferol | D-pantothenate, calcium |

| Vitamin D | Pantothenic acid |
|----------------|------------------------|
| ergocalciferol | D-pantothenate, sodium |
| | dexpanthenol |

| Vitamin D | Vitamin B6 |
|-----------------------------------|--------------------------|
| D-alpha-tocopherol | pyridoxine hydrochloride |
| DL-alpha-tocopherol | pyridoxine 5'-phosphate |
| D-alpha-tocopheryl acetate | pyridoxine dipalmitate |
| DL-alpha-tocopheryl acetate | |
| D-alpha-tocopheryl acid succinate | |

| Vitamin K | Folic acid |
|--------------------------------|--------------------------|
| phylloquinone (phytomenadione) | pteroylmonoglutamic acid |
| menaquinone [footnote 1] | calcium-L-methylfolate |

| Vitamin B1 | Vitamin B12 |
|-----------------------|------------------|
| thiamin hydrochloride | cyanocobalamin |
| thiamin mononitrate | hydroxocobalamin |

| Vitamin B2 | Biotin |
|---------------------------------|----------|
| riboflavin | D-biotin |
| riboflavin 5'-phosphate, sodium | |

| Vitamin C | |
|-----------------|--|
| L-ascorbic acid | |

| Vitamin C | |
|------------------------|--|
| sodium-L-ascorbate | |
| calcium-L-ascorbate | |
| potassium-L-ascorbate | |
| L-ascorbyl 6-palmitate | |

2.2 Mineral substances

calcium carbonate

calcium chloride

calcium citrate malate

calcium salts of citric acid

calcium gluconate

calcium glycerophosphate

calcium lactate

calcium salts of orthophosphoric acid

calcium hydroxide

calcium malate

calcium oxide

calcium sulphate

magnesium acetate

magnesium carbonate

magnesium chloride

magnesium salts of citric acid

magnesium gluconate

magnesium glycerophosphate

magnesium salts of orthophosphoric acid

magnesium lactate

magnesium hydroxide

magnesium oxide

magnesium potassium citrate

magnesium sulphate

ferrous bisglycinate

ferrous carbonate

ferrous citrate

ferric ammonium citrate

ferrous gluconate

ferrous fumarate

ferric sodium diphosphate

ferrous lactate

ferrous sulphate

ferrous ammonium phosphate

ferric sodium EDTA

ferric diphosphate (ferric pyrophosphate)

ferric saccharate

elemental iron (carbonyl + electrolytic + hydrogen reduced)

cupric carbonate

cupric citrate

cupric gluconate

cupric sulphate

copper lysine complex

sodium iodide

sodium iodate

potassium iodide

potassium iodate

zinc acetate

zinc bisglycinate

zinc chloride

zinc citrate

zinc gluconate

zinc lactate

zinc oxide

zinc carbonate

zinc sulphate

manganese carbonate

manganese chloride

manganese citrate

manganese gluconate

manganese glycerophosphate

manganese sulphate

sodium bicarbonate

sodium carbonate

sodium citrate

sodium gluconate

sodium lactate

sodium hydroxide

sodium salts of orthophosphoric acid

selenium enriched yeast [footnote 2]

sodium selenate

sodium hydrogen selenite

sodium selenite

sodium fluoride

potassium fluoride

potassium bicarbonate

potassium carbonate

potassium chloride

potassium citrate

potassium gluconate

potassium glycerophosphate

potassium lactate

potassium hydroxide

potassium salts of orthophosphoric acid

chromium (III) chloride and its hexahydrate

chromium (III) sulphate and its hexahydrate

chromium picolinate

ammonium molybdate (molybdenum (VI))

sodium molybdate (molybdenum (VI))

boric acid

sodium borate

3. Section C: maximum and minimum amounts of vitamins and minerals that may be added to foods

Maximum and minimum amounts of vitamins and minerals which may be added to foods and any associated conditions set in accordance with Article 6 of Regulation (EC) No 1925/2006, as amended.

3.1 Maximum amounts

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3.2 Minimum amounts

The addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to the Annex to Annex XIII to Regulation (EU) No. 1169/2011.

Any derogation from the significant amounts mentioned above, for specific foods or categories of

foods shall be adopted in accordance with the procedure referred to in Article 14(2).

No derogation adopted.

4. Section D: mandatory addition of vitamins and minerals

Information regarding enactments applicable in any part of Great Britain on:

- the mandatory addition of vitamins and minerals to specified foods or categories of food
- the prohibition or restriction on the use of certain other substances in the manufacture of specified foods

4.1 Existing national provisions on the mandatory addition of vitamins and minerals

| Nutrient | Food or food category | Relevant legislation | |
|---|---|---|--|
| Calcium carbonate | Flour, except: (a) wholemeal flour (b) self-raising flour which has a calcium content of not less than 0.2%, and (c) wheat malt flour; unless the flour is being sold or imported into Great Britain for use in the manufacture of communion wafers, matzos, gluten, starch or any concentrated preparation for facilitating the addition of this substance to flour. | The Bread and Flour Regulations 1998 (http://www.opsi.gov.uk/SI/si1998 /19980141.htm) | |
| Iron ferric ammonium citrate, ferrous sulphate, dried ferrous sulphate and/or iron powder) | Flour, except wholemeal flour, where addition is necessary to meet this level; unless the flour is being sold or imported into Great Britain for use in the manufacture of communion wafers, matzos, gluten, starch or any concentrated preparation for facilitating the addition of this substance to flour. | The Bread and Flour Regulations 1998 (http://www.opsi.gov.uk/SI/si1998 /19980141.htm) | |
| Thiamin | Flour, except wholemeal flour, where addition is necessary to meet this level; unless the flour is being sold or imported into Great Britain for use in the manufacture of communion wafers, matzos, gluten, starch or any concentrated preparation for facilitating the addition of this substance to flour. | The Bread and Flour Regulations 1998 (http://www.opsi.gov.uk/SI/si1998 /19980141.htm) | |

| Nutrient | Food or food category | Relevant legislation |
|---|---|---|
| Nicotinic acid or nicotinamide | Flour, except wholemeal flour, where addition is necessary to meet this level; unless the flour is being sold or imported into Great Britain for use in the manufacture of communion wafers, matzos, gluten, starch or any concentrated preparation for facilitating the addition of this substance to flour. | The Bread and Flour Regulations 1998 (http://www.opsi.gov.uk/SI/si1998 /19980141.htm) |
| Divalent ions, with calcium as the principle ion (water hardness) | Bottled drinking water and spring water that has been softened or desalinated. | The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 2018, England (http://www.legislation.gov.uk/uksi/2018 /352/contents/made) The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 2015 Wales (http://www.legislation.gov.uk/wsi/2015 /1867/contents) The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 2015, Scotland (http://www.legislation.gov.uk/ssi/2015 /363/contents/made) |

4.2 New national legislation on the mandatory addition of vitamins and minerals to specified foods or categories of foods notified to the appropriate authorities in accordance with the procedure laid down in Article 12

No information submitted yet.

5. Section E: restrictions on addition of vitamins and minerals

Restrictions on the addition of vitamins and minerals as set out in Article 4 of Regulation (EC) No 1925/2006, as amended.

5.1 Article 4: Restrictions on the addition of vitamins and minerals

Vitamins and minerals may not be added to:

• unprocessed foodstuffs, including, but not limited to, fruit, vegetables, meat, poultry and fish

- beverages containing more than 1,2 % by volume of alcohol, except and by way of derogation from Article 3(2), to products:
 - referred to in paragraph B3 of Annex VIII to Regulation (EU) No. 1308/2013
 - which were marketed prior to the adoption of this Regulation
 - which have been notified to the appropriate authorities in accordance with Article 11^[footnote 3], and provided that no nutrition or health claim is made

Additional foods or categories of foods to which particular vitamins and minerals may not be added may be determined in accordance with the procedure referred to in Article 14(2) in the light of scientific evidence and taking into account their nutritional value.

Empty

6. Section F: substances referred to in Annex 3 of Regulation (EC) No 1925/2006, as amended

Information about the substances referred to in Annex 3 of Regulation (EC) No 1925/2006, as amended, and the reasons for their inclusion therein.

6.1 Annex 3: substances whose use in foods is prohibited, restricted or under community scrutiny

Part A: prohibited substances

On 6 November 2013, the European Food Safety Authority (EFSA) adopted a scientific opinion on the safety evaluation of Ephedra species for use in food. It found that although the marketing of foods containing Ephedra herb and its preparations in retail outlets is not documented in Europe, food supplements containing Ephedra herbs or their preparations that are typically used for weight loss and athletic performance can easily be purchased via the internet.

<u>EFSA</u> concluded that it cannot be excluded that consumers may purchase herbal tea from Ephedra herb via the internet. Given that Ephedra herb and its preparations are marketed almost exclusively as food supplements, <u>EFSA</u> calculated potential exposure levels to the herb from food supplements. It concluded that Ephedra herb and its preparations in food supplements may result in exposure to total ephedra alkaloids or ephedrine which falls within or may exceed the therapeutic dose ranges for the individual ephedra alkaloids or ephedrine, in medicinal products.

<u>EFSA</u> concluded that due to the absence of adequate toxicity data, it could not provide advice on a daily intake of Ephedra herb and its preparations from all foods that does not give rise to concerns for human health. Nevertheless, it concluded that exposure to total ephedra alkaloids or ephedrine in foods, mainly in food supplements could lead to severe adverse effects on the cardiovascular and central nervous systems (such as hypertension and stroke), which may be enhanced in combination with caffeine. Therefore, the use of Ephedra herb and its preparations containing ephedra alkaloids in food is of significant safety concern for human health.

Considering the significant safety concern associated with the use of Ephedra herb and its preparations in foods, in particular with regard to exposure to ephedra alkaloids present in food supplements, and considering that no daily intake of Ephedra herb and its preparations that does not give rise to concerns for human health could be set, the use of that substance in foods should be

prohibited. Therefore, Ephedra herb and its preparations should be included in Annex 3, Part A of Regulation (EC) No 1925/2006.

Part B: restricted substances

Empty

Part C: substances under scrutiny

On 3 July 2013, the European Food Safety Authority (<u>EFSA</u>) adopted a scientific opinion on the evaluation of the safety in use of Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille) (3).

It concluded that the chemical and toxicological characterisation of yohimbe bark and its preparations used in food originating from Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille) are not adequate to conclude on their safety as ingredients of food.

Therefore, it was not possible for <u>EFSA</u> to provide advice on a daily intake of yohimbe bark and its preparations that does not give rise to concerns for human health.

As there is a possibility of harmful effects on health associated with the use of Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille) and its preparations in foods, but scientific uncertainty persists, the substance should be placed under Union scrutiny and therefore, should be included in Part C of Annex 3 to Regulation (EC) No 1925/2006.

7. Section G: information about substances listed in Annex 3, Part C, whose use is generally allowed

Information about the substances listed in Annex 3, Part C, whose use is generally allowed as referred to in Article 8(5) of Regulation(EC) No 1925/2006, as amended.

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- 1. Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.
- 2. 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.
- 3. Products marketed as 'tonic wine' or 'ginger tonic wine' have been notified by Ireland and United Kingdom for the derogation provided for in Article 4(b) of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to food.

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