
Demonstration of Innovative Functional food production systems based on more sustainable value chains of marine and freshwater raw materials for conscientious EU consumers

A large, stylized graphic on the left side of the slide. It consists of a green leaf-like shape at the top, a blue water droplet in the center, and three blue curved lines at the bottom, all in a light blue color. The graphic is partially obscured by the dark blue box containing the section headers.

3.0 Legal requirements, policies and quality management

3.2 Functional Food regulations

Main objective

 Define Functional Foods according to regulatory definition

Learning outcomes

 Know the definition of Functional Foods and how they are regulated in the EU

 Understand the importance of adequate labelling of Functional Foods

Agenda

-  Definition Functional Food
-  Regulation within the EU
-  Nutrition Claims
-  Health Claims
-  Addition of vitamins, minerals and certain other substances

General Food Law - Overview

TABLE 9.1 Overview of the EU regulations for food/feed

Regulatory topic	Description
1. General Food Law Regulation	Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety • Guarantee a high level of protection of human life and health and the protection of consumers' interests. Also guarantee fair practices in food trade, taking into account animal health and welfare, plant health, and the environment • Ensure free movement of food and feed manufactured and marketed in the Union, in accordance with the General Food Law Regulation • Facilitate global trade of safe feed and safe, wholesome food by taking into account international standards and agreements when developing Union legislation, except where this might undermine the high level of consumer protection pursued by the Union

Regulatory topic	Description
2. Labeling and nutrition	• Food labeling legislation—(EU) No. 1169/2011 • Nutrition and Health Claims—(EC) No. 1924/2006 • Food supplements—Directive 2002/46/EC • Addition of vitamins and minerals—(EC) No. 1925/2006 • Food for specific groups—(EU) No. 609/2013 • <i>Trans</i> fat in food—(EC) No. 1925/2006
3. Biological and chemical safety	• Food hygiene—(EC) 852/2004 • Feed hygiene—(EC) Regulation 767/2009 • Feed additives—(EC Regulation 1831/2003) • Undesirable substances in animal feed—Council Directive 2002/32/EC. • Contaminants in foodstuff—(EC) No. 1881/2006
4. Novel food	(EU) 2015/2283 "Food business operators can place a novel food on the European Union market only after the Commission has processed an application for the authorization of a novel food, and has adopted an implementing act authorizing the placing on the market of a novel food and updating the Union list"
EU, European Union.	

Source: Markou G. (2021)

Functional Foods

A food that beneficially affects one or more target functions in the body beyond adequate nutritional effects in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease. It is consumed as part of a normal food pattern. It is not a pill, a capsule or any form of dietary supplement.

European Commission, EU

Natural or processed foods that contain biologically active compounds; which, in defined, effective, and non-toxic amounts, provide a clinically proven and documented health benefit utilizing specific biomarkers for prevention, management, or treatment of chronic diseases or its symptoms.

Functional Food Centre, US

Functional Foods

Generally, foods can be placed on the European market BUT

→ For the fortification, enhancement or enrichment with a substance or the promotion of health benefits of a (functional) food regulatory frameworks must be considered.

Nutrition and Health Claims are regulated by



[Regulation \(EC\) No. 1924/2006](#)

30.12.2006

EN

Official Journal of the European Union

L 404/9

**REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 December 2006
on nutrition and health claims made on foods**

Addition of vitamins and minerals are regulated by



[Regulation \(EC\) No. 1925/2006](#)

L 404/26

EN

Official Journal of the European Union

30.12.2006

**REGULATION (EC) No 1925/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 December 2006
on the addition of vitamins and minerals and of certain other substances to foods**



Nutrition and Health Claims

Nutrition and health claims - overview

Nutrition Claims (Chapter III)	Health Claims (Chapter IV)		
• Relating to any particular beneficial nutritional property of a food (e.g. energy, substances).	Function Health Claims (Art. 13) • Relating to growth, development and functions of the body • Referring to psychological and behavioural functions • On slimming or weight-control	Risk Reduction Health Claims (Art. 14-1a) • Reducing risk factors in the development of diseases	Claims referring to children's development (Art. 14-1b) • e.g. relevant for normal growth

General requirements of Claims

Reg. 1924/2006 – Art. 5 & 6



Based on generally accepted scientific evidence

- Sufficient bioavailability of the substance/nutrient in question, where needed
- Significant quantity of substance/nutrient in the final product OR
- Absence or reduced quantity of the substance/nutrient in the final product



Claims refers to the food ready for consumption in accordance with manufacturer's instructions



The average consumer can be expected to understand the beneficial effects as they are expressed in the claim

→ In any case, the claims used must be included in a **list of authorised claims** or authorised in an **individual authorisation procedure**.

Nutrition and health claims SHALL NOT

Reg. 1924/2006 – Art. 3

-  Be false, ambiguous or misleading
-  Give rise to doubt about the safety and/or nutritional adequacy of other foods
-  Encourage or condone excess consumption of a food
-  State, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general
-  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



Nutrition Claims

Nutrition claims

 Inform about increased, reduced or missing nutrients, in food

 Examples

- „high fibre“
- „reduced calories“
- „sugar-free“
- „contains Vitamin C“

 The list of nutrition claims and conditions applying to them are **listed in the Annex of Reg. (EC) 1924/2006**

 Special rules for **comparative claims** (e.g. reduced saturated fat)

- Comparison
 - within the same food category
 - Of the same quantity
 - Involve a range of similar products (that do not already carry a claim and are from different brands)
- Difference must be stated clearly for consumers

Example: Omega-3-fatty acids



Sources of Omega-3-fatty acids:

A claim that a food is a source of omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,3 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.



High Omega-3-fatty acids:

Contains at least 0,6 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal..

Example: unsaturated fat



High monounsaturated fat

At least 45 % of the fatty acids present in the product derive from monounsaturated fat under the condition that monounsaturated fat provides more than 20 % of energy of the product.



High polyunsaturated fat

At least 45 % of the fatty acids present in the product derive from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20 % of energy of the product.



High unsaturated fat

At least 70 % of the fatty acids present in the product derive from unsaturated fat under the condition that unsaturated fat provides more than 20 % of energy of the product.



Demonstration of Innovative Functional food production systems based on more sustainable value chains of marine and freshwater raw materials for conscientious EU consumers



Health Claims



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Health Claims – the most important facts



Shall be prohibited unless they comply with the general requirements for Claims and specific requirements for Health Claims and are authorised.



Specific requirements:

The following information needs to be included in the labelling, or if no such labelling exists, in the presentation and advertising:

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



Health Claims – banned Claims



Specific prohibitions:

- claims which suggest that health could be affected by not consuming the food.
- claims which refer to the rate or amount of weight loss.
- claims which refer to recommendations of individual doctors or health professionals and other associations not referred to in the regulation (i.e. other than national associations of medical, nutrition or dietetic professionals and health-related charities)



Reference to general, non-specific benefits of nutrients or foods for **overall good health or health-related well-being** is not allowed unless accompanied by a specific authorised health claim.

Health Claims according to Art. 13

 The list of authorised claims includes 450 claims, which are summarized in [Regulation \(EU\) No 432/2012](#).

25.5.2012

EN

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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

(Text with EEA relevance)

Health Claims according to Art. 14

 Only allowed after **individual authorisation procedure**.

Health Claims – according to Art 13 Regulation (EG) No. 1924/2006



Example: Omega-3-fatty acids:

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Eicosapentaenoic acid and docosahexaenoic acid (EPA/DHA)	EPA and DHA contribute to the normal function of the heart	The claim may be used only for food which is at least a source of EPA and DHA as referred to in the claim SOURCE OF OMEGA-3 FATTY ACIDS as listed in the Annex to Regulation (EC) No 1924/2006. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of EPA and DHA.		2010;8(10):1796 2011;9(4):2078	504, 506, 516, 527, 538, 703, 1128, 1317, 1324, 1325, 510, 688, 1360
Alpha-linolenic acid (ALA)	ALA contributes to the maintenance of normal blood cholesterol levels	The claim may be used only for food which is at least a source of ALA as referred to in the claim SOURCE OF OMEGA-3 FATTY ACIDS as listed in the Annex to Regulation (EC) No 1924/2006. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of ALA.		2009; 7(9):1252 2011;9(6):2203	493, 568



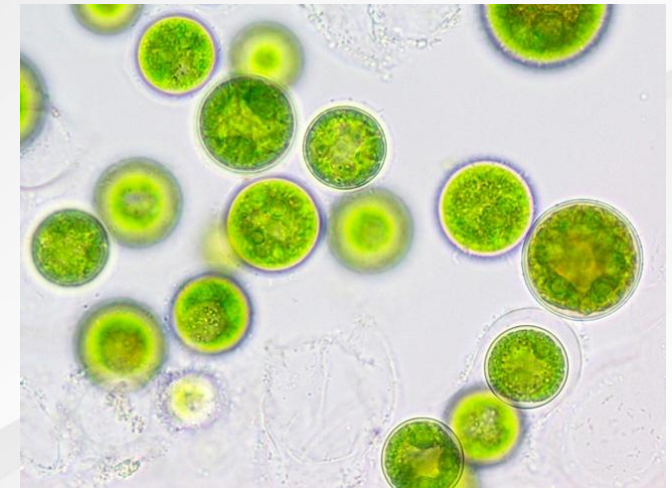
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*e.g. Health claim for microalgae *Schizochytrium* sp.*

 “DHA contributes to the maintenance of normal brain function.”

 “DHA contributes to the maintenance of normal vision.”

→ The statement of the Health Claim is only allowed if minimum requirements are met.



Microalgae *Schizochytrium* sp. ([misPeces, 2025](#))

Health Claims – according to Art 13 Regulation (EG) No. 1924/2006



Example: saturated fatty acids

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Foods with a low or reduced content of saturated fatty acids	Reducing consumption of saturated fat contributes to the maintenance of normal blood cholesterol levels	The claim may be used only for food which is at least low in saturated fatty acids, as referred to in the claim LOW SATURATED FAT or reduced in saturated fatty acids as referred to in the claim REDUCED [NAME OF NUTRIENT] as listed in the Annex to Regulation (EC) No 1924/2006.		2011;9(4): 2062	620, 671, 4332
Oleic acid	Replacing saturated fats in the diet with unsaturated fats contributes to the maintenance of normal blood cholesterol levels. Oleic acid is an unsaturated fat.	The claim may be used only for food which is high in unsaturated fatty acids, as referred to in the claim HIGH UNSATURATED FAT as listed in the Annex to Regulation (EC) No 1924/2006.		2011;9(4): 2043	673, 728, 729, 1302, 4334



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Health Claims – according to Art 13 Regulation (EG) No. 1924/2006



Example: fish

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Meat or fish	Meat or fish contributes to the improvement of iron absorption when eaten with other foods containing iron	The claim may be used only for food which contains at least 50 g of meat or fish in a single quantified portion. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained by consuming 50 g of meat or fish together with food(s) containing non-haem iron.		2011;9(4): 2040	1223

Request for addition to Community list (Art. 13) and individual authorisation of Claims referring to Art.14



Regulation

- [Commission Regulation \(EC\) No 353/2008](#) (establishing implementing rules for applications for authorisation of health claims as provided in Art 15 of Reg. No 1924/2006)

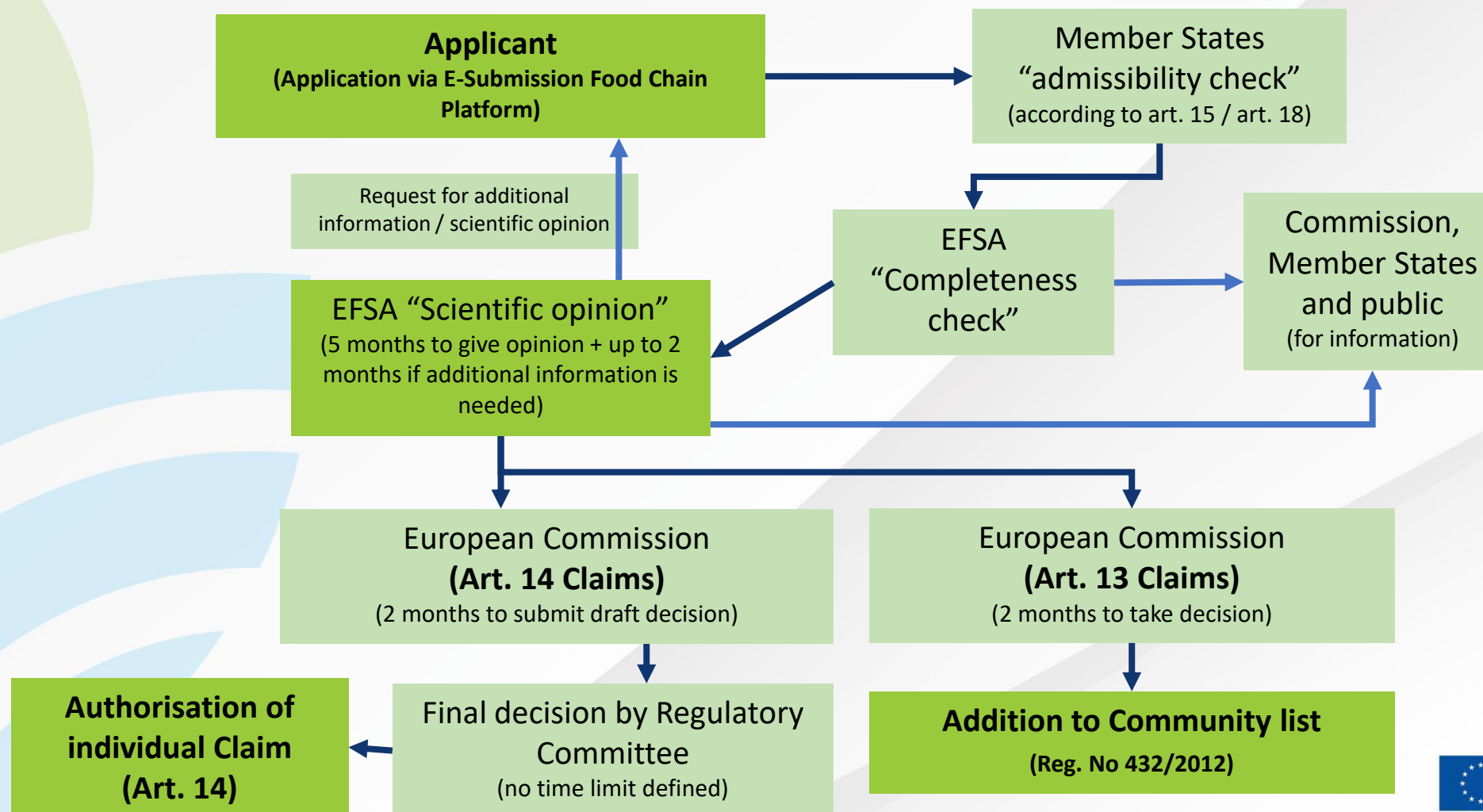


Guidance document

- [Scientific and technical guidance for the preparation and presentation of a health claim application \(Revision 3\)1](#)



Application process according to Art. 15 to Art. 18





Addition of vitamins, minerals and certain other substances



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Enriched Food with vitamins/ minerals – Regulation (EC) No 1925/2006



Why adding vitamins and minerals?

- Restore content, where it has been reduced during production, storage, handling procedures (e.g. lost vitamins through heating)
- Provide additional nutritional value
- Provide similar nutritional value to mimicked food (e.g. plant-based milk enriched with Vit D and B12)



Support fair trade across the EU and protect consumers' health.

- Annex 1: includes vitamins and minerals which may be added to foods.
- Annex 2: includes vitamin formulations and mineral substances which may be added to foods.
- Annex 3: includes substances whose use in foods is prohibited, restricted or under community scrutiny.

Requirements for the addition of vitamins and minerals:

-  Only vitamins and/or minerals **listed in Annex I, in the forms listed in Annex II**, may be added to foods.
-  Vitamins and minerals **in a form that is bio-available** to the human body may be added to foods, even if they aren't normally found in them, when there is a good reason to do so. E.g.:
 - Proven deficiency in the general population or specific groups (e.g. children, elderly) - demonstrated by clinical or sub-clinical evidence of deficiency or indicated by estimated low levels of intake of nutrients
 - To improve the nutrition of the general population or specific groups to compensate for dietary habits that lead to low vitamin or mineral intake
 - When new scientific research shows that certain vitamins or minerals play an important role in human health.

Novel food prototype development, Cluj-Napoca, Romania

 Technical University of Cluj-Napoca

 Enhanced nutritional profile of

- Hamburger buns
- Hamburger patties
- Hamburger sauce

Key facts

Hamburger

Product



Alaria esculenta

Used
species



Video



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Literature

- Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods
- Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods
- 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
- Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council
- Health Claims (art. 14) <https://www.efsa.europa.eu/en/topics/health-claims-art-14> 20.05.2025
- Scientific and technical guidance for the preparation and presentation of a health claim application. (2021). EFSA Journal, 19(3):6554.
- BVL – Nährwert- und gesundheitsbezogene Angaben über Lebensmittel (Health Claims). (n.d.). https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/04_AntragstellerUnternehmen/01_HealthClaims/Im_healthClaims_node.html;jsessionid=AAAD35F31D039E077A96FF356A1F768D.internet992#doc11035652bodyText3 20.05.2025
- Markou, G. Chentir, I. Tzovenis, I. (2021). Microalgae and cyanobacteria as food: Legislative and safety aspects. In Cultured Microalgae for the Food Industry (pp. 249-264). Academic Press. <https://doi.org/10.1016/B978-0-12-821080-2.00003-4>



Thank you very much for your attention!

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