

## **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 responsible for establishing, publishing and maintaining this Register, which is updated when necessary.

Last update: 01.01.2021

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

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

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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, Commission Regulation (EU) No 1161/2011, Commission Regulation (EU) No 119/2014 and Commission Regulation (EU) 2017/1203**

**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, Commission Regulation (EU) No 1161/2011, Commission Regulation (EU) No 119/2014 and Commission Regulation (EU) 2017/1203**

**1. Vitamin formulations**

	nicotinic acid
	nicotinamide
VITAMIN A	
retinol	PANTOTHENIC ACID
retinyl acetate	D-pantothenate, calcium
retinyl palmitate	D-pantothenate, sodium
beta-carotene	dexpanthenol
VITAMIN D	VITAMIN B6
cholecalciferol	pyridoxine hydrochloride
ergocalciferol	pyridoxine 5'-phosphate
	pyridoxine dipalmitate
VITAMIN E	FOLIC ACID
D-alpha-tocopherol	pteroylmonoglutamic acid
DL-alpha-tocopherol	calcium-L-methylfolate
D-alpha-tocopheryl acetate	
DL-alpha-tocopheryl acetate	VITAMIN B12
D-alpha-tocopheryl acid succinate	cyanocobalamin
	hydroxocobalamin
VITAMIN K	BIOTIN
phylloquinone (phytomenadione)	D-biotin
menaquinone (*)	
VITAMIN B1	VITAMIN C
thiamin hydrochloride	L-ascorbic acid
thiamin mononitrate	sodium-L-ascorbate
	calcium-L-ascorbate
VITAMIN B2	potassium-L-ascorbate
riboflavin	L-ascorbyl 6-palmitate
riboflavin 5'-phosphate, sodium	
NIACIN	

## 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  
calcium phosphoryl oligosaccharides  
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

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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

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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  
chromium (III) lactate tri-hydrate  
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. No maximum amounts have been set.

#### **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 husholdnings salt og salt i brød og almindeligt bagværk m.v.,, <a href="http://147.29.40.90/GETDOC/B20000062705-REGL">http://147.29.40.90/GETDOC/B20000062705-REGL</a>

### 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 <a href="http://www.slv.se/upload/dokument/Lagstiftning/1980-talet/1983_02.pdf">http://www.slv.se/upload/dokument/Lagstiftning/1980-talet/1983_02.pdf</a>
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 <a href="http://www.slv.se/upload/dokument/Lagstiftning/1980-talet/1983_02.pdf">http://www.slv.se/upload/dokument/Lagstiftning/1980-talet/1983_02.pdf</a>

### 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 (Northern Ireland)

<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 <a href="http://www.opsi.gov.uk/SI/si1998/19980141.htm">http://www.opsi.gov.uk/SI/si1998/19980141.htm</a>
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 <a href="http://www.opsi.gov.uk/SI/si1998/19980141.htm">http://www.opsi.gov.uk/SI/si1998/19980141.htm</a>
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 <a href="http://www.opsi.gov.uk/SI/si1998/19980141.htm">http://www.opsi.gov.uk/SI/si1998/19980141.htm</a>
Nicotinic acid or nicotinamide	Flour, except wholemeal flour, where addition is necessary to	The Bread and Flour Regulations 1998 <a href="http://www.opsi.gov.uk/SI/si1998/19980141.htm">http://www.opsi.gov.uk/SI/si1998/19980141.htm</a>

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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>Northern Ireland</p> <p><a href="http://www.opsi.gov.uk/sr/sr1999/19990301.htm">http://www.opsi.gov.uk/sr/sr1999/19990301.htm</a></p> <p><a href="http://www.opsi.gov.uk/sr/sr2003/20030182.htm">http://www.opsi.gov.uk/sr/sr2003/20030182.htm</a></p> <p><a href="http://www.opsi.gov.uk/sr/sr2004/20040115.htm">http://www.opsi.gov.uk/sr/sr2004/20040115.htm</a></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 11<sup>1</sup>,

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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<sup>1</sup> 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 herb and its preparations originating from *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.

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

##### **Yohimbe bark and its preparations originating from Yohimbe (*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.

No interested parties submitted any scientific data to EFSA to demonstrate the safety of Yohimbe within the time limit referred to in Article 5(2) of Implementing Regulation (EU) No 307/2012. Therefore, Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) and its preparations should be included in Part A of Annex III to Regulation (EC) No 1925/2006 which means that their use in food is prohibited.

### **Part B – Restricted substances:**

Empty

### **Part C – Substances under Community scrutiny**

Empty

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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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