

Health safety aspects of foods

Functional foods: focus on health and nutrition claims



Content



- Functional foods and ingredients
- EFSA role
- Health and nutrition claims on foods: definitions, legislation, examples
- Food supplements: legislation, definition, basic rules of health safety



Introduction

We want more!

Change in nutrition

- Suitable nutrition (delivery of nutrients)
- Optimal nutrition (added value)

WHY???

- Intense increases the scientific developments in nutrition
 - Well being
 - Lifestyle related diseases
 - New market potential





Brain health

Heart health

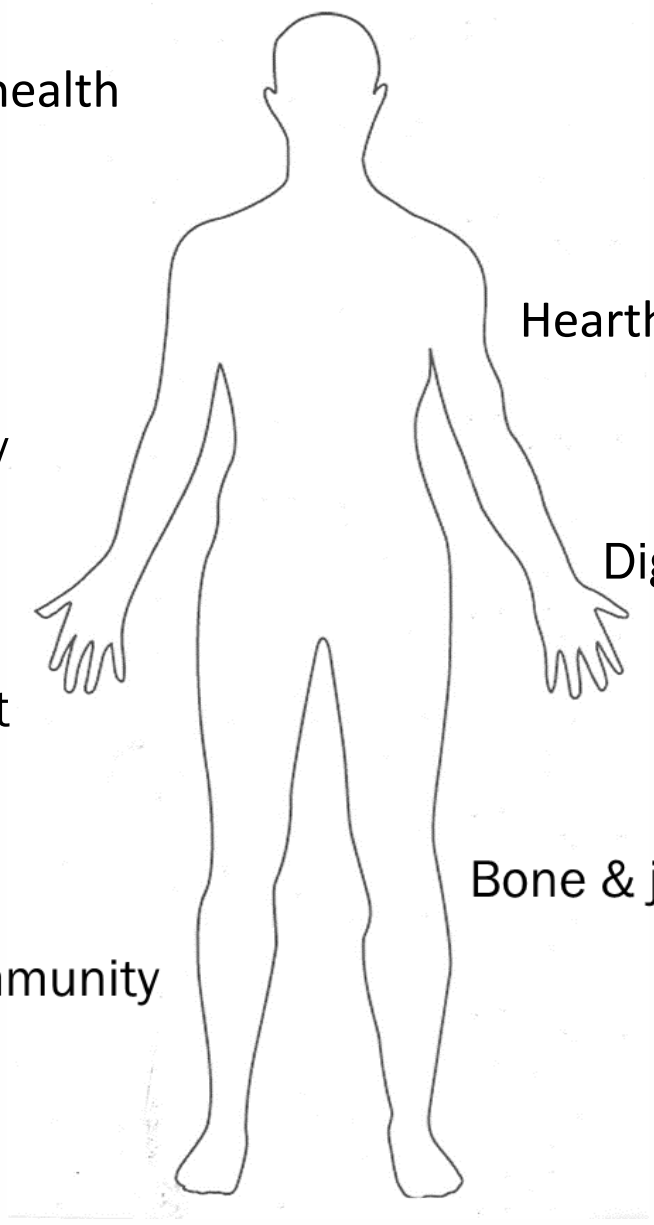
Inside beauty

Digestive health

Weight management

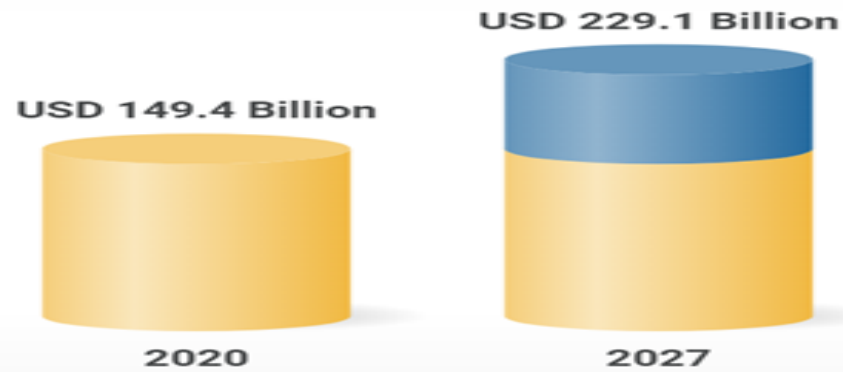
Bone & joint health

Immunity



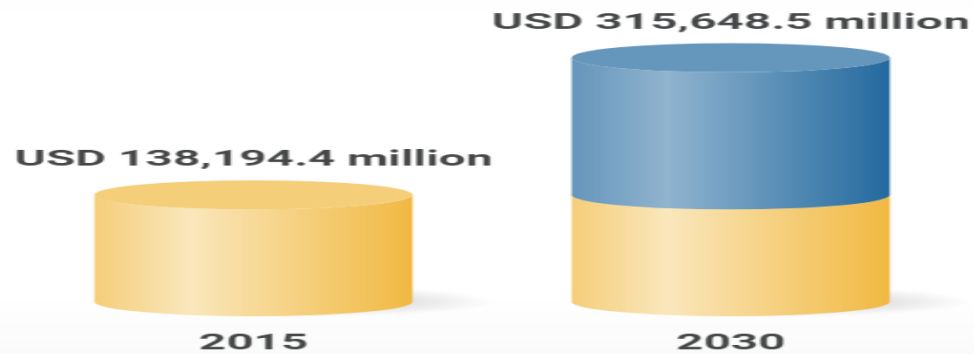
Global Market for Functional Foods and Drinks

Market forecast to grow at CAGR of 6.3%



Global Functional Food Market

Market forecast to grow at a CAGR of 5.7%



Really?



Brain Health?

- Ginkgo biloba extract
- Ginseng extract
- Vitamins folic acid, B12, B6
- Aromatic amino acids (L-tyrosine, L-tyrptophan, phenylalanine)
- Minerals (Iron, Zinc, Iodine, Copper)

HEART HEALTH ?

- Plant sterols and plant sterol esters
- Fiber (soluble /insoluble)
- Vitamins folic acid, E
- Polyphenols





Carotenoids added into foods really act as?

- provitamins A,
- antioxidants,
- anti-cancer activity,
- protection against cardiovascular diseases,
- cataract prevention,
- asthma and allergic diseases
- protective effects on bladder cancer

HEALTH AND NUTRITIONAL CLAIMS ON FOODS



Regulation (EC) No. 1924/2006 on nutrition and health claims

- harmonises the rules governing nutrition and health claims across all Member States while providing assurance to consumers that only standardised nutritional claims or specifically authorised health claims may be carried on food.

COMMISSION REGULATION (EU) No 432/2012

of 16 May 2012

establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

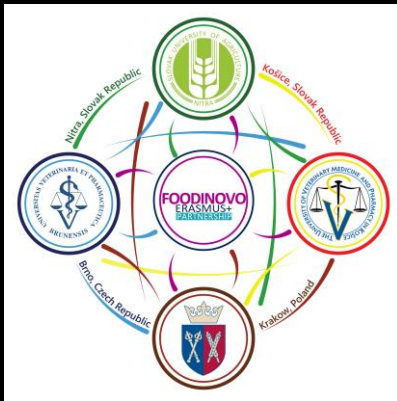




EFSA

**HEALTH AND NUTRITION CLAIMS-
MUST BE APPROVED BY EFSA!!!**

EFSA is responsible for verifying the scientific substantiation of the submitted claims, some of which are currently in use, some of which are proposed by applicants - companies who want to submit claims for authorisation in the EU. This information serves as a basis for the European Commission and Member States, which will then decide whether to authorise the claims.



EFSA's work includes providing scientific advice on:

[General function health claims under Article 13.1](#)

[Claims regarding disease risk reduction and child development or health under Article 14](#)

[Criteria for setting nutrient profiles](#)



European Food Safety Authority

English **EN**

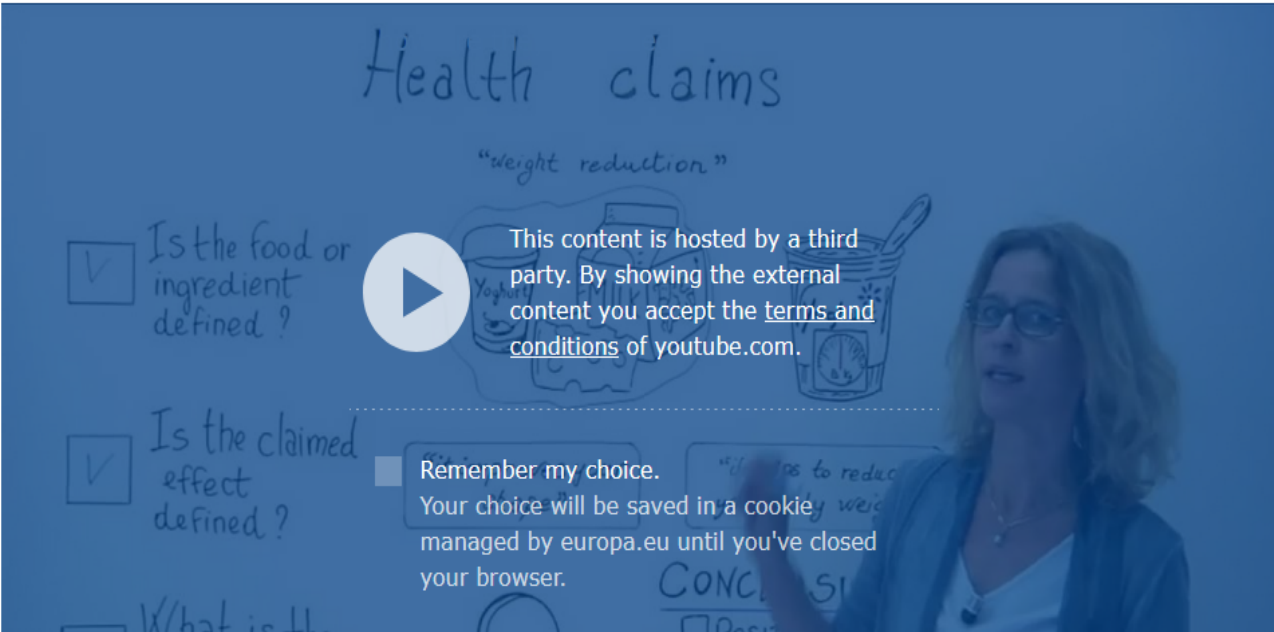
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- APPLICATIONS ▾
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Health claims



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Contents

- FAQ
- Published on this topic
- Related topic(s)

Claims: basic definitions



CLAIM means any message or representation, which is

- not mandatory under Community or national legislation, including
- pictorial, graphic or symbolic representation, in any form, which
- states, suggests or implies that a food has particular characteristics

Výživové hodnoty na 100 g / Nutritional values in 100 g	
Energetická hodnota / Energia / Energy	1685 kJ 400 kcal
Tuky / Fats	8,0 g
- z toho nasycené / nasýtené mastné kyseliny / of which saturated fatty acids	3,6 g
Sacharidy / Carbohydrates	61 g
- z toho cukry / of which sugars	2,9 g
Vláknina / Fibre	10 g
Bílkoviny / Bielkoviny / Proteins	16 g
Sůl / Sol / Salt	1,5 g



Claims: basic definitions

Nutrition claim means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

1. The energy (calorific value) it:
 1. provides
 2. provides at a reduced or increased rate or
 3. does not provide
2. The nutrients or other substances it:
 1. contains
 2. contains in reduced or increased proportions or
 3. does not contain



'Nutrition claim' means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: (a) the energy (calorific value) it

- (i) provides;
- (ii) provides at a reduced or increased rate; or
- (iii) does not provide; and/or

(b) the nutrients or other substances it

- ((i) contains;
- ((ii) contains in reduced or increased proportions; or
- ((iii) does not contain;

Nutrition claims are only permitted if they are listed in the Annex of Regulation (EC) No 1924/2006, lastly amended by [Regulation \(EC\) No 116/2010](#) Updated 10-02-2010

Permitted nutrition claims as listed in the Annex of Regulation (EC) No 1924/2006

LOW ENERGY

A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.

ENERGY-REDUCED

A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.

ENERGY-FREE

A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 4 kcal (17 kJ)/100 ml. For table-top sweeteners the limit of 0,4 kcal (1,7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.

LOW FAT

A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3 g of fat per 100 g for solids or 1,5 g of fat per 100 ml for liquids (1,8 g of fat per 100 ml for semi-skimmed milk).

FAT-FREE

A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of fat per 100 g or 100 ml. However, claims expressed as 'X % fat-free' shall be prohibited.

LOW SATURATED FAT

A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made if the sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1,5 g per 100 g for solids or 0,75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy.

SATURATED FAT-FREE

A claim that a food does not contain saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the sum of saturated fat and trans-fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml.

LOW SUGARS

A claim that a food is low in sugars, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5 g of sugars per 100 g for solids or 2,5 g of sugars per 100 ml for liquids.

SUGARS-FREE

A claim that a food is sugars-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of sugars per 100 g or 100 ml.

WITH NO ADDED SUGARS

A claim stating that sugars have not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURRING SUGARS'.

LOW SODIUM/SALT

A claim that a food is low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.



Health claims: basic definitions



Health claim means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

Reduction of disease risk claim means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;



EU register on nutrition and health claims



is for information only, showing:

- permitted nutrition claims and their conditions of use
- authorised health claims, their conditions of use and applicable restrictions, if any;
- non-authorised health claims and the reasons for their non-authorisation;
- EU legal acts for the specific health claims.

The Commission updates the EU Register when required, namely upon adoption of EU decisions on applications for claims or on changes to conditions of use and restrictions.





Claim type	Nutrient, substance, food or food category	Claim	Conditions of use of the claim / Restrictions of use / Reasons for non-authorisation	Health relationship	EFSA opinion reference	Commission regulation	Status	Entry Id
Art.13(5)	Low-fat fermented milk with a combination of fructo-oligosaccharides (FOS) and live <i>Lactobacillus rhamnosus</i> GG (ATCC 53103), <i>Streptococcus thermophilus</i> (Z57) and <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> (LB2).	Consumption of low-fat fermented milk with a combination of fructo-oligosaccharides (FOS) and live <i>Lactobacillus rhamnosus</i> GG (ATCC 53103), <i>Streptococcus thermophilus</i> (Z57) and <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> (LB2) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals.	Non-compliance with the Regulation because on the basis of the scientific evidence assessed, this claimed effect for this food has not been substantiated.		Q-2015-00488	http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1202&from=EN >Commission Regulation (EU) 2017/1202 of 05/07/2017	Non-authorised	N/A
Art.13(5)	Wheat polar lipid extract	Contributes to improve skin hydration	Non-compliance with the Regulation because on the basis of the scientific evidence assessed, this claimed effect for this food has not been substantiated		Q-2011-01122	Commission Regulation (EU) No 1066/2013 of 30/10/2013	Non-authorised (expiry of transitional period 20/05/2014)	N/A
Art.13(5)	A combination of flaxseed oil and vitamin E	Contributes to maintain skin permeability barrier function	Non-compliance with the Regulation because on the basis of the scientific evidence assessed, this claimed effect for this food has not been substantiated		Q-2012-00337	Commission Regulation (EU) No 1066/2013 of 30/10/2013	Non-authorised (expiry of transitional period 20/05/2014)	N/A
Art.13(5)	<i>Vitis vinifera</i> L. seeds extract	Contributes to promote venous circulation in the legs	Non-compliance with the Regulation because on the basis of the scientific evidence assessed, this claimed effect for this food has not been substantiated.		Q-2012-00387	Commission Regulation (EU) No 155/2014 of 19/02/2014	Non-authorised (expiry of transitional period 12/09/2014)	N/A

Example of authorised health claim: ESSENTIAL FATTY ACIDS



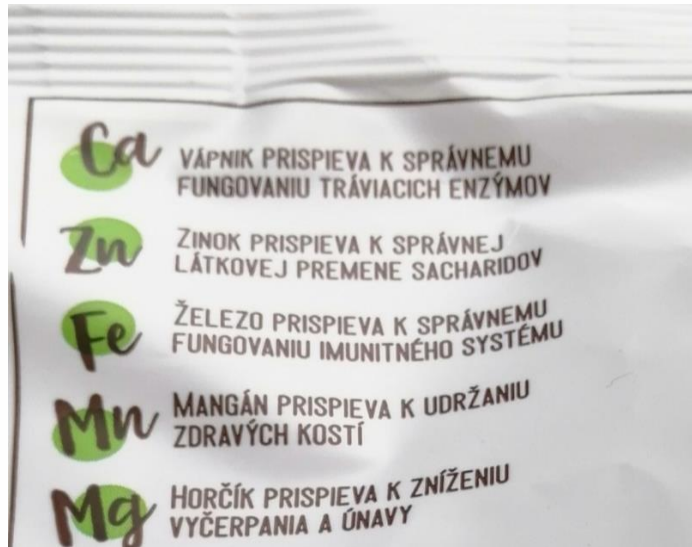
Claim:

Essential fatty acids are needed for normal growth and development of children.

Conditions of use:

Information to the consumer that the beneficial effect is obtained with a daily intake of 2 g of α -linolenic acid (ALA) and a daily intake of 10 g of linoleic acid (LA).

Example of authorised health claim: IRON



Ca contributes to the proper functioning of digestive enzymes

Zn contributes to the proper lath conversion of carbohydrates

Fe contributes to the proper functioning of the immune system

Mn contributes to the maintenance of healthy bones

Mg helps to reduce exhaustion and fatigue

Iron

Iron contributes to the normal function of the immune system

The claim may be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.



Use of claims shall not



- (a) be false, ambiguous or misleading;
- (b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;
- (c) encourage or condone excess consumption of a food;
- (d) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.
- (e) refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations.



HEALTH CLAIMS ARE PERMITTED IF
THE FOLLOWING INFORMATION
IS INCLUDED IN THE LABELLING, THE PRESENTATION
AND ADVERTISING



- (a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;
- (b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
- (c) where appropriate, a statement addressed to persons who should avoid using the food; and
- (d) an appropriate warning for products that are likely to present a health risk if consumed to excess.



Food supplements as foods and their health safety



Article 2

Definition of 'food'

For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

EC 178/2002

- (a) 'food supplements' means 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 effect, 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;

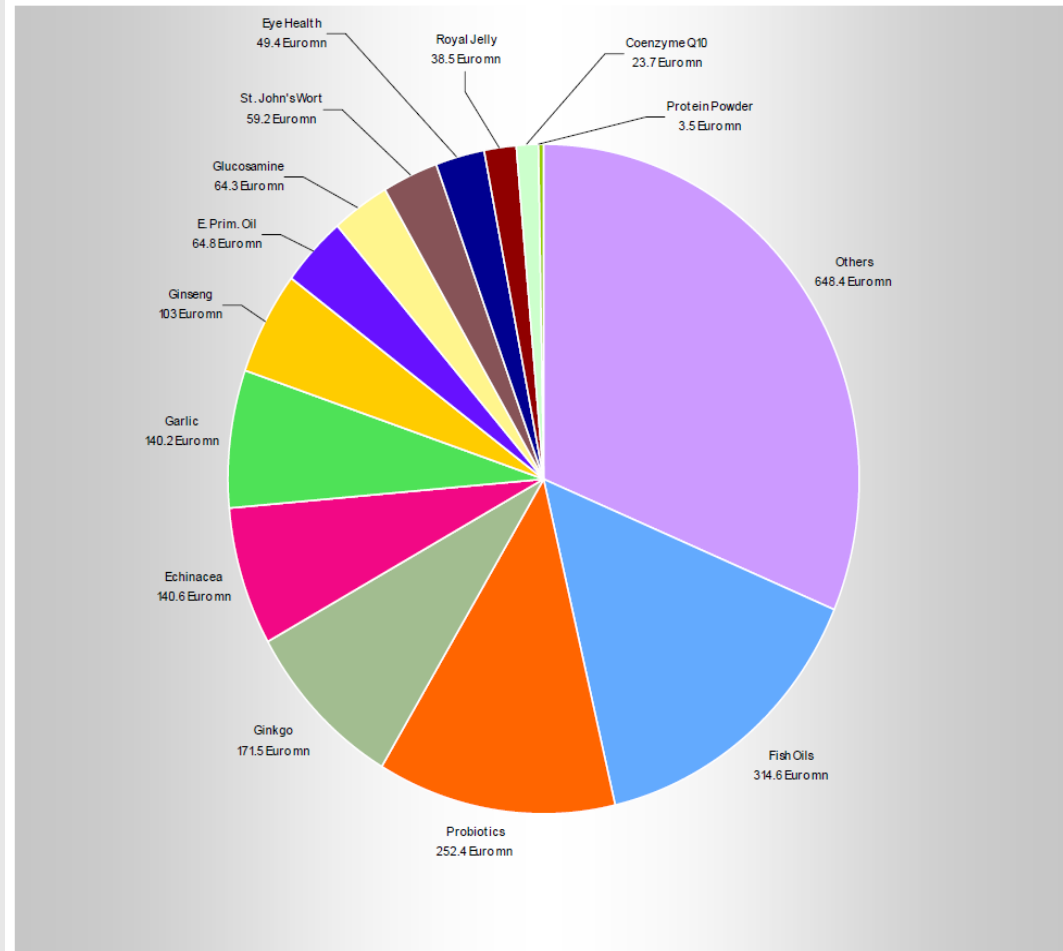
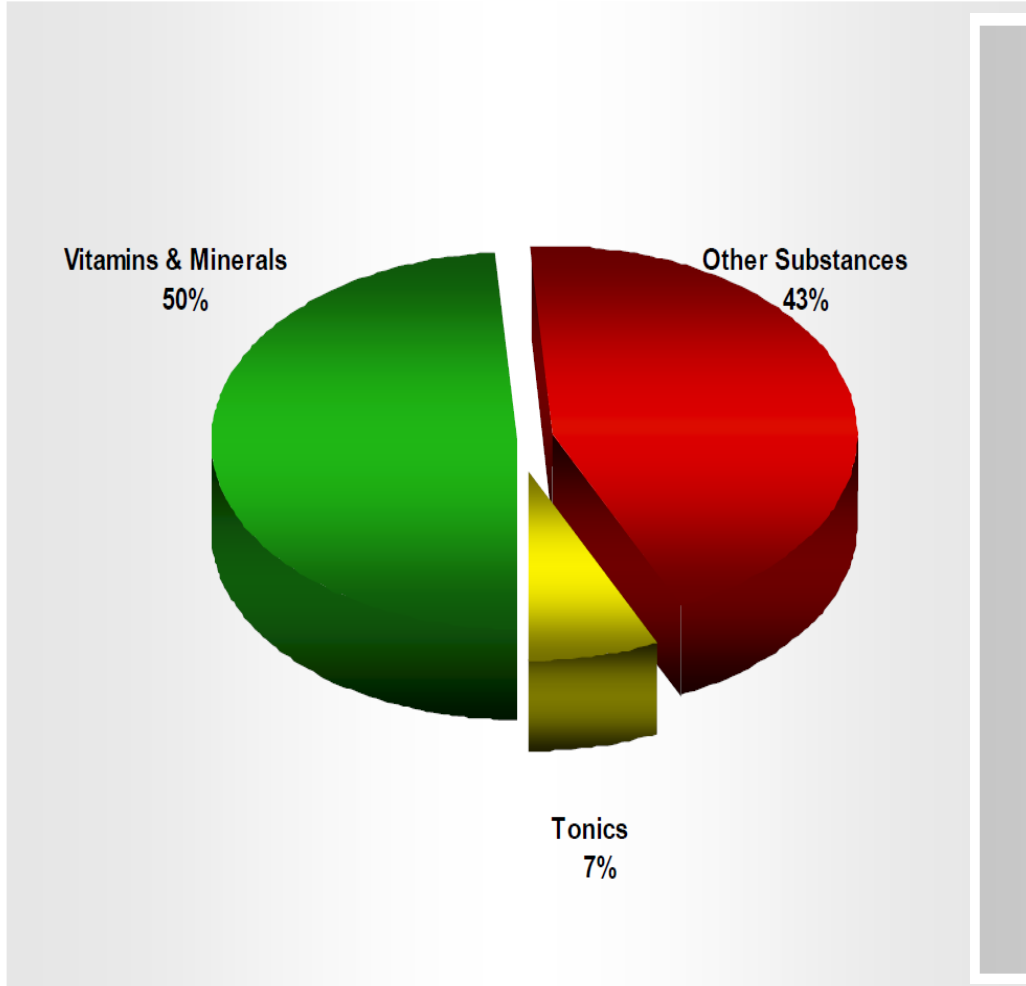
EC 2002/46



Legislative framework of the EU

- By the EU General Food Law, food supplements are considered as foodstuffs. Responsibility for the safety of these products lies with the food business operator placing the product on the market.
- The reference EU legislation is [Directive 2002/46/EC](#), which establishes harmonised lists of the vitamins and minerals substances used in the manufacture of food supplements and the labelling requirements for these products. EFSA provides scientific opinions to support the evaluations carried out by the European Commission.
- The use of substances other than vitamins or minerals in the manufacture of food supplements may be governed by national rules or may be subject to other specific EU legislation:
 - substances without a history of safe use in the EU before 1997, are assessed under [Regulation \(EC\) No 2015/2283](#) on novel food;
 - sources of vitamins, minerals and additional substances proposed for use in the manufacture of food supplements that may also be assessed under [Regulation \(EC\) No 1925/2006](#) on fortification of foods or [Regulation \(EC\) No 609/2013](#) on foods for specific groups;
 - substances added to food supplements to perform certain technological functions, for example to colour, to sweeten or to preserve, that are assessed as food additives under [Regulation \(EC\) No 1333/2008](#). Food supplements may contain additives (e.g. sweeteners, colours, coating agents). In the EU, only food additives that are specifically authorised for use in this food category according to Regulation (EC) No 1333/2008 can be added to food supplements.

Market size and share of the food supplement segment of the EU



Text



Vitamins and minerals which may be declared and their nutrient reference values



Vitamin A (µg)	800	Chloride (mg)	800
Vitamin D (µg)	5	Calcium (mg)	800
Vitamin E (mg)	12	Phosphorus (mg)	700
Vitamin K (µg)	75	Magnesium (mg)	375
Vitamin C (mg)	80	Iron (mg)	14
Thiamin (mg)	1,1	Zinc (mg)	10
Riboflavin (mg)	1,4	Copper (mg)	1
Niacin (mg)	16	Manganese (mg)	2
Vitamin B6 (mg)	1,4	Fluoride (mg)	3,5
Folic acid (µg)	200	Selenium(µg)	55
Vitamin B12 (µg)	2,5	Chromium (µg)	40
Biotin (µg)	50	Molybdenum (µg)	50
Pantothenic acid (mg)	6	Iodine (µg)	150
Potassium (mg)	2 000		

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

Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

ANNEX I

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

- A. Vitamins
1. VITAMIN A
 - (a) retinol
 - (b) retinyl acetate
 - (c) retinyl palmitate
 - (d) beta-carotene
 2. VITAMIN D
 - (a) cholecalciferol
 - (b) ergocalciferol
 3. VITAMIN E
 - (a) D-alpha-tocopherol
 - (b) DL-alpha-tocopherol
 - (c) D-alpha-tocopheryl acetate
 - (d) DL-alpha-tocopheryl acetate
 - (e) D-alpha-tocopheryl acid succinate
 - (f) mixed tocopherols (*)
 - (g) tocotrienol tocopherol (**)
 4. VITAMIN K
 - (a) phytylquinone (phylloquinone)
 - (b) menaquinone (***)
 5. VITAMIN B1
 - (a) thiamin hydrochloride
 - (b) thiamin mononitrate
 - (c) thiamin monophosphate chloride
 - (d) thiamin pyrophosphate chloride
 6. VITAMIN B2
 - (a) riboflavin
 - (b) riboflavin 5'-phosphate, sodium
 - (c) isoalloxazine (isoalloxazine monohydrate)
 7. VITAMIN B3
 - (a) nicotinic acid
 - (b) nicotinic acid amide
 - (c) nicotinic acid dimethylmaleate
 - (d) nicotinic acid dimethylmaleate calcium salt
 - (e) nicotinic acid dimethylmaleate sodium salt
 - (f) nicotinic acid dimethylmaleate potassium salt
 - (g) nicotinic acid dimethylmaleate calcium salt
 - (h) nicotinic acid dimethylmaleate sodium salt
 - (i) nicotinic acid dimethylmaleate potassium salt
 8. VITAMIN B6
 - (a) pyridoxine hydrochloride
 - (b) pyridoxine 5'-phosphate
 - (c) pyridoxal 5'-phosphate
 9. VITAMIN B12
 - (a) cyanocobalamin
 - (b) hydroxycobalamin
 - (c) 5'-deoxyadenosylcobalamin
 - (d) methylcobalamin
 10. FOLATE
 - (a) pteroylmethopterin acid
 - (b) calcium-L-methylfolate
 11. VITAMIN B12
 - (a) cyanocobalamin
 - (b) hydroxycobalamin
 - (c) 5'-deoxyadenosylcobalamin
 - (d) methylcobalamin
 12. BIOTIN
 - (a) D-biotin
 13. VITAMIN C
 - (a) L-ascorbic acid
 - (b) sodium-L-ascorbate
 - (c) calcium-L-ascorbate (***)
 - (d) potassium-L-ascorbate
 - (e) L-ascorbyl 8-palmitate
 - (f) magnesium L-ascorbate
 - (g) zinc L-ascorbate
 14. PANTOTHENIC ACID
 - (a) D-pantothenate, calcium
 - (b) D-pantothenate, sodium
 - (c) dexpantothol
 - (d) pantothenol
 15. VITAMIN B5
 - (a) pyridoxine hydrochloride
 - (b) pyridoxine 5'-phosphate
 - (c) pyridoxal 5'-phosphate
 16. FOLATE
 - (a) pteroylmethopterin acid
 - (b) calcium-L-methylfolate
 17. VITAMIN B12
 - (a) cyanocobalamin
 - (b) hydroxycobalamin
 - (c) 5'-deoxyadenosylcobalamin
 - (d) methylcobalamin
 18. BIOTIN
 - (a) D-biotin
 19. VITAMIN C
 - (a) L-ascorbic acid
 - (b) sodium-L-ascorbate
 - (c) calcium-L-ascorbate (***)
 - (d) potassium-L-ascorbate
 - (e) L-ascorbyl 8-palmitate
 - (f) magnesium L-ascorbate
 - (g) zinc L-ascorbate
 20. PANTOTHENIC ACID
 - (a) D-pantothenate, calcium
 - (b) D-pantothenate, sodium
 - (c) dexpantothol
 - (d) pantothenol
 21. VITAMIN B5
 - (a) pyridoxine hydrochloride
 - (b) pyridoxine 5'-phosphate
 - (c) pyridoxal 5'-phosphate
 22. FOLATE
 - (a) pteroylmethopterin acid
 - (b) calcium-L-methylfolate
 23. VITAMIN B12
 - (a) cyanocobalamin
 - (b) hydroxycobalamin
 - (c) 5'-deoxyadenosylcobalamin
 - (d) methylcobalamin
 24. BIOTIN
 - (a) D-biotin
 25. VITAMIN C
 - (a) L-ascorbic acid
 - (b) sodium-L-ascorbate
 - (c) calcium-L-ascorbate (***)
 - (d) potassium-L-ascorbate
 - (e) L-ascorbyl 8-palmitate
 - (f) magnesium L-ascorbate
 - (g) zinc L-ascorbate





Food and Agriculture Organization of the United Nations

GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS

CAC/GL 55 - 2005



- **The minimum level** of each vitamin and/or mineral contained in a vitamin and mineral food supplement per daily portion of consumption as suggested by the manufacturer **should be 15% of the recommended daily intake.**
- **Maximum amounts of vitamins and minerals** in vitamin and mineral food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:
 - (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;
 - (b) the daily intake of vitamins and minerals from other dietary sources.

Monitoring of food supplement products

EU countries may request notification of the placing on the market in their territory of a food supplement product.

Competent authority for Slovakia is



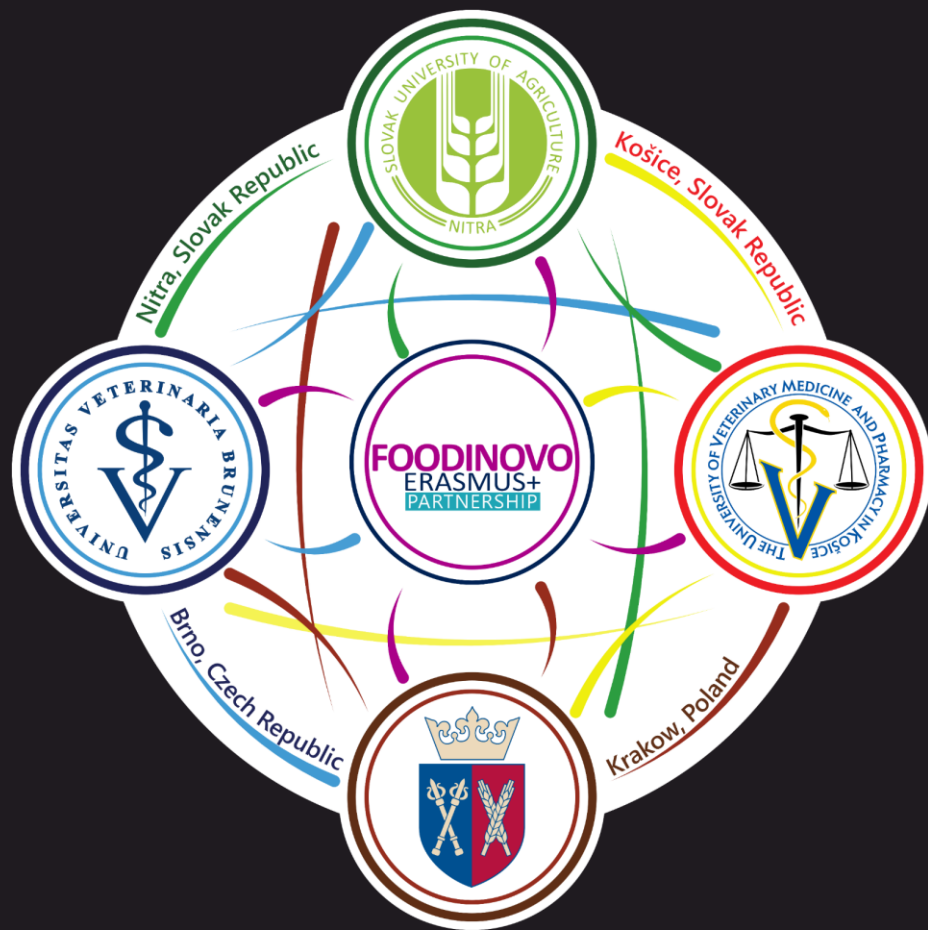
**SLOVAK
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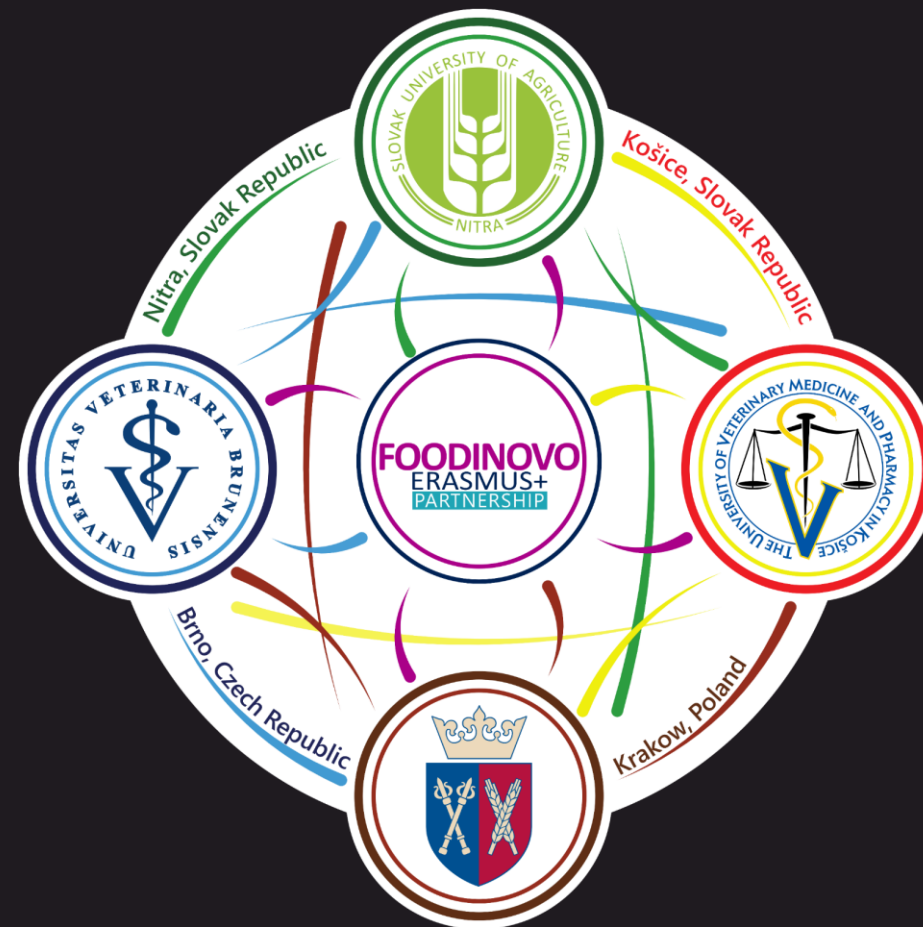
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