

United Kingdom Register on the Addition of Vitamins and Minerals and of Certain Other Substances to Foods [Withdrawn]

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

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

N.B. The Register has only informative purposes and does not replace legal acts.

This publication was withdrawn on 31 January 2020

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Section A: 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

Vitamins

Vitamin A
Vitamin D
Vitamin E
Vitamin K
Vitamin B1
Vitamin B2
Niacin
Pantothenic acid
Vitamin B6
Vitamin B6 Folic acid
Folic acid
Folic acid Vitamin B12
Folic acid Vitamin B12 Biotin

Minerals

Magnesium

Calcium

Iron

Copper

Iodine

Zinc	
Manganese	
Sodium	
Potassium	
Selenium	
Chromium	
Molybdenum	
Fluoride	
Chloride	
Phosphorus	
Boron	

Section B: List of vitamin formulations and mineral substances which may be added to foods as listed in Annex of Regulation (EC) No 1925/2006, as amended

Vitamin formulations

VITAMIN A	NIACIN
retinol	nicotinic acid
retinyl acetate	nicotinamide
retinyl palmitate	
beta-carotene	

VITAMIN D	PANTOTHENIC ACID
cholecalciferol	D-pantothenate, calcium
ergocalciferol	D-pantothenate, sodium
	dexpanthenol

VITAMIN E	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 (*)	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
sodium-L-ascorbate
calcium-L-ascorbate
potassium-L-ascorbate
L-ascorbyl 6-palmitate

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 (**) 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

- (*) Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.
- (**) 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.'

Section C: 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

Maximum amounts

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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

Section D: Information regarding enactments applicable in any part of the United Kingdom on: the mandatory addition of vitamins and minerals to specified foods or categories of food; or the prohibition or restriction on the use of certain other substances in the manufacture of specified foods

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

Nutrient	Food/Food Category	Relevant Legislation/link to 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/Sl/si1998/19980141.htm The Bread and Flour Regulations (Northern Ireland) 1998 http://www.legislation.gov.uk/nisr/1998/24/content s/made
Iron ferric ammonium citrate, ferrous sulphate,	Flour, except wholemeal flour, where addition is necessary to meet this level;	The Bread and Flour Regulations 1998 http://www.opsi.gov.uk/SI/si1998/19980141.htm The Bread and Flour Regulations (Northern Ireland) 1998

Nutrient	Food/Food Category	Relevant Legislation/link to relevant legislation
dried ferrous sulphate and/or iron powder)	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.	http://www.legislation.gov.uk/nisr/1998/24/contents/made
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/Sl/si1998/19980141.htm The Bread and Flour Regulations (Northern Ireland) 1998 http://www.legislation.gov.uk/nisr/1998/24/content-s/made
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/Sl/si1998/19980141.htm The Bread and Flour Regulations (Northern Ireland) 1998 http://www.legislation.gov.uk/nisr/1998/24/content-s/made

Nutrient	Food/Food Category	Relevant Legislation/link to relevant legislation
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 www.legislation.gov.uk/wsi/2015/1867/contents Scotland http://www.legislation.gov.uk/ssi/2015/363/contents/made Northern Ireland http://www.legislation.gov.uk/nisr/2015/365/contents/www.legislation.gov.uk/nisr/2015/365/contents/made

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

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

Article 4: Restrictions on the addition of vitamins and minerals

Vitamins and minerals may not be added to:

- (a) unprocessed foodstuffs, including, but not limited to, fruit, vegetables, meat, poultry and fish;
- (b) beverages containing more than 1,2 % by volume of alcohol, except and by way of derogation from Article 3(2), to products:
 - (i) referred to in paragraph B3 of Annex VIII to Regulation (EU) No. 1308/2013;
 and
 - (ii) which were marketed prior to the adoption of this Regulation; and
 - (iii) which have been notified to the appropriate authorities in accordance with Article 11¹, 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.

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¹ 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

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

Annex III - 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. EFSA 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, EFSA 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.

EFSA 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 III, Part A of Regulation (EC) No 1925/2006.

Part B — Restricted substances:

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Part C — Substances under scrutiny

On 3 July 2013, the European Food Safety Authority (EFSA) 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 EFSA 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 III to Regulation (EC) No 1925/2006.

Section G: Information about the substances listed in Annex III, 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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