

Information on Nutrition and Health Claims and Food Supplements

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Background

This document is support material for the training programme on the regulation of nutrition and health claims and food supplements in Ireland.¹

The document provides an overview of the:

- Nutrition labelling requirements
- Framework of the nutrition and health claims legislation
- Labelling requirements for food products bearing authorised nutrition and health claims
- Framework of the food supplement legislation
- Assessment process for food supplements notified to the Food Safety Authority of Ireland (FSAI)
- Labelling requirements for food supplements

Legislation Referred to in this Document

- 1) Council Directive of 24 September 1990 on nutrition labelling for foodstuffs (90/496/EEC) (as amended)
- 2) S.I. No. 461 of 2009 European Communities (nutrition labelling for foodstuffs) Regulations, 2009
- 3) Regulation (EC) 1924/2006 of the European Parliament and of the council of 20 December 2006 on nutrition and health claims made on food (as amended)
- 4) 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
- 5) S.I. No. 506 of 2007 European Communities (Food Supplement) Regulations, 2007
- 6) Commission Regulation (EC) 1170/2009 of 30th November amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements
- 7) Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and of certain other substances in foods
- 8) Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
- 9) S.I. No. 483 of 2002 European Communities (Labelling, Presentation and Advertising of Foodstuffs) Regulations, 2002
- 10) S.I. No. 540 of 2003 Medicinal Products (prescription and control of supply) Regulations, 2003

Throughout the document where guidance is given on aspects of the legislation, a reference to the relevant articles and legislation is included. This is to facilitate a more detailed examination of the legislation for precise and accurate interpretation.

¹ This document presents the position of nutrition and health claims and food supplements requirements up to and including May 2010. Given that food legislation continues to be adapted and amended updates on nutrition and health claims and food supplements will be provided through the FSAI website (www.fsai.ie).

Nutrition Labelling Requirements

The nutrition labelling information in Directive 90/496/EEC (as amended) is required when a **nutrition or health claim** is made.

(Article 7 of Regulation 1924/2006)

Nutrition labelling requirements:

- Information is expressed per 100g or per 100ml. In addition, the information may be given per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated
- Information provided relates to the foodstuff as sold. The information may relate to the product after preparation, provided that sufficient preparation instructions are given and the label clearly states that the information relates to the food as prepared for consumption
- Information must be presented together in one place in tabular form with the numbers aligned. Where there is insufficient space on the label, the information may be presented in linear form
- Information must be legible, indelible, in a conspicuous location
- Information must be in English. (Other languages including Irish may be used in addition to English)

(Directive 90/496 (as amended))

The information on nutrition labelling may be presented in a Group 1 or a Group 2 format.

The Group 1 format must provide the following information:

Nutrition Information	Per 100g
Energy	kJ/kcal
Protein	g
Carbohydrate	g
Fat	g

The Group 2 format must provide the following information:

Nutrition Information	Per 100g
Energy	kJ/kcal
Protein	g
Carbohydrate of which: ← sugars	g (g)
Fat of which: ← saturates	g (g)
Fibre	g
Sodium	g

Where:
 – sugars g and/or
 – polyols g and/or
 – starch g
 are declared, they must be shown as a component of **carbohydrate** in the nutrition table.

Where:
 – saturates g and/or
 – monounsaturates g and/or
 – polyunsaturates g and/or
 – cholesterol mg
 are declared, they must be shown as a component of **fat** in the nutrition table.

Vitamins and Minerals

Vitamins and minerals can only be declared if they are present in the food in “**significant amounts**”. A significant amount is defined as 15% of the recommended daily allowance (RDA). For the purposes of nutrition labelling, the RDAs in the Annex to directive 90/496/EEC, as amended, must be used.

If vitamins and/or minerals are declared, they should be listed under the compulsory information (Group 1 or Group 2 format) and must provide:

- A declaration of their quantity with the appropriate unit (µg/mg/g) and
- An indication of the percentage of the RDA

Note:

There should be **at least 15%** of the RDA present in either 100g or 100ml of the product (or **at least 15%** of the RDA present per packet of the foodstuff where the packet only contains a single serving).

An example of an **Group 2** nutrition table including vitamin and mineral declarations.

Nutrition Information	Per 100g
Energy	245kJ 600kcal
Protein	23.4g
Carbohydrate of which: sugars	18.6g 1.7g
Fat of which: saturates mono-unsaturates polyunsaturates	47.5g 4.7g 9.8g 31.0g
Fibre	6.0g
Sodium	Trace
Vitamin A	120µg (15% RDA)
Vitamin C	16mg (20% RDA)
Iron	7.5mg (54% RDA)

Regulation 1924/2006 on nutrition and health claims states that:

- Products making nutrition claims may use Group 1 or Group 2 format as appropriate
- Products making health claims must use Group 2 format
- Where a nutrition or health claim relates to substances that do not appear in the nutrition labelling, the information for these substances must appear in the same field of vision as the nutrition information and be expressed as required by Article 6 of Directive 90/496
- Where a health claim is made in generic advertising, e.g. dairy is good for your bones, nutrition information is **not** required

Note:

- General labelling requirements as per Directive 2000/13/EC, as amended apply to all prepackaged foodstuffs
- Specific labelling rules may also apply to other products, e.g. beef and beef products, chocolate, honey etc.

Nutrition and Health Claims Overview

Regulation 1924/2006 on nutrition and health claims on food came into effect on 1st July 2007. It covers all foods including foods for particular nutritional uses (PARNUTS), natural mineral waters, water intended for human consumption and food supplements.

The Regulation applies to nutrition and health claims made in commercial communications (whether in the labelling, presentation or advertising) of the food to be delivered to the final consumer.

It includes foods:

- Placed on the market unpacked or supplied in bulk
- Intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers

The Regulation **does not** apply to claims made in non-commercial communications such as:

- Dietary guidelines
- Advice issued by public health authorities and bodies
- Information in the press and in scientific publications

Claims should not:

- X Be false or misleading
- X Give rise to doubt about the safety and/or nutrition adequacy of other foods
- X Encourage or condone excess consumption of a food
- X State, suggest or imply that a properly balanced and varied diet cannot provide adequate quantities of nutrients
- X In general, refer to changes in bodily function that could give rise to, or exploit fear in the consumer either textually or through pictorial, graphic or symbolic representation

(Article 3 of Regulation 1924/2006)

- X Attribute to any foodstuff the property of preventing, treating or curing a human disease, or referring to such properties

(Article 2 (1)(b) of Directive 2000/13 as amended)

In order to make a claim, the following conditions must be fulfilled:

- ✓ The substances for which a claim is made, must be shown to have beneficial nutritional or physiological effects established by **generally accepted scientific principles**
- ✓ The beneficial nutrient or substance for which the claim is made, is present in the final product in a **significant quantity**
 - the nutrient or substance for which the claim is made is in a form that is **“available for use by the body”** (bioavailable)
 - the claimed beneficial effect has to be provided by a **‘reasonable quantity of the consumed product’**. This means that an adequate amount of the active nutrient or substance has to be present in a reasonable amount of the food product
 - if the claimed beneficial effect is due to the absence or reduction of a nutrient or substance, then the nutrient or substance should be absent or reduced to the extent that produces the nutritional or physiological effect claimed
- ✓ The **average consumer should understand** the beneficial effects expressed in the claim
- ✓ The claim refers to the **food ready for consumption** according to the manufacturer’s instructions
- ✓ The claim complies with the specific conditions for nutrition claims and health claims (as outlined in this document)

(Article 5 of Regulation 1924/2006)

Nutrient Profiles

Food products bearing claims cannot be inherently “unhealthy”. This means that foods bearing claims shall not have high levels of nutrients that need to be restricted to prevent chronic diseases, e.g. fat, saturated fatty acids, trans fatty acids, sugars and salt. Rules setting “nutrient profiles” will establish healthy limits for different categories of foods.

(Article 4 of Regulation 1924/2006)

These nutrient profiles have yet to be established by the Commission and Member States.

Comparative Claims

A comparison may only be made between foods of the same category, taking into consideration a range of foods of that category. The difference in the quantity of a nutrient and/or the energy value must be stated and the comparison must relate to the same quantity of food.

(Article 9 of Regulation 1924/2006)

Comparative claims continue to be discussed at EU level.

Nutrition Claims

Regulation 1924/2006 defines a **nutrition claim** as:

‘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.’

and a **nutrient** as:

‘protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in the Annex to Directive 90/496/EEC, and substances which belong to or are components of one of those categories’.

Nutrition claims are the simplest type of claim about the nutrients a food contains, e.g. orange juice contains vitamin C.



Listed below are the permitted nutrition claims with their conditions of use as detailed in the Annex of Regulation 1924/2006 (as amended). These claims or claims of a similar nature which are likely to have same meaning to the consumer, may be used. This list came into effect on 19th January, 2010.

Nutrition Claim	Condition of Use
Low energy	product does not contain more than – 40 kcal (170 kJ)/100g for solids or 20 kcal (80 kJ)/100ml for liquids <i>For table-top sweeteners the limit of 4 kcal (17kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose), applies.</i>
Energy-reduced	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	product does not contain more than – 4kcal (17kJ)/100ml. <i>For table-top sweeteners the limit of 0.4kcal (1.7kJ)/portion, with equivalent sweetening properties to 6g of sucrose (approximately 1 teaspoon of sucrose), applies.</i>
Low fat	product contains no more than – 3g of fat per 100g for solids or 1.5g of fat per 100ml for liquids (1.8g of fat per 100ml for semi-skimmed milk)
Fat-free	product contains no more than – 0.5g of fat per 100g or 100ml Claims expressed as ‘X% fat-free’ are prohibited.
Low saturated fat	the sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1.5g per 100g for solids or 0.75g per 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.
Source of omega-3 fatty acids	the product contains: at least 0.3g alpha-linolenic acid per 100g and per 100kcal, or at least 40mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal
High omega-3 fatty acids	the product contains: at least 0.6g alpha-linolenic acid per 100g and per 100kcal, or at least 80mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal
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
Saturated fat-free	the sum of saturated fat and trans-fatty acids does not exceed 0.1g of saturated fat per 100g or 100ml

Nutrition Claim	Condition of Use
Low sugars	the product contains no more than – 5g of sugars per 100g for solids or 2.5g of sugars per 100ml for liquids
Sugars-free	product contains no more than 0.5g of sugars per 100g or 100ml.
With no added sugars	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	product contains no more than 0.12g of sodium , or 0.3g of salt , per 100g or per 100ml. For waters , other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2mg of sodium per 100ml .
Very low sodium/salt	product contains no more than 0.04g of sodium , or 0.1g of salt , per 100g or per 100ml. This claim shall not be used for natural mineral waters and other waters .
Sodium-free/salt-free	product contains no more than 0.005g of sodium , or 0.0125g of salt , per 100g
Source of fibre	product contains at least 3g of fibre per 100g or at least 1.5g of fibre per 100kcal
High fibre	product contains at least 6g of fibre per 100g or at least 3g of fibre per 100kcal
Source of protein	at least 12% of the energy value of the food is provided by protein
High protein	at least 20% of the energy value of the food is provided by protein
Source of [name of vitamin/s] and/or [name of mineral(s)]	the product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC (values are given on page 11) or an amount provided for by derogations granted according to Article 6 of 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. (Note: the derogations referred to here have not been agreed yet)
High [name of vitamin/s] and/or [name of mineral(s)]	where the product contains at least twice the value of ‘source of [name of vitamin/s] and/or [name of mineral/s]’ (values are given on page 11)
Contains [name of the nutrient or other substance]	for which specific conditions are not laid down in this Regulation, may only be made where the product complies with all the applicable provisions of this Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim ‘source of’ shall apply.
Increased [name of nutrient]	product meets the conditions for the claim ‘source of’ and the increase in content is at least 30% compared to a similar product
Reduced [name of nutrient]	where the reduction in content is at least 30% compared to a similar product , except for micronutrients (vitamins and minerals), where a 10% difference in the reference values as set in Directive 90/496/EEC shall be acceptable, and for sodium, or the equivalent value for salt, where a 25% difference shall be acceptable
Light/lite	conditions as those set for the term ‘reduced’ ; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food ‘light’ or ‘lite’
Naturally natural	Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term ‘naturally/natural’ may be used as a prefix to the claim .

Nutrition Claims and Energy Conversion Factors

- “source of protein”
- “high protein”
- “high monounsaturated fat”
- “high polyunsaturated fat”
- “high unsaturated fat”

To make these claims, a food must provide a minimum amount of energy from the specific nutrient.

To verify the amount of energy provided by either protein or fat, the following conversion factors from Directive 90/496/EEC, as amended, are used.

Nutrient	Conversion Factor	Amount of Energy per 1g of Nutrient
Protein	4 kcal/g 17 kJ/g	1g protein x 4kcal = 4kcal per g protein
Fat	9 kcal/g 37 kJ/g	1g fat x 9kcal = 9kcal per g fat

Therefore

$$\% \text{ energy from the nutrient} = \frac{\text{Grams of nutrient per 100g of product} \times \text{Conversion factor for nutrient} \times 100}{\text{Total Energy per 100g of product}} \quad 1$$

The nutrition table below is for a product making a ‘source of protein’ claim. A ‘source of protein’ claim requires that **at least 12% of the energy** in the food is provided by protein.

Nutrition Information	Per 100g
Energy	1136kJ 268kcal
Protein	13g
Carbohydrate of which: sugars	48.8g 41g
Fat of which: saturates	2.3g 0.67g
Fibre	14.9g
Sodium	0.425g

The calculation below uses the protein conversion factor of 4 kcal/g to determine the amount of the energy from protein in the product.

$$\% \text{ energy from protein} = \frac{\text{Grams of protein per 100g of product} \times \text{Conversion factor for protein} \times 100}{\text{Total Energy per 100g}} \quad 1$$

$\frac{13 \times 4}{268} \times \frac{100}{1} = \mathbf{19.4\%}$ is the amount of energy from protein. Therefore the claim ‘**source of protein**’ can be used for this product.

Vitamins and Minerals

Annex 1 to Directive 90/496/EEC, lists vitamins and minerals and their RDA values. This Annex was amended by Directive 2008/100/EC, however, the RDAs from Directive 90/496/EEC are still valid until 31st October 2012. Therefore, for some vitamins and minerals, two RDAs apply and can run side by side until 31st October 2012.

The vitamins and minerals from Directive 2008/100/EC and Directive 90/496/EEC (applicable until 31st October 2012) are listed in the table below. The vitamins and minerals are listed with their **RDA values** and the minimum values required to meet the conditions for a **“source of”** and a **“high”** claim.

Vitamin/ mineral	Directive 2008/100/EC			Directive 90/496/EEC		
	RDA	Claims that are a “Source of”	Claims that are “High”	RDA	Claims that are a “Source of”	Claims that are “High”
Vitamin A	800µg	120µg	240µg	800µg	120µg	240µg
Vitamin D	5µg	0.75µg	1.5µg	5µg	0.75µg	1.5µg
Vitamin E	12mg	1.8mg	3.6mg	10mg	1.5mg	3.0mg
Vitamin K	75µg	11.25µg	22.5µg			
Vitamin C	80mg	12mg	24mg	60mg	9mg	18mg
Thiamin	1.1mg	0.165mg	0.33mg	1.4mg	0.21mg	0.42mg
Riboflavin	1.4mg	0.21mg	0.42mg	1.6mg	0.24mg	0.48mg
Niacin	16mg	2.4mg	4.8mg	18mg	2.7mg	5.4mg
Vitamin B6	1.4mg	0.21mg	0.42mg	2mg	0.3mg	0.6mg
Folic acid*	200µg	30µg	60µg	200µg	30µg	60µg
Vitamin B12	2.5µg	0.38µg	0.76µg	1µg	0.15µg	0.30µg
Biotin	50µg	7.5µg	15µg	0.15mg	0.0225mg	0.045mg
Pantothenic acid	6mg	0.90mg	1.8mg	6mg	0.90mg	1.8mg
Potassium	2000mg	300mg	600mg			
Chloride	800mg	120mg	240mg			
Calcium	800mg	120mg	240mg	800mg	120mg	240mg
Phosphorus	700mg	105mg	210mg	800mg	120mg	240mg
Magnesium	375mg	56.25mg	112.5mg	300mg	45mg	90mg
Iron	14mg	2.1mg	4.2mg	14mg	2.1mg	4.2mg
Zinc	10mg	1.5mg	3.0mg	15mg	2.25mg	4.5mg
Copper	1mg	0.15mg	0.30mg			
Manganese	2mg	0.30mg	0.60mg			
Fluoride	3.5mg	0.525mg	1.05mg			
Selenium	55µg	8.25µg	16.5µg			
Chromium	40µg	6µg	12µg			
Molybdenum	50µg	7.5µg	15µg			
Iodine	150µg	22.5µg	45µg	150µg	22.5µg	45µg

*Folic acid may be declared as folacin until 31st October 2012.

Note:

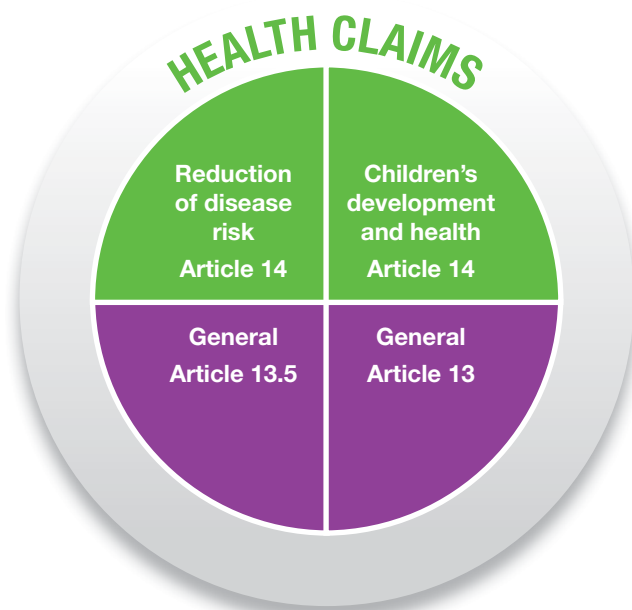
a “source of” claim represents at least 15% of the RDA.
a “high” claim represents at least 30% of the RDA.

Health Claims

Regulation 1924/2006 on nutrition and health claims defines a **health claim** as:

'any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.' e.g. this drink will help you feel more energetic/this food will help you concentrate etc.

There are four types of health claims.



Claim	Type of Claim
Article 14 health claims	reduction of disease risk claims and
	claims referring to children's development and health
Article 13(5) health claims	health claims other than disease risk reduction and children's development and health These claims are based on newly developed scientific evidence and may include a request for the protection of proprietary data.
Article 13 health claims	health claims other than disease risk reduction and children's development and health

Article 14 claims

'Reduction of disease risk claim' is defined as:

'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.'

(Regulation 1924/2006)

'Children's development and health claims' are defined as:

'health claims solely referring to the development and health of children and where the science is only valid for children, e.g. calcium is good for children's growth'.

and/or

'health claims used on products intended exclusively for children, like follow on formulae, processed cereal-based foods and baby foods.'

(EU Guidance on the implementation of Regulation No 1924/2006 on nutrition and health claims made on foods conclusions of the standing committee on the food chain and animal health 14th December 2007).

The following health claims are not permitted:

- X Claims that suggest that health could be affected by not consuming the food
- X Claims which make reference to the rate or amount of weight loss
- X Claims that make reference to recommendations of individual doctors or health professionals and other associations, not provided for in community or national rules

Health claims must include:

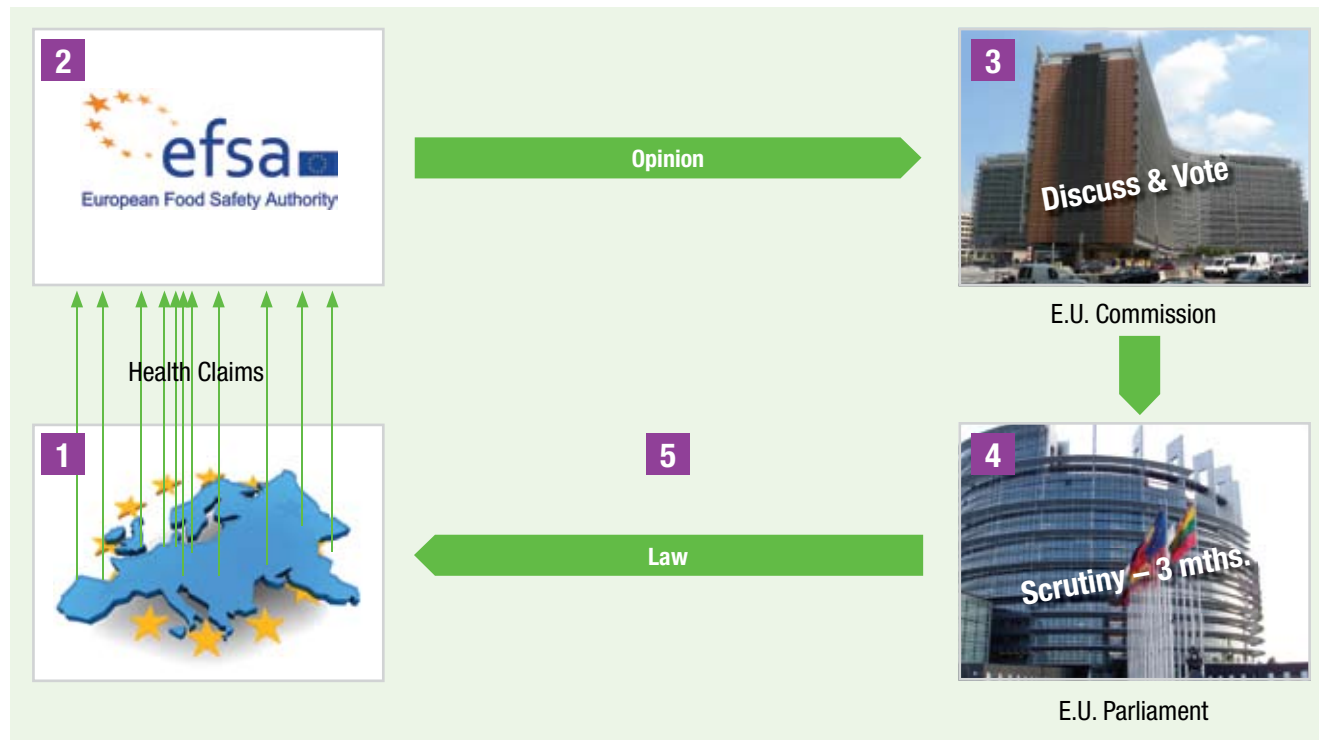
- ✓ A statement indicating the importance of a varied and balanced diet and a healthy lifestyle
- ✓ The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect
- ✓ Where appropriate, a statement addressed to persons who should avoid using the food
- ✓ An appropriate warning for products that are likely to present a health risk if consumed to excess
- ✓ Other statements will be mandatory depending on the specific claim

The above information must be included in the labelling, or if no such labelling exists, in the presentation and advertising.

(Article 10 of Regulation 1924/2006)

Authorisation of Health Claims

EU Claims Process



Current status on health claims

Reduction of disease risk and children's development and health claims (Article 14)	Claims based on newly developed scientific evidence (Article 13.5)	Claims other than reduction of disease risk and children's development and growth claims (Article 13)
Some of these claims have been fully processed and have a legal basis. Lists of authorised and rejected claims are on the Commission's and the FSAI's websites.	Some of these claims have been fully processed and have a legal basis. Lists of authorised and rejected claims are on the Commission's and the FSAI's websites.	Some of these claims are still being evaluated by the European Food Safety Authority (EFSA). The Commission and Member States have not taken decisions on any EFSA opinions that have been issued.

The Commission website hosts the community register (Article 20, Regulation 1924/2006) of authorised and rejected health claims. It provides up-to-date information on the legal status of health claims. The website address and a snapshot of the information provided are given below:

http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/authorised_health_claims_en.htm

Community Register of nutrition and health claims made on food - Authorised health claims

Authorised health claims and the conditions applying to them provided for in Articles 13(3) and (5), 14(1), 19(2), 21, 24(2), and 29(5) of [Regulation \(EC\) No 1924/2006](#) and the national measures referred to in Article 23(3)

Authorised health claims

Authorised health claims that can be used by all food business operators provided that they comply with the particular conditions of use of the authorised claim and with the principles and requirements of Regulation (EC) No 1924/2006

- Article 14(1)(a) health claims referring to the reduction of a risk factor in the development of a disease
- Article 14(1)(b) health claims referring to children's development and health
- Article 13(3) health claims based on newly developed scientific evidence and/or including a request for the protection of proprietary data

2 Article 14(1)(a) health claims referring to the reduction of a risk factor in the development of a disease

Nutrient, substance, food or food category	Claims	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference	Commission Regulation
Plant sterols: Sterols extracted from plants, free or esterified with food grade fatty acids.	Plant sterols have been shown to lower/ reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of at least 2 g plant sterols.	Q-2005-285	Commission Regulation (EC) No 983/2006 of 21/03/2006
Plant stanol esters	Plant stanol esters have been shown to lower/ reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of at least 2 g plant stanols.	Q-2005-118	Commission Regulation (EC) No 983/2006 of 21/03/2006
Chewing gum sweetened with 100% xylitol	Chewing gum sweetened with 100% xylitol has been shown to reduce dental plaque. High content/ level of dental plaque is a risk factor in the development of caries in children	Information to the consumer that the beneficial effect is obtained with a consumption of 2-3g of chewing gum sweetened with 100% xylitol at least 3 times per day after the meals	Q-2005-321	Commission Regulation (EC) No 1024/2006 of 28/03/2006

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3 Article 14(1)(b) health claims referring to children's development and health

The FSAI website provides more detailed information on the authorised and rejected health claims. The website address is given below.

http://www.fsai.ie/science_and_health/nutrition_and_health_claims.html

It provides lists of the permitted health claims and the related nutrition and health claim labelling requirements.

Permitted EU Claims Article 14 (1) b: Children’s Development and Health

Product Claim	Nutrient, Substance or Food Category	Company Name	EFSA Opinion Reference	Legal Status: Permitted	Placed on market	Conditions of use of the claim	Legal Labelling Requirements	
							Nutrition Labelling	Mandatory Statements
Phosphorus is needed for the normal growth and development of bone in children	Phosphorus	Danone SA, Spain	Q-2008-217	Permitted (1024/2009)	19th November 2009	The claim can be used only for food which is at least a source of Phosphorus 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 <i>Therefore 105mg Phosphorous must be present in 100g or 100ml of this food</i>	(1) Group 2 nutrition labelling information as per Directive 90/496, as amended (Article 7 Reg 1924/2006) (see also labelling information document) (2) Phosphorous must appear in the nutrition labelling with %RDA	Shall include 4 statements (Reg 1924/2006) indicating: (1) the importance of a varied and balanced diet and a healthy lifestyle (2) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect (3) where appropriate, a statement addressed to persons who should avoid using the food (4) an appropriate warning for products that are likely to present a health risk if consumed to excess.

The FSAI website also provides the time frame for removal from the market of rejected claims.

Rejected EU Claims Article 14 (1) b: Children’s Development and Health

Product Claim	Nutrient, Substance or Food Category	Company Name	EFSA Opinion Reference	Legal Status: Rejected	Date taken off Market
Aids minor intestinal ailments (as colic, constipation, digestive symptoms)	Follow-on formulae with a fixed combination of short-chain galacto-oligosaccharides, acidified milk, nucleotides and beta palmitate	Plada Industriale Srl ; Italy	Q-2008-270	Rejected (1167/2009)	21st June 2010

The sample label below is for a correctly labelled orange smoothie bearing a permitted children's development and health claim



Directive 2000/13
- product name with a product description

Regulation 983/2009

Nutrition labelling detailed as per Directive 90/496 and required by Regulation 1924/2006

Directive 2000/13
- ingredient list
- name and address
- storage instructions

Regulation 1924/2006
- statement about a varied balanced diet and active lifestyle
- statement regarding quantity of food and pattern of consumption

Directive 2000/13
- net quantity
- date of durability

Food Supplements

Directive 2002/46/ EC defines **'food supplements'** as: *"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.**"*

There are a wide range of nutrients and other substances used as ingredients that might be present in food supplements including, but not limited to:

- Vitamins
- Minerals
- Amino acids
- Essential fatty acids
- Fibre
- Various plant extracts and
- Herbal extracts

Under Article 10 of Directive 2002/46/EC, Member States may require food businesses to notify their national competent authority (FSAI in Ireland) of food supplements being placed on the market as follows:

"to facilitate efficient monitoring of food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product".

Ireland has taken up the option of notification.

S.I. No. 506 of 2007 states *"any person placing a food supplement product on the market in the State, shall notify the Authority of that placing on the market by forwarding it a model of the label used for the product"*.

Therefore, all food supplements marketed in Ireland must be notified to the FSAI.

Maximum and minimum limits will be established for the amounts of vitamins and minerals permitted in the daily portion of food supplements.

(Article 5 of Regulation 2002/46)

These maximum and minimum levels have yet to be set by the Commission and Member States.

Labelling Requirements for Food Supplements

Food supplements are only allowed to be sold in pre-packaged forms under the name '**Food Supplement**'.

In addition to the general labelling rules, there are specific labelling requirements for food supplements as outlined below.

The label should declare:

- ✓ The **category names** of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances, e.g. multi-vitamins, probiotics, herbal substances, fish oils etc
- ✓ The **portion** of the product recommended for **daily consumption**
- ✓ The amount of the **nutrients or substances** with a nutritional or physiological effect that is **provided by the daily recommended portion**. This information shall be provided in numerical form. The units for vitamins and minerals are specified in Schedule 1 of S.I. No. 506 of 2007 (see next page)
 - Information on the amounts **vitamins and minerals should also be expressed as a percentage** of the **RDA** as specified in Directive 90/496/EEC, as amended (see next page). This information may also be given in graphical form
- ✓ A **warning not to exceed the recommended daily dose**
- ✓ A statement indicating that the product **shall not be used as a substitute for a varied diet**
- ✓ A statement indicating that the products **should be stored out of reach of young children**

(Articles 6, 7, 8 & 9 of Directive 2002/46/EC)

The labelling, presentation and advertising **must not**:

- X Suggest in any way, that food supplements can prevent, treat or cure a human disease
- X Include any suggestion indicating that a balanced and varied diet cannot provide appropriate quantities of nutrients in general

The list below, taken from Directive 2008/100/EC and Directive 90/496/EEC (applicable until 31st October 2012) details the units of measurement and the RDAs for the vitamins and minerals permitted in food supplements.

Vitamin/Mineral	RDA From Directive 2008/100/EC	RDA From Directive 90/496/EEC	Unit of Measurement
Vitamin A	800	800	µg
Vitamin D	5	5	µg
Vitamin E	12	10	mg
Vitamin K	75		µg
Vitamin C	80	60	mg
Thiamin	1.1	1.4	mg
Riboflavin	1.4	1.6	mg
Niacin	16	18	mg
Vitamin B6	1.4	2	mg
Folic acid	200	200	µg
Vitamin B12	2.5	1	µg
Biotin	50µg	0.15mg	µg/mg
Pantothenic acid	6	6	mg
Potassium	2,000		mg
Chloride	800		mg
Calcium	800	800	mg
Phosphorus	700	800	mg
Magnesium	375	300	mg
Iron	14	14	mg
Zinc	10	15	mg
Copper	1		mg
Manganese	2		mg
Fluoride	3.5		mg
Selenium	55		µg
Chromium	40		µg
Molybdenum	50		µg
Iodine	150	150	µg

Note:

Nutrition labelling requirements outlined in Directive 90/496/EEC do not apply to food supplements.

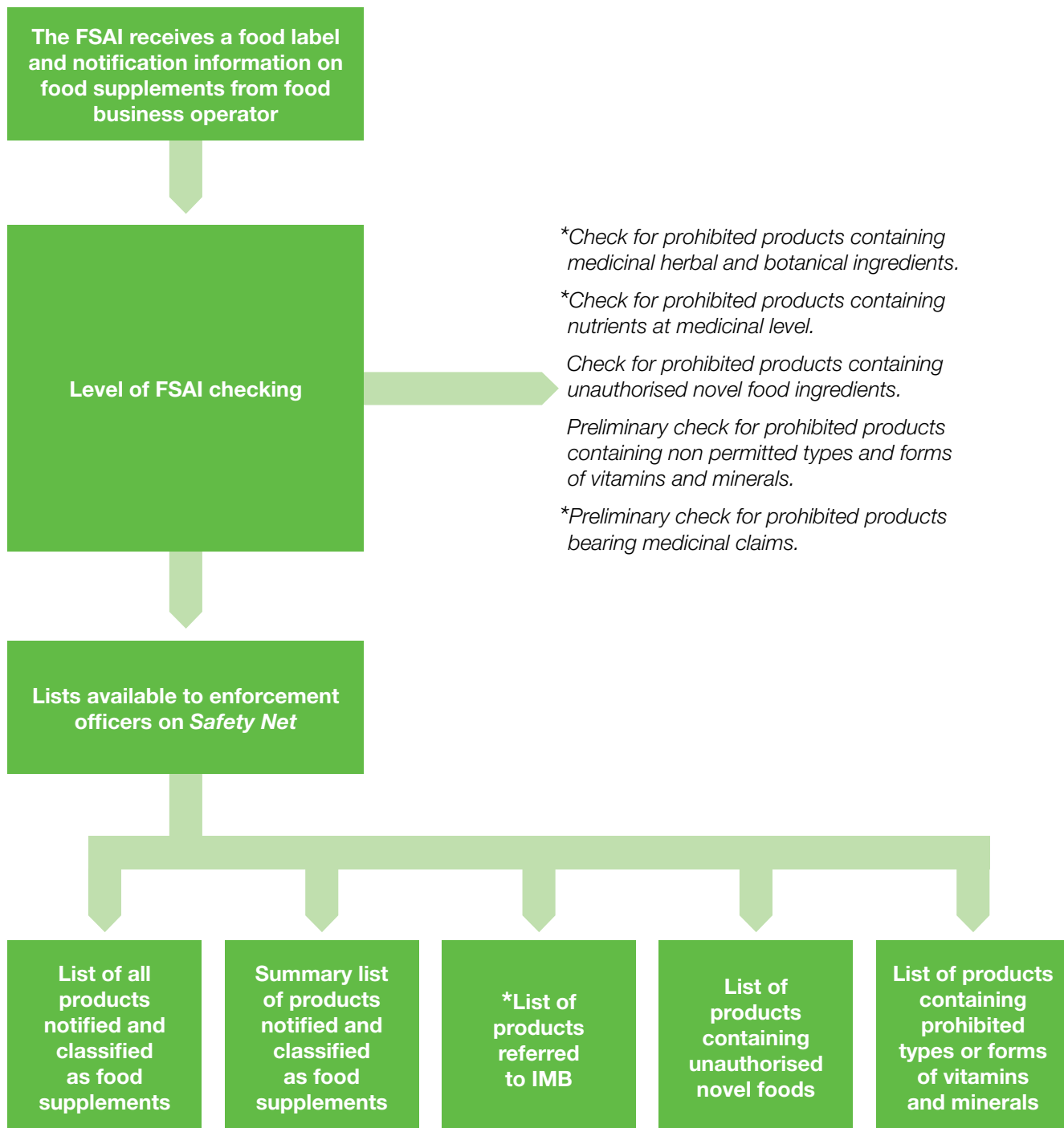
Notifications of Food Supplements

Under food and medicines legislation, the types and levels of nutrients and other substances that are permitted for use in food supplements are restricted. On notification of a food supplement to the FSAI, the ingredient list, nutrition information and claims on the label are checked to ensure compliance with legislation. Details on the level of checking carried out by the FSAI are outlined below.

Ingredient/ Nutrient/Claims	Details
Herbal medicines	<p>The Irish Medicines Board (IMB) controls all products that contain medicinal ingredients. No food supplement can contain a medicinal ingredient.</p> <p>The FSAI checks for medicinal ingredients and refers products of concern to the IMB.</p> <p>A list of products confirmed to be under the remit of the IMB is maintained on Safety Net.</p>
Nutrients at medicinal levels	<p>There are 7 vitamins that are deemed to be medicines above particular levels (S.I. No. 540 of 2003 Medicinal Products (Prescription and Control of Supply) Regulations, 2003). Products containing these vitamins at medicinal levels are under the remit of the IMB.</p> <p>Appendix 1 lists the 7 vitamins and the levels above which they are deemed to be medicinal.</p> <p>The FSAI checks products for these vitamins at medicinal levels and refer products of concern to the IMB.</p> <p>These products are included in the list of products confirmed to be under the remit of the IMB.</p>
Novel food ingredients	<p>Unauthorised novel food ingredients are not permitted for use in food supplements</p> <p>A list of products found to contain unauthorised novel food ingredients is maintained on Safety Net.</p>
Permitted types and forms of vitamins and minerals	<p>Only certain vitamins and minerals are permitted in food supplements and only certain chemical formats of these vitamins and minerals are allowed.</p> <p>There are 30 types (13 vitamins + 17 minerals) and 181 chemical forms (45 vitamins + 136 minerals) permitted in food supplements.</p> <p>Appendix 2 lists the types and forms of vitamins and minerals permitted in food supplements (Regulation (EC) No 1170/2009 (amending Directive 2002/46/EC))</p> <p>The FSAI carries out preliminary checks to ensure vitamins and minerals are in compliance with this list. A list of products of concern is maintained on Safety Net.</p>
Medicinal claims	<p>The IMB controls all products bearing medicinal claims. No food supplement can bear a medicinal claim*.</p> <p>The FSAI carries out preliminary checks for medicinal claims and refers products of concern to the IMB. A list of products of concern is maintained on Safety Net.</p>

* A medicinal claim is a health claim, which states or implies that a product has the property of treating, preventing or curing human disease.

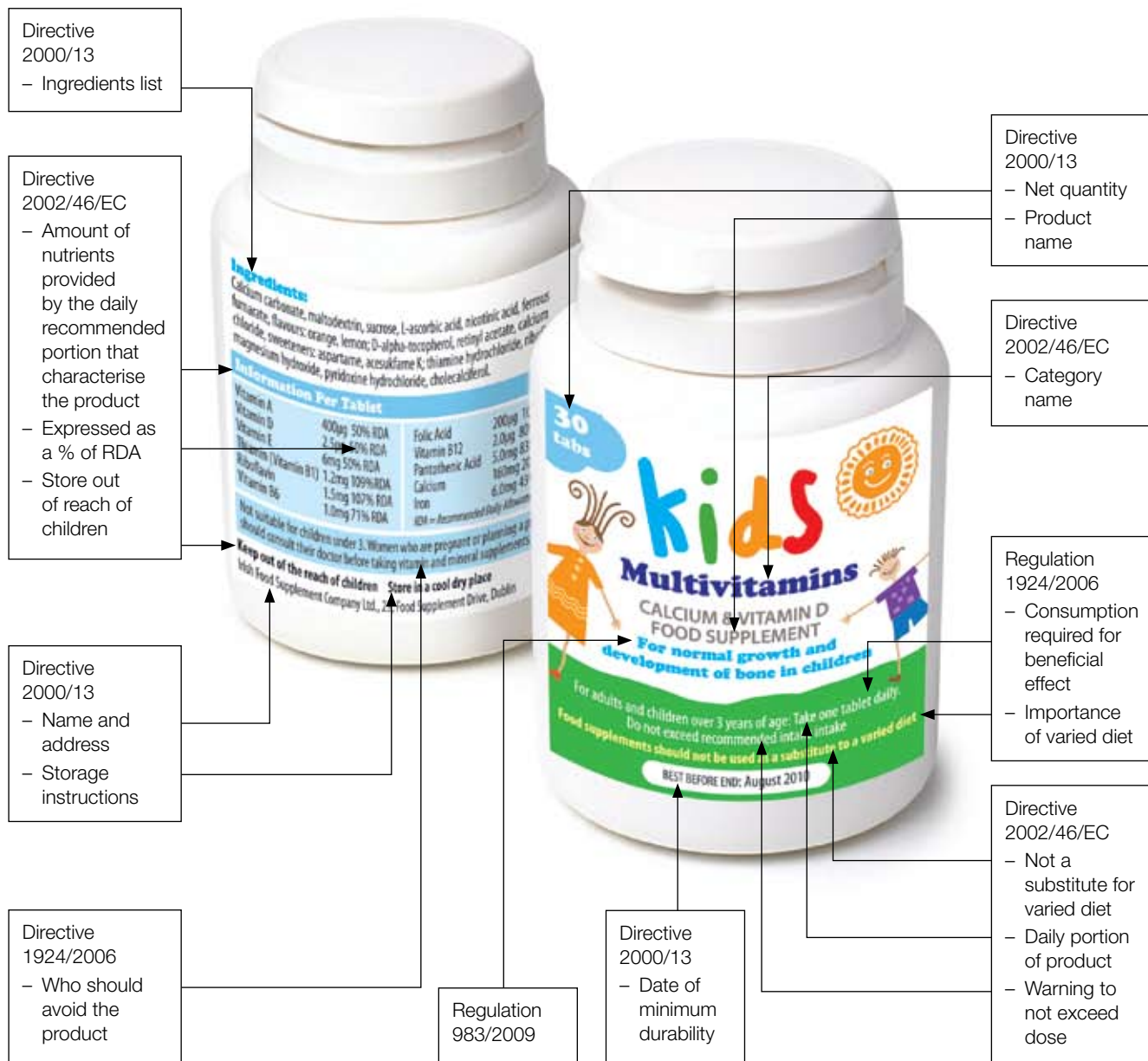
Summary of FSAI Process for Assessing Notified Food Supplements



The sample label below is for a correctly labelled food supplement that does not bear a health claim



The sample label below is for a correctly labelled food supplement bearing a permitted children’s development and health claim



As there are specific rules for vitamins and minerals specified in Directive 2002/46 the labels shown in this document are for food supplements containing vitamins and minerals.

Note:

There are food supplements that contain nutrients or substances other than vitamins and minerals e.g. herb extracts and other botanicals. The labelling requirements outlined on page 19 of this document apply to these products.

EFSA has compiled a compendium of botanicals and is currently working on a risk assessment for these products. When this work is more developed, further legislation will be introduced on the control of botanical ingredients in food supplements.

Appendix 1. Nutrients at Medicinal Levels

Nutrient	Form (Ingredient)	Medicinal Level
Vitamin A	Retinol	2250ug / 7500IU
	Retinyl Acetate	2250ug / 7500IU
	Retinyl Palmitate	2250ug / 7500IU
Vitamin D	Cholecalciferol	75ug / 0.0075mg / 3000IU
	Ergocalciferol	75ug / 0.0075mg / 3000IU
Vitamin K	Phylloquinone (Phytomenadione)	
Niacin	Nicotinic Acid	600mg
	Inositol Hexanicotinate (Inositol Hexaniacinate)	
Folic Acid	Pteroylmonoglutamic Acid	500ug
Vitamin B6	Pyridoxine Hydrochloride	50mg
Vitamin B12	Cyanocobalamin 25ug	25ug
	Hydroxocobalamin	25ug

Appendix 2. Permitted Types and Forms of Vitamins and Minerals

Types of Vitamins	Permitted Forms
Vitamin A (µg RE)	retinol
	retinyl acetate
	retinyl palmitate
	beta-carotene
Vitamin D (µg)	cholecalciferol
	ergocalciferol
Vitamin E (mg -TE)	D-alpha-tocopherol
	DL-alpha-tocopherol
	D-alpha-tocopheryl acetate
	DL-alpha-tocopheryl-acetate
	D-alpha-tocopheryl acid succinate
	mixed tocopherols
	tocotrienol tocopherol
Vitamin K (µg)	phylloquinone (phytomenadione)
	menaquinone
Vitamin B1 (mg)	thiamin hydrochloride
	thiamin mononitrate
	Thiamine monophosphate chloride
	thiamine pyrophosphate chloride
Vitamin B2 (mg)	riboflavin
	riboflavin 5'-phosphate, sodium
Niacin (mg NE)	nicotinic acid
	nicotinamide
	inositol hexanicotinate (inositol hexaniacinate)
Pantothenic acid (mg)	D-pantothenate, calcium
	D-pantothenate, sodium
	dexpanthenol
	pantethine
Vitamin B6 (mg)	pyridoxine hydrochloride
	pyridoxine 5'-phosphate
	pyridoxal 5'-phosphate

Types of Vitamins	Permitted Forms
Folic acid (µg)	pteroylmonoglutamic acid
	calcium-L-methylfolate
Vitamin B12 (µg)	cyanocobalamin
	hydroxocobalamin
	5'-deoxyadenosylcobalamin
	methylcobalamin
Biotin (µg)	D-biotin ²
Vitamin C (mg)	L-ascorbic acid
	sodium-L-ascorbate
	calcium-L-ascorbate
	potassium-L-ascorbate
	L-ascorbyl 6-palmitate
	magnesium L-ascorbate
	zinc L-ascorbate

Type of Mineral	Mineral Forms
Calcium (mg)	calcium acetate
	calcium L-ascorbate
	calcium bisglycinate
	calcium carbonate
	calcium chloride*
	calcium citrate malate
	calcium salts of citric acid
	calcium gluconate
	calcium glycerophosphate
	calcium lactate
	calcium pyruvate
	calcium salts of orthophosphoric acid
	calcium succinate
	calcium hydroxide
	calcium L-lysinate
	calcium malate
	calcium oxide
	calcium L-pidolate
calcium L-threonate	
calcium sulphate	

Type of Mineral	Mineral Forms
Magnesium (mg)	magnesium acetate
	magnesium L-ascorbate
	magnesium bisglycinate
	magnesium carbonate
	magnesium chloride*
	magnesium salts of citric acid
	magnesium gluconate
	magnesium glycerophosphate
	magnesium salts of orthophosphoric acid
	magnesium lactate
	magnesium L-lysinate
	magnesium hydroxide
	magnesium malate
	magnesium oxide
	magnesium L-pidolate
	magnesium potassium citrate
	magnesium pyruvate
	magnesium succinate
	magnesium sulphate
magnesium taurate	
magnesium acetyl taurate	
Iron (mg)	ferrous carbonate
	ferrous citrate
	ferric ammonium citrate
	ferrous gluconate
	ferrous fumarate
	ferric sodium diphosphate
	ferrous lactate
	ferrous sulphate
	ferric diphosphate (ferric pyrophosphate)
	ferric saccharate
	Elemental iron(carbonyl+electrolytic+hydrogen reduced)
	ferrous bisglycinate
	ferrous L-pidolate
	ferrous phosphate
	iron (II) taurate

Type of Mineral	Mineral Forms
Copper (µg)	cupric carbonate
	cupric citrate
	cupric gluconate
	cupric sulphate
	copper L-aspartate
	copper bisglycinate
	copper lysine complex
Iodine (µg)	copper (II) oxide
	sodium iodide
	sodium iodate
	potassium iodide
	potassium iodate
Zinc (mg)	zinc acetate
	zinc L-ascorbate
	zinc L-aspartate
	zinc bisglycinate
	zinc chloride*
	zinc citrate
	zinc gluconate
	zinc lactate
	zinc L-lysinate
	zinc malate
	zinc mono-L-methionine sulphate
	zinc oxide
	zinc carbonate
	zinc L-pidolate
	zinc picolinate
	zinc sulphate

Type of Mineral	Mineral Forms
Manganese (mg)	manganese ascorbate
	manganese L-aspartate
	manganese bisglycinate
	manganese carbonate
	manganese chloride*
	manganese citrate
	manganese gluconate
	manganese glycerophosphate
	manganese pidolate
	manganese sulphate
Sodium (mg)	sodium bicarbonate
	sodium carbonate
	sodium chloride*
	sodium citrate
	sodium gluconate
	sodium lactate
	sodium hydroxide
	sodium salts of orthophosphoric acid
Potassium (mg)	potassium bicarbonate
	potassium carbonate
	potassium chloride*
	potassium citrate
	potassium gluconate
	potassium glycerophosphate
	potassium lactate
	potassium hydroxide
	potassium L-pidolate
	potassium malate
	potassium salts of orthophosphoric acid
Selenium (µg)	L-selenomethionine
	selenium enriched yeast
	selenious acid
	sodium selenate
	sodium hydrogen selenite
	sodium selenite

Type of Mineral	Mineral Forms
Chromium (µg)	chromium (III) chloride
	chromium (III) lactate trihydrate
	chromium nitrate
	Chromium picolinate
	chromium (III) sulphate
Molybdenum (µg)	Ammonium molybdate (molybdenum (VI))
	potassium molybdate (molybdenum (VI))
	sodium molybdate (molybdenum (VI))
Fluoride (mg)	calcium fluoride
	potassium fluoride
	sodium fluoride
Phosphorus (mg)	sodium monofluorophosphate
Boron (mg)	boric acid
	sodium borate
Silicon (mg)	choline-stabilised orthosilicic acid
	silicon dioxide
	silicic acid

*These are all the chemical formats of chloride that are permitted within food supplements.

High in Vitamin C Rich in calcium Contains omega 3 With no added sugars Fat free Cholesterol free Low energy Energy-reduced Energy-free Low fat Fat-free Low saturated fat Source of omega-3 fatty acids High omega-3 fatty acids High monounsaturated fat High polyunsaturated fat High unsaturated fat Saturated fat-free Low sugars Sugars-free With no added sugars Low sodium/salt Very low sodium/salt Sodium-free/salt-free Source of fibre High fibre Source of protein High protein Source of vitamins and minerals Contains nutrients Increased nutrients Increased nutrients Light % RDA Natural High in Vitamin C Rich in calcium Contains omega 3 With no added sugars Fat free Cholesterol free Low energy Energy-reduced Energy-free Low fat Fat-free Low saturated fat Source of omega-3 fatty acids High omega-3 fatty acids High monounsaturated fat High polyunsaturated fat High unsaturated fat Saturated fat-free Low sugars Sugars-free With no added sugars Low sodium/salt Very low sodium/salt Sodium-free/salt-free Source of fibre High fibre Source of protein High protein Source of vitamins and



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