

Community Register on the addition of vitamins and minerals and of certain other substances to foods

This Community Register on the addition of vitamins and minerals and of certain other substances to foods (“the 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.

The European Commission is conferred with the task of establishing, publishing and maintaining this Register. The Register is updated regularly.

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

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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 and as amended by Commission Regulation (EC) No 1170/2009

1. Vitamins

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

2. Minerals

Calcium
Magnesium
Iron
Copper
Iodine
Zinc
Manganese
Sodium
Potassium
Selenium
Chromium
Molybdenum
Fluoride
Chloride
Phosphorus
Boron

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Section B

List of the vitamin formulations and mineral substances which may be added to foods as listed in Annex II of Regulation (EC) No 1925/2006 and as amended by Commission Regulation (EC) No 1170/2009

1. Vitamin formulations

VITAMIN A
retinol
retinyl acetate
retinyl palmitate
beta-carotene

VITAMIN D
cholecalciferol
ergocalciferol

VITAMIN E
D-alpha-tocopherol
DL-alpha-tocopherol
D-alpha-tocopheryl acetate
DL-alpha-tocopheryl acetate
D-alpha-tocopheryl acid succinate

VITAMIN K
phylloquinone (phytomenadione)
menaquinone (*)

VITAMIN B1
thiamin hydrochloride
thiamin mononitrate

VITAMIN B2
riboflavin
riboflavin 5'-phosphate, sodium

NIACIN
nicotinic acid
nicotinamide

PANTOTHENIC ACID
D-pantothenate, calcium
D-pantothenate, sodium
dexpantenol

VITAMIN B6
pyridoxine hydrochloride
pyridoxine 5'-phosphate
pyridoxine dipalmitate

FOLIC ACID
pteroylmonoglutamic acid
calcium-L-methylfolate

VITAMIN B12
cyanocobalamin
hydroxocobalamin

BIOTIN
D-biotin

VITAMIN C
L-ascorbic acid
sodium-L-ascorbate
calcium-L-ascorbate
potassium-L-ascorbate
L-ascorbyl 6-palmitate

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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)

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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

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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

Maximum amounts

The Commission may submit proposals for the maximum amounts by 19 January 2009

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 Directive 90/496/EEC.

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 national provisions on the mandatory addition of vitamins and minerals referred to in Article 11 of Regulation (EC) No 1925/2006

1. Existing national provisions on the mandatory addition of vitamins and minerals. (Information submitted to the Commission by Member States by 19 July 2007)

Austria

<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
iodine	salt	Speisesalzgesetz, Federal Law Gazette Nr. 112/1963, amended by Federal Law Gazette Nr. 288/1990 and Federal Law Gazette I Nr. 115/1999

Belgium

<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
Vitamin A	margarine, low-fat margarine, and fats for baking	Royal decree of 2 October 1980 on the manufacturing and marketing of margarine and food fats Arrête royal du 2 octobre 1980 relatif à la fabrication et la mise dans le commerce de la margarine et des graisses comestibles Koninklijk besluit van 2 oktober 1980 betreffende de fabricage van en het in de handel brengen van margarine en voedingsvetten
Vitamin D	margarine, low-fat margarine, and fats for baking	Royal decree of 2 October 1980 on the manufacturing and marketing of margarine and food fats Arrête royal du 2 octobre 1980 relatif à la fabrication et la mise dans le commerce de la margarine et des graisses comestibles Koninklijk besluit van 2 oktober 1980 betreffende de fabricage van en het in de handel brengen van margarine en voedingsvetten

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Denmark

<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
Iodine (13 mg per kg salt)	Household salt and salt used as an ingredient in bread and bakery products.	Bekendtgørelse nr. 627 af 29/06/2000 om tilsætning af jod til husholdningssalt og salt i brød og almindeligt bagværk m.v.,, http://147.29.40.90/GETDOC/B20000062705-REGL

Estonia

No provisions


France

No provisions

Germany

No provisions

Italy









<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
Iodio (ioduro e/o iodato di potassio)	Sale Obbligo per il punti vendita di sale destinato al consumo diretto di assicurare la disponibilità di sale arricchito con iodio oltre che di sale alimentare comune.	Legge 21 Marzo 2005, n. 55 Decreto del Ministero della sanità 10 Agosto 1995, n. 562  Decreto 562

Lithuania

<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
Iodine (20-40 mg/kg of iodine)	Salt (all food retail enterprises shall sell and all mass caterers and bakeries shall use only iodized salt)	Lithuanian Hygiene Norm HN 15:2005 "Food Hygiene" adopted by order No. V-675 of September 1, 2005 of Minister of Health which was published in Official Gazette No 110-4023 on September 9, 2005 and entered into force from 1 January, 2006. Article 7 of the abovementioned Hygiene Norm states: "In order to protect public health against diseases caused by Lithuanian geographical location specific iodine deficiency, all food retail enterprises shall sell and all mass caterers and bakeries shall use only iodized salt containing 20-40 mg/kg of iodine "

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Netherlands

<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
Vitamine A	Smeerbare vetproducten	<p>- Warenwetbesluit Toevoeging Micro-voedingsstoffen aan levensmiddelen, (artikel 5)</p> <p style="text-align: center;"> Tekst Wwbesluit toevoeging microvoer</p> <p>- Convenant vitaminering van Smeerbare vetten</p> <p style="text-align: center;">  Convenant vitaminering smeerba Verlenging Convenant vitamineri</p>
Vitamine D	Smeerbare vetproducten	<p>- Warenwetbesluit Toevoeging Micro-voedingsstoffen aan levensmiddelen, (artikel 5)</p> <p style="text-align: center;"> Tekst Wwbesluit toevoeging microvoer</p> <p>- Convenant vitaminering van Smeerbare vetten</p> <p style="text-align: center;">   Convenant vitaminering smeerba Verlenging Convenant vitamineri Wwreg Vrijstelling toevoeging foliumzuu</p>
Jodium	Keukenzout, brood, broodvervangers en vleesproducten	<p>- Warenwetbesluit Toevoeging Micro-voedingsstoffen aan levensmiddelen (artikel 9 a – a/b/c)</p> <p style="text-align: center;"> Tekst Wwbesluit toevoeging microvoer</p>

Poland

<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
Vitamin A	Margarine with normal and reduced contents of fat, butter with reduced	Ordinance of the Minister of Health of 19 December 2002 concerning enriching substances added to food and terms of their use (<i>Official Journal</i>)

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	contents of fat, butter and oil mixture	<i>from 2003 No 27, item 237)</i>
Vitamin D	Margarine with normal and reduced contents of fat, butter with reduced contents of fat, butter and oil mixtures	
Iodine	Salt intended for human consumption	

Sweden

<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
Vitamin D	Milk with maximum 1,5 % fat and intended for direct consumption shall contain 3,8-5,0 microgram vitamin D per litre The Swedish National Food Administration may grant exemptions.	SLVFS 1983:2 as amended by LIVSFS 2007:9 http://www.slv.se/upload/dokument/Lagstiftning/1980-talet/1983_02.pdf
Vitamin A	Margarine and fat blends as well as corresponding products with lower fat content shall contain 0,9-1,5 RE vitamin A and 7,5-10 microgram vitamin D per 100 gram. The Swedish National Food Administration may grant exemptions	SLVFS 1983:2 as amended by LIVSFS 2007:9 http://www.slv.se/upload/dokument/Lagstiftning/1980-talet/1983_02.pdf

Slovenia

<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
Iodine	Salt	Article 8 of the Rules on the quality of salt (Official Gazette of the Republic of Slovenia, No 70/03 and 31/04) 25 mg of potassium iodide per 1 kg of salt±5 32 mg of potassium iodate per 1 kg of salt±4

Slovakia

<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
Potassium iodide and potassium iodate	Edible salt	Decree of the Ministry of Agriculture of the Slovak Republic and Ministry of Health of the Slovak Republic of 15th March 2004 No. 608/8/2004-100 by that is issued the Chapter of Slovak Food Code on particular ingredient of the foodstuffs

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United Kingdom

<i>Nutrient</i>	<i>Food/Food Category</i>	<i>Relevant Legislation/link to relevant legislation</i>
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
Nicotinic acid or nicotinamide	Flour, except wholemeal flour, where addition is necessary to	The Bread and Flour Regulations 1998 http://www.opsi.gov.uk/SI/si1998/19980141.htm

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	<p>meet this level;</p> <p>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.</p>	
<p>Divalent ions, with calcium as the principle ion (water Hardness)</p>	<p>Bottled drinking water and spring water that has been softened or desalinated.</p>	<p>The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999 (as amended) http://www.opsi.gov.uk/si/si1999/19991540.htm</p> <p>England http://www.opsi.gov.uk/si/si2003/20030666.htm http://www.opsi.gov.uk/si/si2004/20040656.htm</p> <p>Wales http://www.opsi.gov.uk/legislation/wales/wsi2003/20033042e.htm http://www.opsi.gov.uk/legislation/wales/wsi2004/20041509e.htm</p> <p>Scotland http://www.opsi.gov.uk/legislation/scotland/ssi2003/20030139.htm http://www.opsi.gov.uk/legislation/scotland/ssi2004/20040132.htm</p> <p>Northern Ireland http://www.opsi.gov.uk/sr/sr1999/19990301.htm http://www.opsi.gov.uk/sr/sr2003/20030182.htm http://www.opsi.gov.uk/sr/sr2004/20040115.htm</p>

Section D continued

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

No information submitted yet

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Section E

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

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 Article 44(6) and (13) of Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine (1); and

(ii) which were marketed prior to the adoption of this Regulation; and

(iii) which have been notified to the Commission by a Member State 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.

Empty

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.

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Section F

List of the substances for which dossiers have been submitted as provided for in Article 17(1)(b) of Regulation (EC) No 1925/2006

Substances

Dossiers for the following substances have been submitted by the Commission to the Authority for evaluation:

Chromium (III) Lactate Trihydrate
Iodized ethyl esters of poppy seed oil

The following substances do not comply with the requirements laid down in Article 17 (1) and have been withdrawn from the Register:

Choline-stabilized orthosilicic acid
Calcium L-Lysinate
Calcium Pyruvate
Calcium Succinate
Magnesium L-Lysinate
Magnesium Malate
Magnesium Pyruvate
Magnesium Succinate
Magnesium Taurate
Zinc L-Aspartate
Zinc L-Lysinate
Zinc Malate
Inositol Hexanicotinate
Mixed Tocopherols
Calcium ascorbate (with threonate)

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Section G

Information about the substances referred to in Annex III of Regulation (EC) No 1925/2006 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

Ephedra species

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 Community scrutiny

Pausinystalia yohimbe (K.Schum) Pierre ex Beille

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.

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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.

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Section H

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.

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