Údarás Sábháilteachta Bia NA hÉIREANN
Food Safety AUTHORITY OF IRELAND

2024

Food Supplements – Legislative Requirements

Food Supplements – Legislative Requirements

Published by:
Food Safety Authority of Ireland

The Exchange, George's Dock, IFSC,
Dublin 1, D01 P2V6

T +353 1 817 1300
E info@fsai.ie

www.fsai.ie

ISBN: 978-1-910348-71-0

Contents

1. High level overview of food supplements

1.1 Overview of legislation applicable to food supplements

Within the European Union, the vertical legislation[1] which lays down specific requirements for food supplements is Directive 2002/46/EC. This legislation includes rules on:

- Composition of food supplements (regarding the type and form of vitamins and minerals)
- Labelling, presentation and advertising of food supplements
- Notification of food supplements

Food supplements must also comply with relevant horizontal food legislation[2]. Examples are provided in Text Box 1.

TEXT BOX 1:

EXAMPLES OF FOOD LEGISLATION APPLICABLE TO FOOD SUPPLEMENTS

✓ Directive 2002/46/EC on Food Supplements

✓ Regulation (EC) No 178/2002 on the General Principle**s** and Requirements of Food Law

✓ Regulation (EC) No 852/2004 on the Hygiene of Foodstuffs

✓ Regulation (EC) No 853/2004 laying down specific Hygiene Rules for Food of Animal Origin

✓ Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs

✓ Regulation (EC) No 1333/2008 on Food Additives

✓ Regulation (EC) No 1334/2008 on Food Flavourings

✓ Regulation (EC) No 1332/2008 on Food Enzymes

✓ Regulation (EU) 2015/2283 on Novel Foods

✓ Regulation (EC) No 1829/2003 on Genetically Modified Foods

✓ Regulation (EC) No 1925/2006 on the Addition of Vitamins and Minerals and of Certain Other Substances to Foods

✓ Commission Regulation (EC) No 1881/2006 on Food Contaminants

✓ Regulation (EC) No 1924/2006 on Nutrition and Health Claims

✓ Regulation (EU) No 1169/2011 on Food Information to Consumers

✓ Regulation (EC) No 1935/2004 on Food Contact Material

[1] Vertical legislation applies to a specific food (e.g., Directive 2002/46/EC on Food Supplements)
[2] Horizontal legislation applies to all foods (e.g., Regulation (EC) No 1333/2008 on Food Additives, Regulation (EC) No 1924/2006 on Nutrition and Health Claims)

In addition, legislation / texts from other sectors may also directly/indirectly impact food supplements. Some examples are provided in Text Box 2.

TEXT BOX 2:

EXAMPLES OF LEGISLATION / TEXTS FROM OTHER SECTORS WHICH MAY IMPACT FOOD SUPPLEMENTS

- ✓ Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use
- ✓ United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971

Understanding this myriad of legislation / information is essential for food businesses involved in the food supplement sector to ensure all food supplements placed on the market comply with relevant rules.

1.2 Definition / Description of food supplements

'Food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients[3] 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 (Article 2a, Directive 2002/46/EC).

This definition can be broken into 4 key aspects:

Role:	To supplement the normal diet
Composition:	Concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination
Physical Form:	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
Quantity of consumption:	Designed to be taken in measured small unit quantities

[3] Nutrients means the following substances: vitamins and minerals (Article 2b, Directive 2002/346/EC)

In Ireland, the FSAI is the competent authority for all foods, including food supplements. Currently, there is an obligation to notify the FSAI when food supplements are placed on the Irish market. This is addressed further in Section 3.2.

1.3 Choosing the correct food category

Within the EU, foods are typically categorised as:

- Food supplements
- Foods for specific groups
- Fortified food[4]
- General food[5]

These categories can be differentiated based on a myriad of factors such as role, intended consumer group, product composition, product claims and physical form. Whilst there are many commonalities between categories, there are also many differences. Determination of the correct category is essential for each food placed on the market to ensure compliance with relevant rules. Due consideration must also be given to medicinal products to ensure that a medicinal product is not inadvertently used in a food or incorrectly categorised as a food.

Incorrect categorisation of food supplements could have many consequences. These include:

- Wasted resources in bringing a product to market
- Failure to comply with the correct legislative requirements, including notification requirements
- Potential food safety implications for intended consumer groups

Key features of foods for specific groups, fortified foods and general foods are addressed in the following three sections. Key features of medicinal products are addressed in Section 4.7.

1.3.1 Foods for specific groups

Foods for specific groups (FSGs) are regulated in the European Union via Regulation (EU) No. 609/2013 and its supplementing regulations. FSGs capture:

- Foods intended for infants (<12 months) and young children (between 1 & 3 years), i.e.:

[4] This is not an 'official' product category; however, specific legislation applies to fortified foods
[5] This is not an 'official' product category; however, by default it applies to all foods other than food supplements, foods for specific groups and fortified foods – 'Food' is defined in Article 2 of Regulation (EC) No. 178/2002.

  - Infant formula[6] and follow-on formulae[7]
  - Processed cereal-based foods[8] and Baby foods[9]
- Food for special medical purposes[10]
- Total diet replacement for weight control[11]

Definitions for each of these categories are laid down in Article 2 of Regulation (EU) No. 609/2013.

As their name implies, FSGs are designed for specific consumer groups (usually vulnerable groups). Some FSGs are the sole source of nutrition for the intended consumer group; whilst others form a significant part of the daily food intake. FSGs must comply with specific rules established in Regulation (EU) No 609/2013 (and its supplementing regulations) and with relevant rules established in horizontal legislation.

In Ireland, there is an obligation to notify the FSAI when the following foods for specific groups are placed on the market: infant formula, follow-on formula, foods for special medical purposes and total diet replacement for weight control.

1.3.2 Fortified foods

The World Health Organisation (WHO) states that 'Fortification is the practice of deliberately increasing the content of one or more micronutrients (i.e., vitamins and minerals) in a food or condiment to improve the nutritional quality of the food supply and provide a public health benefit

---

[6] '**infant formula'** means food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding

[7] '**follow-on formula'** means food intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants

[8] '**processed cereal-based food'** means food:
(i) intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation, to ordinary food; and
(ii) pertaining to one of the following categories:
- simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids,
- cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid,
- pastas which are to be used after cooking in boiling water or other appropriate liquids,
- rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids;

[9] '**baby food'** means food intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to ordinary food, excluding:
(i) processed cereal-based food; and
(ii) milk-based drinks and similar products intended for young children;

[10] **'food for special medical purposes'** means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone

[11] '**total diet replacement for weight control'** means food specially formulated for use in energy restricted diets for weight reduction which, when used as instructed by the food business operator, replaces the whole daily diet

with minimal risk to health. As well as increasing the nutritional content of staple foods, the addition of micronutrients can help to restore the micronutrient content lost during processing'.

In other words, fortified foods are 'general foods' to which micronutrients are added. Examples include:

- Milk fortified with Vitamin D
- Fruit juices fortified with Vitamin C
- Bread fortified with folic acid

Within the EU, 'fortified foods' must comply with Regulation (EC) No. 1925/2006 which lays down requirements regarding the addition of vitamins and minerals and certain other substances to foods. Chapter II lays down the requirements for the addition of vitamins and minerals to food[12]; whilst Chapter III lays down requirements for the addition of certain other substances (i.e., substances prohibited, restricted or under Community scrutiny).[13] According to this Regulation, vitamins and minerals may not be added to:

- unprocessed foodstuffs, including, but not limited to, fruit, vegetables, meat, poultry and fish;
- beverages containing more than 1.2 % by volume of alcohol

In addition, fortified foods must comply with relevant rules established in horizontal legislation.

Although the **role** of both fortified foods and food supplements is similar, i.e., to supplement the diet, there are many key differences in terms of their:

Composition:	**The composition of a fortified food is related to the composition of the 'general food' plus the added micronutrients**
Physical Form:	Fortified foods are similar in physical form to 'general foods' (e.g., bread, juice, milk)
Quantity of consumption:	Fortified foods are designed to be consumed in larger quantities than food supplements. Furthermore, the energy intake from 'fortified foods' is typically higher than from 'food supplements'

[12] The provisions of Chapter II regarding vitamins and minerals do not apply to food supplements (requirements for vitamins and minerals in food supplements are addressed in Directive 2002/46/EC).
[13] The provisions of chapter III apply to all foods, including food supplements

In Ireland, there is currently no obligation to notify the FSAI when fortified foods are placed on the market.

1.3.3 General foods

By default, 'general foods' are considered all foods other than food supplements, fortified foods and foods for specific groups. Consumption of the correct mix of general foods is essential for a balanced and nutritious diet. These foods must comply with relevant rules laid down in horizontal legislative including those relating to composition (e.g., food improvement agents, GMM and novel foods), labelling and product claims. Their physical form is typically very different to food supplements (which are marketed in "dose" form e.g., pills, tablets, capsules, liquids in measured doses).

2. Obligations on food business operators

This section highlights some of the key legal obligations on food business operators, which are not addressed elsewhere in this compliance building material. This section is not intended to be a comprehensive / exhaustive overview of all legal obligations.

2.1 General requirements

The general principles and requirements of food law are established in Regulation (EC) No 178/2002. These include:

2.1.1 Definition of food

Article 2 of Regulation 178/2002 defines food:

'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.

'Food' shall not include:

(a) feed;
(b) live animals unless they are prepared for placing on the market for human consumption;
(c) plants prior to harvesting;
(d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;
(e) cosmetics within the meaning of Council Directive 76/768/EEC;
(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;

(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
(h) residues and contaminants;
(i) medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council

2.1.2 Responsibilities of food business operators

Article 17 of Regulation 178/2002 places the onus on food business operators at all stages of the food chain to ensure that food under their control satisfy the requirements of food law which are relevant to their activities, and to verify that such requirements are met.

2.1.3 Unsafe food

Article 14 of Regulation 178/2002 lays down food safety requirements. It states that food shall not be placed on the market if it is unsafe. Food is deemed to be unsafe if it is considered injurious to health or unfit for human consumption.

2.1.4 Traceability requirements

Article 18 of Regulation 178/2002 lays down traceability requirements. It is worded in terms of its goal and intended result, rather than detail about how that result is to be achieved. The requirements apply to food business operators at all stages of the food chain, from primary production, food processing to distribution and supply, including brokers, regardless of whether they take physical possession of the food in question.

2.1.5 Product withdrawal and recall

Article 19 of Regulation 178/2002 lays down requirements regarding product withdrawal and recall. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, the food business operator is obliged to withdraw / recall the food from the market. The food business operator is obliged to inform and collaborate with the competent authority on action taken to avoid or reduce risks posed by the food. All food business operators have a legal obligation to cooperate in a product withdrawal / recall by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

2.1.6 Presentation

Article 16 of Regulation 178/2002 lays down general provision that the labelling, advertising and presentation of food shall not mislead consumers.

For further information on the requirements listed above, please consult: www.fsai.ie

2.2 Food Hygiene

The safety of foods is principally ensured by a structured preventive approach such as the application of procedures based on Good Hygiene Practices and Hazard Analysis Critical Control Point (HACCP) principles. This approach enables hazards to be identified and controlled before they threaten the safety of food and the health of consumers. Hygiene requirements are laid down in a myriad of legislation including:

- Regulation (EC) No. 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on specific hygiene rules for food of animal origin
- Implementing rules
- Transitional measures

For further information on food hygiene requirements, please consult: www.fsai.ie

2.3 Food Safety Culture

Regulation (EC) No 852/2004 on the hygiene of foodstuffs introduced in March 2021 requires all food businesses to establish, maintain and provide evidence of a food safety culture. The aim of a food safety culture is to raise awareness and improve the behaviour of employees. Work is ongoing to develop guidance and support for regulators and food business operators in relation to Food Safety Culture compliance at both national and European level.

For further information, please consult: www.fsai.ie for the latest position.

2.4 Food contact materials

Any material intended to come into contact with food, that is already in contact with food, or that can reasonably be expected to come into contact with food, is considered to be a food contact material (FCM). This includes packaging materials, containers, processing machinery, etc.

Food business operators at all stages, from packaging manufacturers and suppliers to retailers, must comply with relevant rules relating to FCMs and must ensure that information on the FCMs is incorporated into their traceability system.

For further information, please consult: www.fsai.ie

2.5 Food imports

Food imports refer to the movement of products into the EU from countries outside the EU (often referred to as Third Countries). This includes imports of:

- Raw materials for the manufacture of ingredients to be used in food supplements
- Ingredients to be used in the manufacture of food supplements
- Food supplements
- Food packaging and wrapping (food contact materials)

When importing foods into the EU from a third country, food businesses must ensure compliance with the general principles of food law set out in Regulation (EC) No 178/2002/EC. Food businesses must also ensure compliance with the specific requirements laid down in EU legislation for importing of foods.

Specific import requirements, based on risk, are established for:

- Products of animal origin (POAO)[14] e.g., fish oils, glucosamine
- Products of non-animal origin (PONAO)
- Composite products[15]

Certain food supplements may contain ingredients of animal origin (e.g., fish oils, dairy extracts). Products of animal origin imported into Ireland from a third country are subject to veterinary controls at one of Ireland's Border Control Posts[16] (BCPs). They are also subject to specific requirements such as registration of the importer with the Department of Agriculture Food and the Marine (DAFM), pre-notification of its arrival via TRACES, submission of mandatory documentation, and identity and physical checks on arrival at the BCP.

The importation of food products is strictly monitored:

- For certain food products, the importer must register with TRACES NT (Trade Control and Expert System).
- The importer must know the classification code (CN) of the products
- Some products (POAO and certain composite products) can only be imported into the EU from authorised third countries and authorised establishments.
- Some high-risk PONAO are subjected to temporary increased controls or emergency measures; whilst others are suspended from entry into the EU.

[14] 'Product of animal origin' means product of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004

[15] 'Composite product' means food containing both products of plant origin and processed products of animal origin; Article 2.21 Regulation 2022/2292.

[16] Border control post' means a place, and the facilities belonging to it, designated by a Member State for the performance of the official controls provided for in Article 47(1) (Article 3.38, Regulation 2017/625)

- Specific rules are established for the point of entry into the EU i.e. BCP or other point of entry) of all imports. Each BCP is approved to inspect and approve particular product designations.

It is the responsibility of the importer to ensure that the correct category for the import (POAO, PONAO, Composite product) has been determined and that the products are checked at a BCP that is designated for their product type.

For further information, please consult: www.fsai.ie

3. Registration and notification

3.1 Registration

Article 6, paragraph 2 of Regulation (EC) No 852/2004 requires food businesses to be registered with the competent authority. The purpose of registration is to allow the competent authorities in the Member States know the location and activities of the business so that official controls can be carried out. Further information on registration is available at the following link: Starting a Food Business | Food Safety Authority of Ireland (fsai.ie)

3.2 Notification

All food supplements placed on the market in Ireland (including online) must be notified to the FSAI. This is a legal obligation under national legislation, S.I. 506 of 2007. The purpose of notification is to enable effective monitoring of food supplements.

The duty to notify the FSAI falls on the manufacturer if the product is manufactured in Ireland and on the importer if the product is imported into Ireland. If a FBO intends to place a food supplement on the market in Ireland, it should check with its supplier to verify if the food supplement has already been notified:

- If yes, there is no need to submit a duplicate notification (however the FBO should request a copy of the notification number(s) from its supplier and retain this as part of its records)
- If no, the FBO should submit the notification.

The notification can be submitted online. It involves submitting a model of the label used for the product. It is not an approval or authorisation process and the submission of a notification to the FSAI does not imply compliance with relevant EU food legislation. The obligation to comply with relevant legislation rests solely with the food business. Information on how to submit a notification can be found here.

4. Composition of Food Supplements

4.1 Introduction

A wide range of nutrients and other ingredients might be present in food supplements, including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, microorganisms, botanicals, additives, flavourings and enzymes.

4.2 Vitamins and Minerals

Directive 2002/46/EC lays down specific requirements regarding the use of vitamins and minerals in food supplements.

4.2.1 Permitted vitamins and minerals

The vitamins and minerals which may be used in the manufacture of food supplements are listed in Annex I of Directive 2002/46/EC. As of September 2023, 13 vitamins and 17 minerals are listed:

Permitted Vitamins	Permitted Minerals
Vitamin A (µg RE)	Calcium (mg)
Vitamin D (µg)	Magnesium (mg)
Vitamin E (mg a-TE)	Iron (mg)
Vitamin K (µg)	Copper (mg)
Vitamin B1 (mg)	Iodine (µg)
Vitamin B2 (mg)	Zinc (mg)
Niacin (mg NE)	Manganese (mg)
Pantothenic acid (mg)	Sodium (mg)
Vitamin B6 (mg)	Potassium (mg)
Folic acid (µg)	Selenium (µg)
Vitamin B12 (µg)	Chromium (µg)
Biotin (µg)	Molybdenum (µg)
Vitamin C (mg)	Fluoride (mg)
	Chloride (mg)
	Phosphorus (mg)

	Boron (mg) Silicon (mg)

These vitamins and minerals can only be used in the forms listed Annex II of the Directive. For example, for Vitamin A, four forms are currently permitted:

Permitted forms of Vitamin A
Retinol
Retinyl acetate
Retinyl palmitate
Beta-carotene

The lists provided in Annex I & II of the Directive are subject to change, i.e.,

- New substances can be added:
  - Stakeholders wishing to market a new nutrient source can apply to the European Commission. The application (i.e., the dossier) is assessed by the EFSA and based on the opinion of the EFSA, the new source will be either authorised or rejected by the European Commission. Once authorised, a new Regulation amending the relevant Annex in Directive 2002/46/EC is published.
  - For example, on 6th July 2017, Commission Regulation (EU) 2017/1203 was published. This amends Annex II of Directive 2002/46/EC by adding two new substances to the list, i.e., 'organic silicon (monomethylsilanetriol)' and calcium phosphoryl oligosaccharides'.
- Existing substances may be removed:
  - This is done by the European Commission on imperative grounds of urgency.

Therefore, FBOs must monitor changes in these lists to ensure any product placed on the market is fully compliant with this Directive.

4.2.2 Purity criteria

Currently, Directive 2002/46/EC does not specify purity criteria for any of the substances listed in Annex II. However, the Directive is clear that the following hierarchy applies until it adopts its own purity criteria:

1. If purity criteria are specified in any other Community legislation for the use of the substance in the manufacture of foodstuffs, they must be used.

Example: Commission Regulation (EU) No. 231/2012 lays down purity criteria for food additives. If purity criteria are laid down in this Regulation for any substance listed in Annex II of Directive 2002/46/EC, they must be used (e.g., L-ascorbic acid[17]).

2. If purity criteria addressed under point 1 do not exist, purity criteria recommended by international bodies shall apply.

Example: Purity criteria established by JECFA (The Joint FAO/WHO Expert Committee on Food Additives).

4.2.3 Minimum amounts

Directive 2002/46/EC does not establish minimum amounts for vitamins and minerals. However, it anticipates that these will be established in the future by the European Commission.

However, if the FBO makes a claim that the food supplement is a '*source of', 'contains' or is 'high in'* vitamins and/or minerals, minimum amounts must be met according to the Regulation on Nutrition and Health Claims (Regulation (EC) No. 1924/2006):

NUTRITION CLAIMS PERTAINING TO VITAMINS & MINERALS

- A claim that a food supplement is a *'source of'* a vitamin/mineral, may only be made where the food supplement contains at least a *significant amount* of that vitamin/mineral (Ref Regulation (EC) No. 1924/2006)
- A claim that a food supplement *'contains'* a vitamin/mineral, may only be made where the food supplement contains at least *a significant amount* of that vitamin/mineral (Ref Regulation (EC) No 1924/2006)
- A claim that a food supplement is *'high in'* a vitamin/mineral, may only be made where the food supplement contains at least *twice the significant amount* of that vitamin/mineral (Ref Regulation (EC) No. 1924/2006)

Please refer to Section 7.2.1 of this material for further information on significant amounts as they pertain to food supplements.

4.2.4 Maximum amounts

Directive 2002/46/EC does not establish maximum amounts for vitamins and minerals. However, it is anticipated that these will be established in the future by the European Commission.

[17] Some substances may have dual use in foods. For example, L-ascorbic acid is an authorised form of Vitamin C (Annex II, Directive 2002/46/EC) and it is also an authorised food additive (Regulation (EC) No 1333/2008)

EU General Food Law states an FBO shall not place unsafe food on the market (Article 14.1 of Regulation (EC) No. 178/2002). A food supplement could be considered unsafe if the amount of a vitamin or mineral in food plus the amount in a food supplement (added together) leads to an excessive intake. By law, food supplements can only supplement the diet, they must not replace it. Safety becomes a consideration if very high intakes of some vitamins and minerals are consumed in food supplements alongside the diet.

In the absence of maximum levels in EU legislation, the FSAI has developed guidance for FBOs on maximum levels of vitamins and minerals in food supplements in Ireland.[18] The guidance is based on relevant EU legislation and on the advice provided to the FSAI by its independent Scientific Committee.[19]

The guidance establishes maximum safe levels (MSLs) for selected vitamins and minerals in food supplements placed on the Irish market. The vitamins and minerals (7 in total) were selected based on their potential public health importance and on FSAI engagements with FBOs:

Nutrient	MSL Permitted in Food Supplements in Ireland
Vitamin A (retinol, RE µg)*	▪ Adults (>18 y): 1700 ▪ Teens (11-17y): 1300 ▪ Children (4-10y): 650
Beta Carotene (mg)	▪ Adults (>18 y): 8 ▪ Children (4-10y): 8
Vitamin D (µg)	▪ Adults (>18 y): 75 ▪ Children (4-10y): 35
Vitamin B6 (mg)	▪ Adults (>18 y): 20 ▪ Children (4-10y): 5mg
Folic Acid (µg)	▪ Adults (>18 y): 500 ▪ Children (4-10y): 200
Magnesium g (mg)	▪ Adults (>18 y): 250 ▪ Children (4-10y): 250
Vitamin C (mg)	▪ Adults (>18 y): 1800 ▪ Children (4-10y): 500

*Vitamin A supplements are not recommended during pregnancy and not suitable for postmenopausal women

The MSLs are per daily dose of food supplement as recommended by the manufacturer. The MSLs are set for adults and children separately. The adult value is also suitable for teens except for Vitamin A (retinol, RE µg).

[18] FSAI. 2020. Guidance for Food Businesses: The Safety of Vitamins and Minerals in Food Supplements. Establishing Maximum Safe Levels and Risk Assessment Approach for Products Marketed in Ireland
[19] FSAI. 2020. 'The Safety of Vitamins and Minerals in Food Supplements – Establishing Tolerable Upper Intake Levels and a Risk Assessment Approach for Products Manufactured in Ireland' (Revision 2)

The guidance also outlines the risk assessment approach used to establish MSLs for other vitamins and minerals in food supplements placed on the market in Ireland.[20] FBOs are advised to consult this guidance to establish the MSLs for other vitamins and minerals in food supplements placed in the market in Ireland.

VITAMINS & MINERALS - CHECKLIST

Factors which must be considered by FBOs prior to the use of vitamins and minerals in food supplements include:

- The vitamin / mineral must be authorised for use in food supplements
- The form of the vitamin / mineral must be authorised for use in food supplements
- The vitamin / mineral must meet relevant purity criteria (where they exist)
- If the food supplement carries a nutrition claim, i.e., '*source of', 'contains' or 'high in'* vitamins and/or minerals, minimum amounts must be met (See Section 7.2.1 for further information)
- The level of vitamin / mineral in the food supplement must not render the food supplement unsafe

VITAMINS & MINERALS – INFORMATION SOURCES

Relevant information sources include:

- 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 (OJ L 183 12.7.2002, p. 51)
- FSAI. 2020. Guidance for Food Businesses: The Safety of Vitamins and Minerals in Food Supplements. Establishing Maximum Safety Levels and Risk Assessment Approach for Products Marketed in Ireland
- FSAI. 2020. 'The Safety of Vitamins and Minerals in Food Supplements – Establishing Tolerable Upper Intake Levels and a Risk Assessment Approach for Products Manufactured in Ireland' (Revision 2)

4.3 Food improvement agents

4.3.1 Food additives

Food additives are regulated in the EU via **Regulation (EC) No. 1333/2008**.

[20] The risk assessment approach is based on the fact that: the daily amount of a micronutrient from a food supplement, added to the usual daily intake from food sources (i.e., from foods, including fortified foods, but excluding supplements), in the highest consumers (i.e., the 95th percentile), should not exceed the tolerable upper intake levels (UL) for the population group(s) for whom the food supplement is intended.

The European Union legislation defines food additives as " *any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods*." (Article 3(2)(a), Regulation (EC) No. 1333/2008)

All food additives used in the EU must be **authorised**[21] by the European Commission prior to use.

- The procedure for authorisation of a food additive is common to the one established for food flavourings and enzymes under Regulation (EC) No. 1331/2008
- More details about this procedure can be found on the European Commission website

Annex I of Regulation (EC) No 1333/2008 defines the 27 functional classes of authorised food additives. Food additives may be assigned a functional class on the basis of the principal intended technological function of the food additive, but this does not preclude it from being used for several functions. These include:

- 'sweeteners' are substances used to impart a sweet taste to foods or in table-top sweeteners.
- 'colours' are substances which add or restore colour in a food and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other edible natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of the Regulation.

Annex II & Annex III of Regulation (EC) No. 1333/2008 lays down the Union list of authorised food additives (the Union list can also be consulted in the Food Additives Database.[22]

- **Annex II of Regulation (EC) No. 1333/2008 lists the additives which are authorised for use in foods.** The authorised additives are listed according to food category. Food

[21] All food additives authorised for use in the EU are assigned an E number. For example, E 202 is assigned to potassium sorbate.
[22] This database is made available solely for the purpose of information. It has no legal value. The Commission declines any responsibility or liability whatsoever for errors or deficiencies in this database. Information in the database may not be timely, complete or accurate. Neither the Commission nor any person acting on behalf of the Commission is responsible with regard to the improper use of the database and its contents. The official authorisations of food additives are published in the Official Journal of the European Union.

category 17 applies to food supplements. This category is further sub-divided based on the form (solid or liquid) of the food supplement, i.e.,

- Category 17.1 lists additives authorised for use in supplements supplied in a solid form, excluding food supplements for infants and young children
- Category 17.2 lists additives authorised for use in food supplements supplied in a liquid form, excluding food supplements for infants and young children

Further explanations of these subcategories can be found in the following publication: 'Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives' (Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives).[23]

NOTE: The additives authorised under categories 17.1 and 17.2 are not authorised for use in food supplements intended for infants and young children.[24] Currently no additives are authorised for use in food supplements for infants & young children either directly or via the use of the carry over principle.

- **Annex III of Regulation (EC) No. 1333/2008 lists the additives which are authorised for use in other food additives, food enzymes, food flavourings and nutrients.** This includes carriers, which don't need to be labelled.
- **Annex II & Annex III of Regulation (EC) No. 1333/2008 also list the conditions of use for each authorised additive.** Conditions of use include the maximum limit and any restriction or exemptions. The maximum levels of use refer to food supplements ready for consumption (i.e., prepared following the instructions of use provided by the manufacturer). For food supplements which must be diluted or dissolved, the dilution factor must be communicated on the label together with the instructions of use.

Regulation (EU) No. 231/2012 lays down purity criteria (specifications) which are assigned to each authorised additive. Manufacturers must ensure that any additive used in food supplements meets relevant purity criteria. Manufacturers can do this by working closely with their food additive suppliers.

[23] The guidance document does not represent the official position of the Commission and it does not intend to produce legally binding effects

[24] REGULATION (EU) No 609/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control defines 'infant' as 'a child under the age of 12 months' (Article 2.2.a) and 'young child' as 'a child aged between one and three years' (Article 2.2.b)

FBOs should be mindful that **authorised additives are subject to change**, i.e.,

- New additives may be authorised based on application from relevant stakeholders
- Existing authorisations may change
    - The EFSA currently has a re-evaluation programme underway for food additives. This is to take into consideration new scientific data, as many additives were authorised many years ago. Based on the advice of EFSA, the European Commission may propose a revision of the current conditions of use of the additives and, if needed, remove an additive from the Union list.

Therefore, FBOs must always refer to the latest consolidated version of Regulation (EC) No. 1333/2008 and monitor changes to ensure any product placed on the market is fully compliant with legislative requirements.

Finally, all additives used in the production of food supplements are considered ingredients and must be listed in the ingredients list using the name of their principle intended technological purpose (i.e., functional class) followed by their specific name or E number (e.g., Sweetener: Advantame or Sweetener: E969) as per Annex VII, Part C of Regulation (EU) No 1169/2011. To note, “specific name” concerns the name used to refer to an additive in the Annex II of Regulation (EC) No. 1333/2008 or an alternative name contained in Regulation (EU) No. 231/2012, excluding synonyms. Furthermore, Annex V of Regulation (EC) No. 1333/2008 lists the food colours referred to in Article 24 of that Regulation for which the labelling of foods shall include additional information (please note that not all of these food colours are permitted in food supplements). Further information on labelling and food information is provided in Section 6 of this document.

FOOD ADDITIVES – CHECKLIST

Factors which must be considered by FBOs prior to the use of a food additive in a food supplement include:

- The food additive must be authorised for use in the correct form of the food supplement (i.e., solid or liquid)
- The chemical characteristics of the food additive must meet relevant purity criteria
- All conditions of use for the authorised food additive must be met (i.e., maximum limit and any restriction or exemptions)
- The food additive must be included on the ingredients list of the food supplement, and it must be listed using the name of the functional class (on the basis of the food additive’s principal intended technological purpose) followed by its specific name or E number

- No food additives are authorised for use in food supplements for infants and young children

FOOD ADDITIVES – INFORMATION SOURCES

Relevant information sources include:

- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives *(OJ L 354, 31.12.2008, p. 16)*
- Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008, p. 1)
- Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 083 22.3.2012, p. 1)
- European Commission Food Additives Database
- Codex General Standard for Food Additives (GSFA) Online Database
- Guidance document describing the food additives in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives
- FSAI 2015 Guidance on Food Additives Revision 2
- FSAI website

4.3.2 Food flavourings

Food flavourings are regulated in the EU via Regulation (EC) No. 1334/2008. Smoke flavourings used or intended for use in or on foods are regulated in the EU via Regulation (EC) No. 2065/2003.

Food flavourings are defined as *products:*

(i) not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste;

(ii) made or consisting of the following categories:

- *flavouring substances*
- *flavouring preparations*
- *thermal process flavourings*
- *smoke flavourings*
- *flavour precursors*
- *food ingredients with flavouring properties*

- *other flavourings or mixtures thereof*

(Article 3(2)(a), Regulation (EC) No. 1334/2008)

Note: Definitions are provided in Article 3(2)(b-i), Regulation (EC) No. 1334/2008[25]

AUTHORISATIONS:

1. Flavourings (other than smoke flavours)

Article 9 of Regulation (EC) No. 1334/2008 specifies the flavourings and source materials for which an authorisation (evaluation and approval) is required; whilst Article 8 of Regulation (EC) No. 1334/2008 specifies the flavourings and food ingredients with flavouring properties for which an authorisation (evaluation and approval) is not required. This is linked to the definitions provided in Article 3(2) of Regulation (EC) No.1334/2008:

Flavouring / Source Material / Food Ingredient with Flavouring Properties	**Evaluation & Approval Required [(a)] / Not Required [(b)]**	
	Required **For flavourings and source materials, defined in the following Articles of Regulation (EC) No. 1334/2008**	**NOT Required :** **For flavourings and food ingredients with flavouring properties, defined in the following Articles of Regulation (EC) No. 1334/2008**
Flavouring Substance	3(2)(b)	
Flavouring Preparation	3(2)(d)(ii)	3(2)(d)(i)
Thermal Process Flavouring (c)	3(2)(e)(ii)	3(2)(e)(i)
Flavour Precursor	3(2)(g)(ii)	3(2)(g)(i)
Other flavouring	3(2)(h)	
Source Material	3(2)(j)(ii)	
Food Ingredient with Flavouring Properties		3(2)(i)

[25] Regulation (EC) No 1334/2008 does not apply to substances with only an exclusively sweet (e.g., sugar), salty (e.g., salt) or sour taste, or to raw foods or mixtures such as fresh, dried or frozen spices and/or herbs, or to teas and infusions as such as long as they have not been used as food ingredients.

(a) Evaluation and approval (authorisation) required as outlined in Article 9 of Regulation (EC) No. 1334/2008. In summary, this is required for flavourings and source materials that are not made from food. The procedure for authorisation is common to the one established for food additives and enzymes under Regulation (EC) No. 1331/2008. Further details are available on the European Commission website.

(b) Evaluation and approval (authorisation) not required as outlined in Article 8 of Regulation (EC) No. 1334/2008. In summary, authorisation is not required for flavourings and food ingredients with flavouring properties which are made from food. However, they may only be used in or on foods if they meet the following conditions: they must not pose a safety risk to the health of the consumer (based on available scientific evidence) and their use must not mislead the consumer.

(c) For further information, please review Article 9.c and Article 3.2.e.i of Regulation (EC) No. 1334/2008

If an authorisation is required for a flavouring / source material, that flavouring / source material can only be placed on the market / used in food if a) it has been authorised for use by the European Commission, i.e., published on the Union list and b) if all requirements / conditions of use are met. The Union List of authorised flavours / source materials is published in Annex 1, Regulation (EC) No. 1334/2008:

Flavouring Category/ Source Material	**Location of Union List in Regulation 1334/2008**	**Populated with Authorisations (*)**
Flavouring Substance	Part A, Annex 1	Yes
Flavouring Preparation	Part B, Annex 1	No
Thermal Process Flavouring	Part C, Annex 1	No
Flavour Precursor	Part D, Annex 1	No
Other flavouring	Part E, Annex 1	Yes
Source Material	Part F, Annex 1	No

(*) To date, most authorisations have been for the category ‘Flavouring Substance’. There has been one authorisation for the category ‘Other flavourings’. There are currently no authorisations for the remaining categories.

To date, only **flavouring substances** have been authorised for use in food supplements. For each authorised flavouring substance, the following information is provided on the Union list: the FL number (this is assigned upon authorisation), the purity requirements and any restrictions of use. Maximum levels are not established for most flavouring substances (the use of flavourings in food

is self-limiting, dependent on consumer preferences, and generally only small amounts are needed to achieve the desired effect). The Union list of authorised flavouring substances is also searchable via the Food Flavourings Database.

2. Smoke Flavours

Authorisation is also required for smoke flavourings; however, these are regulated separately from other flavourings in the EU as they consist of complex mixtures of substances, which give rise to different safety issues:

- Regulation EU No. 2065/2003 establishes a procedure for the evaluation and authorisation of smoke flavourings every 10 years for use within the EU.
- Regulation EU No. 1321/2013 establishes the Union list of authorised smoke flavourings for use as such in or on foods and/or for the production of derived smoke flavourings.

To date, no smoke flavourings have been authorised for use in food supplements.

SPECIFIC RESTRICTIONS

Specific restrictions are established in Annex III and IV of Regulation (EC) No. 1334/2008.

- Annex III lays down rules regarding the presence of certain substances:
  - Part A lists certain substances which shall not intentionally be added to any food (this includes food supplements)
  - Part B lays down maximum levels for certain substances which are naturally present in **flavourings** and/or **food ingredients with flavouring properties**. The maximum levels apply to certain compound foods: i) to which **flavourings** and/or **food ingredients with flavouring properties** have been added, ii) as consumed. Currently, the maximum levels outlined in Part B of Annex III do not apply to food supplements.
- Annex IV lists source materials to which restrictions apply for their use in the production of **flavourings** and **food ingredients with flavouring properties:**
  - Part A lists the source materials which shall not be used in the production of **flavourings** and **food ingredients with flavouring properties**
  - Part B lays down the conditions of use for **flavourings** and **food ingredients with flavouring properties** produced from certain source materials. To date, **flavourings** and **food ingredients with flavouring properties** produced from the source materials listed in Part B of Annex IV must not be used to produce food supplements.

LABELLING OF FOOD FLAVOURS

Finally, all flavourings and food ingredients with flavouring properties used in the production of food supplements must be listed on the ingredients list. Further information on labelling and food information is provided in Section 6 of this document.

FOOD FLAVOURINGS – CHECKLIST

Factors which must be considered by FBOs prior to the use of a flavour in a food supplement include:

- If authorisation is required for a flavouring in accordance with Article 3(2) of Regulation (EC) No. 1334/2008:
  - The flavouring must be published on the Union list, and it must be authorised for use in food supplements [(1)]
  - The authorised flavour must meet all purity criteria
  - All conditions of use must be met when using the authorised flavouring
- If authorisation is not required for a flavouring in accordance with Article 3(2) of Regulation (EC) No. 1334/2008:
  - The flavouring can be used in a food supplement once it complies with all other relevant aspects of food law (e.g., it must be safe, if novel it must be authorised under the novel food regulation etc)
- The food supplement must not contain any substance listed in Part A, Annex III of Regulation (EC) No. 1334/2008
- Source materials listed in Part A, Annex IV of Regulation (EC) No. 1334/2008 must not be used in the production of flavourings and food ingredients with flavouring properties
- Flavourings and food ingredients with flavouring properties produced from the source materials listed in Part B, Annex IV of Regulation (EC) No. 1334/2008, must not be used to produce food supplements
- The food flavour must be specified on the ingredients list [(2)]

[(1)] To date, only flavouring substances are authorised for use in food supplements

[(2)] Further details in Text Box 5 of Section 6.4

FOOD FLAVOURINGS – INFORMATION SOURCES

Relevant information sources include:

- Regulation (EC) No. 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354 31.12.2008, p. 34)

- Regulation (EC) No. 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008, p. 1)
- Regulation (EC) No. 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309 26.11.2003, p. 1)
- Commission Implementing Regulation (EU) No. 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings (OJ L 333 12.12.2013, p. 54)
- EFSA. 2010. EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids: Guidance on the data required for the risk assessment of flavourings. EFSA Journal 2010; 8(6):1623.
- European Commission Food Flavourings Database
- FSAI 2012 Guidance on Food Flavourings
- FSAI website

4.3.3 Food enzymes

Food enzymes are regulated via Regulation (EC) No. 1332/2008.

'food enzyme' means a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms:

- *containing one or more enzymes capable of catalyzing a specific biochemical reaction; and*
- *added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods;*

'food enzyme preparation' means a formulation consisting of one or more food enzymes in which substances such as food additives and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dilution or dissolution

Article 3.3, Regulation (EC) No. 1332/2008

There is currently no Union list of authorised food enzymes;[26] however, Regulation (EC) No. 1332/2008 lays down provisions for its establishment. For food enzymes to be authorised in the EU, they should fulfil the following criteria:

- They must be safe when used on the basis of available scientific evidence
- There must be a reasonable technological need for their use
- Their use must not mislead the consumer.

The entry of a food enzyme in the Union list will specify the name of the food enzyme; the specifications of the food enzyme, the foods to which the food enzyme may be added; the conditions under which the food enzyme may be used; any restrictions on the sale of the food enzyme directly to the final consumer and where necessary, specific requirements relating to the labelling of food in which the food enzymes have been used.

The process to draw up the Union list required the submission of applications during the period 11 September 2011 to 11 March 2015. During this period, the Commission received over 300 food enzyme applications. Considering all applications must go through a safety evaluation by EFSA and subsequent approval by the EC, it will take some years to establish the Union list. All valid applications have been published by the European Commission on a Register of food enzymes to be considered for inclusion on the Union List (Link). For an application to be considered valid, the product must be in scope of the food enzyme regulation, and the dossier should contain all information and data required for the risk assessment and risk management of the food enzyme. The Register is not a list of authorized food enzymes.

As soon as the Union list of food enzymes is applicable, only food enzymes on that Union List will be allowed on the EU market. In the meantime, without prejudice to other applicable Union legislation, including Regulation (EC) No 178/2002, national provisions in force concerning the placing on the market and use of food enzymes and food produced with food enzymes continue to apply. In those Member States (including Ireland) where national rules do not exist, food enzymes can continue to be used until the Union List is established only if they are on the “Register”. Any new food enzymes not on the register will be subject to the authorisation process and may not be placed on the EU market or used in food until they are present on the Union List.

In line with the scope of Regulation (EC) No. 1332/2008, the Union list will cover enzymes that are added to food to perform a technological function in the manufacture, processing, preparation,

[26] As of November 2023

treatment, packaging, transport or storage of such food. This includes enzymes used as processing aids. It will not cover:

- enzymes used exclusively in the production of food additives (safety is assessed and regulated under the food additives regulation)
- enzymes that are not added to food to perform a technological function, such as enzymes intended for human consumption (e.g., enzymes for nutritional or digestive purposes).

Note: Food enzymes which fall within the scope of Regulation (EC) No. 1829/2003 on genetically modified food and feed must be authorised in accordance with that Regulation, as well as under Regulation (EC) No. 1332/2008.

FOOD ENZYMES – CHECKLIST

Factors which must be considered by FBOs prior to the use of a food enzyme in a food supplement relate to the purpose/function of the food enzyme. These include:

- If the food enzyme is used to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of a food supplement, the factors to be considered are as follows:
  - **Prior to the establishment of the Union list:**
    In Member States where national rules exist, food enzymes can continue to be used in accordance with national rules until the Union list is established. In Member States where national rules do not exist (e.g., Ireland), food enzymes can only be used if they are included on the European Commission Register of food enzymes.
  - **Post establishment of a Union list:**
    In all Member States, food enzymes can only be used if they are included on the Union list.
- Enzymes used for other reason (other than technological function) in a food supplement
  - **Must comply with all relevant horizontal legislation**

FOOD ENZYME – INFORMATION SOURCES

Relevant information sources include:

- Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)

- European Commission Guidance Document on Criteria for Categorisation of Food Enzymes
- The purpose of this document is to provide food business operators and competent authorities with criteria for determining the status of a food enzyme either as an ingredient or as a processing aid in a given context of use, and hence whether it needs to be listed in the ingredient list of foods intended for the final consumer

4.4 Extraction Solvents

Extraction solvents used or intended for use in the production of foodstuffs or food ingredients are regulated via Directive 2009/32/EC.[27]

Directive 2009/32/EC defines an 'extraction solvent' as:

- *a solvent which is used in an extraction procedure during the processing of raw materials, of foodstuffs, or of components or ingredients of these products and which is removed but which may result in the unintentional, but technically unavoidable, presence of residues or derivatives in the foodstuff or food ingredient.*

All extraction solvents must be authorised by the European Commission prior to use.

Authorised extraction solvents are listed in Annex I of the Directive. They must be used in accordance with good manufacturing practices, which present no danger to human health. Furthermore, they must comply with general and specific purity criteria. For some extraction solvents, the conditions of use and maximum residue limits are also specified.

Ethanol is an example of an authorised extraction solvent which is commonly used in the production of botanical preparations. Although it must be used under good manufacturing practices, it is possible that it may result in the unintentional, but technically unavoidable, presence of residues or derivatives in the foodstuff or food ingredient. These residues/derivatives should be as low as possible; however, it should be noted that if they exceed 1.2% by volume/weight, there are labelling obligations. Under the Food Information to Consumers Regulation, there is a mandatory requirement to label the actual alcoholic strength by volume of beverages containing more than 1.2% by volume of alcohol. Furthermore, the FSAI recommends that the alcohol content

[27] This Directive does not apply to extraction solvents used in the production of food additives, vitamins and other nutritional additives, unless such food additives, vitamins or nutritional additives are listed in Annex I of the Directive.

of solid foods is also declared if it contains more than 1.2% by weight of alcohol. These labelling requirements apply to all beverages and foods, including food supplements.

EXTRACTION SOLVENTS – CHECKLIST

FBOs must ensure that:

- Only authorised extraction solvents are used during the production of food supplements and its food ingredients
- Use of authorised extraction solvents comply with conditions of use and maximum residue limits where they apply

EXTRACTION SOLVENTS – INFORMATION SOURCES

Relevant information sources include:

- Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141 6.6.2009, p. 3)

4.5 Genetically Modified Organisms

Genetically Modified Organisms (GMOs) are organisms, such as plants, animals and microorganisms whose DNA has been altered in a way that does not occur naturally by mating and/or natural recombination. Foods which contain, consist of, or are produced from GMOs are called genetically modified (GM) foods. Under EU legislation, GM food must not:

- have adverse effects on human health, animal health or the environment
- mislead the consumer and
- differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer

Under EU legislation, specific rules relating to the authorisation, labelling and traceability of GM foods are in place.

AUTHORISATION

Under Regulation (EC) No. 1829/2003, it is not permissible to place on the market:

- a GMO for food use,
- food containing or consisting of GMOs; and
- food produced from or containing ingredients produced from GMOs,

unless it is covered by an authorisation granted in accordance with the Regulation and the relevant conditions of the authorisation are satisfied. The procedure for authorisation is outlined in Articles 4 to 7 of the Regulation. Authorisations are valid for 10 years and following this an application for renewal must be submitted as outlined in Article 11 of the Regulation.

The European Commission maintains a Community register of GM food and feed Regulation (EC) No 1829/2003.

LABELLING

Regulation (EC) No. 1829/2003 sets out specific labelling requirements for GM foods which are to be delivered as such to the final consumer and which:

- contain or consist of GMOs; or
- are produced from or contain ingredients produced from GMOs

TRACEABILITY

Regulation (EC) No. 1830/2003 lays down traceability requirements for food or food ingredients containing, consisting of, or produced from GMOs. The Regulation requires that business operators must transmit and retain information about products that consist of or contain GMOs at each stage of the placing on the market of the product. Under Article 4 of Regulation (EC) No. 1830/2003, operators must ensure that the following information is transmitted in writing to the operator receiving the product:

- that it contains or consists of GMOs
- the unique identifier(s) assigned to those GMOs (there is an exemption for the transmission of this information if specific identification systems such as lot numbers are in place)

Food businesses must also have in place systems and standardised procedures to allow the holding of information and the identification of the operator by whom and the operator to whom the products have been made available.

EXEMPTION TO LABELLING AND TRACEABILITY REQUIREMENTS

Conventional food products may unintentionally contain traces of GMOs, for example, due to cross-pollination, or due to adventitious or technically unavoidable mixing of GM and non-GM ingredients during harvesting, storage, transport or processing. Such products are not subject to traceability or labelling requirements if the GMO traces are no higher than 0.9% of the individual ingredient and where the operator can demonstrate to the competent authority that they have taken appropriate steps to avoid the presence of GM material.

In Ireland, the FSAI is the competent authority for the implementation of legislation governing GM food. As competent authority, the FSAI ensures that only EU-authorised GM foods are allowed on the market and that they are labelled appropriately.

GMO – CHECKLIST

Factors which must be considered by FBOs include:

If the food supplement or any ingredient used in the food supplement falls within the scope of Regulation (EC) No. 1829/2003 on genetically modified food and feed:

- Authorisation must be granted in accordance with Regulation (EC) No. 1829/2003 and relevant conditions of the authorisation must be satisfied.
- Labelling requirements (as outlined in Regulation 1829/2003) and traceability requirements (as outlined in Regulation (EC) No. 1830/2003) must be satisfied.

GMO – INFORMATION SOURCES

Relevant information sources include:

- Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268 18.10.2003, p. 1)
- Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ((OJ L 268 18.10.2003, p. 24)
- Food Safety Authority of Ireland website
- European Commission (EC) website

4.6 Novel Foods

Novel foods are regulated via Regulation (EU) No. 2015/2283.

Regulation (EU) No. 2015/2283[28] defines 'novel food' as any food that was not used for human consumption to a significant degree[29] within the Union before 15 May 1997 and that falls under at least one of the following categories[30] (both conditions must be met):

- *Foods consisting of, isolated from or produced from:*
  - *microorganism, fungi or algae*
  - *material of mineral origin*
  - *plants or their parts*
  - *animals or their parts*
  - *cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae*
- *foods (including vitamins and minerals) consisting of engineered nanomaterials*
- *foods with new or intentionally modified molecular structure*
- *foods (including vitamins and minerals) resulting from a new production process not used within the EU before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances*
- *food used exclusively in food supplements within the Union before 15 May 1997, but now intended to be used in other foods*

UNION LIST OF AUTHORISED NOVEL FOODS

Any food which meets the definition of 'novel' falls within the scope of the Novel Foods Regulation and must be authorised by the European Commission prior to placing on the EU market. All authorised novel foods are listed in the Union List of Authorised Novel Foods in Commission Implementing Regulation (EU) No. 2017/2470. The Union list includes conditions of use, labelling requirements, and specifications for each authorised novel food. Once all these requirements are met, any FBO can place the authorised novel food on the market, unless a five-year exemption has been granted by the Commission based on proprietary data.

[28] The Regulation does not apply to genetically modified foods falling within the scope of Regulation (EC) No 1829/2003; food enzymes falling within the scope of Regulation (EC) No 1332/2008; food additives falling within the scope of Regulation (EC) No 1333/2008; food flavourings falling within the scope of Regulation (EC) No 1334/2008; extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC. However, if additives, food enzymes and flavourings are used as ingredients, rather than their technological function, they may still come under its scope.

[29] Information and guidance on 'human consumption to a significant degree'

[30] Detailed in Article 3.2, Regulation (EU) 2015/2283

To date, numerous novel foods have been authorised for use in food supplements. Examples include Iron hydroxide adipate tartrate (IHAT), Yeast beta-glucans, Xylo-oligosaccharides, Vitamin D2 mushroom powder, UV-treated baker's yeast (Saccharomyces cerevisiae) and Sunflower oil extract.

NOVEL FOOD APPLICATION PROCEDURE

If an FBO intends to place a food on the market which is considered novel but is not already authorised (i.e., not included on the Union list of authorised novel foods), it must submit an application directly to the European Commission using the e submission system. The application dossier must be developed in accordance with Commission Implementing Regulation (EU) No. 2017/2469.

The procedure for authorising a novel food or food ingredient is set out in Articles 10, 11 and 12 of the novel food Regulation. This generally involves a pre-market safety assessment by the European Food Safety Authority (EFSA) followed by a vote on a draft Commission proposal at the Standing Committee on Plants, Animals, Food and Feed: Novel Food and Toxicological Safety of the Food Chain.

NOVEL OR NOT NOVEL?

The obligation rests with the food business to verify whether the food it intends to place on the EU market falls within the scope of the Novel Food Regulation. This is an important decision as it determines the difference between a pre-market authorisation of the food and direct market access. If a food business is unsure about the novel food status of a food or ingredient it wishes to place on the market, there are some information resources that can be useful:

- **THE EC UNION LIST OF AUTHORISED NOVEL FOODS**
  - All authorised novel foods are included on the Union list.
- **THE EC NOVEL FOOD CATALOGUE**
  - The novel food catalogue is maintained by the European Commission and is an informal record of conclusions reached at EU level about the novel food status of various foods and ingredients as questions arise. The absence of a food or ingredient from the catalogue means that its novel food status has not been addressed. Furthermore, the novel food status of foods and ingredients listed in the catalogue is subject to change in the event of new reliable information. Thus, the novel food status needs to be verified by the food business.
- **OUTCOME OF ARTICLE 4 CONSULTATIONS WITH MEMBER STATES**
  - In accordance with Article 4 of the Novel Food Regulation, food businesses can consult the Member State where they first intend to market a food about its novel

food status (novel/not novel). Whilst the outcomes are uploaded to the EC Novel Food Catalogue, more specific details can be found on the European Commission website.

- **SUMMARY OF APPLICATIONS & NOTIFICATIONS**
  - A summary of all applications and notifications for novel food authorisation can be found on the European Commission website.

- **TERMINATED APPLICATIONS**
  - According to Article 10(6) of the novel food regulation, the Commission may terminate the authorisation procedure at any stage, where it considers that this is justified. Details of all applications which have been terminated can be found on the European Commission website.

If a food business is still unsure whether a food falls within the scope of the Novel Food Regulation, it may consult the Member State where it first intends to market the food (Article 4 of Regulation (EU) No. 2015/2283):

- Specific rules are laid down in legislation (Commission Implementing Regulation (EU) No. 2018/456) regarding the procedure for this consultation.
- The Recipient Member State must decide on the novel food status within four months of the consultation request; however, in certain circumstances this can be extended by a further four months. The Recipient Member State can also consult other Member States and the Commission on the novel food status. Once the decision is made and the food business is informed, the Commission will make the novel food status publicly available on the European Commission website.

NOVEL FOOD – CHECKLIST

Before any food supplement or ingredient used in a food supplement is placed on the EU market, the FBO must:

- Determine if it meets the definition of a novel food. If unsure:
  - Consult all relevant information resources (e.g., Union list of authorised novel foods, EC Novel Food Catalogue, Outcome of article 4 consultations with member states, Summary of applications & notifications, Overview of terminated applications).
  - Consult the Member State where the food will first be marketed (procedure for consultation outlined in Article 4, Regulation (EU) No. 2015/2283.
- If novel, the food must be authorised before it can be placed on the EU market

- The procedure for authorisation is outlined in Articles 10, 11 and 12 of Regulation (EU) No. 2015/2283.
- If already authorised, all requirements (including conditions of use, labelling requirements, and specifications) associated with the authorisation must be met prior to placing on the market

NOVEL FOOD – INFORMATION SOURCES

Relevant legislation includes:

- Regulation (EU) No. 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods (OJ L 327 11.12.2015, p. 1)
- Commission Implementing Regulation (EU) No. 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) No. 2015/2283 of the European Parliament and of the Council on novel foods (*OJ L 351, 30.12.2017, p. 64)*
- Commission Implementing Regulation (EU) No. 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) No. 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351 30.12.2017, p. 72)
- Commission Implementing Regulation (EU) No. 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 *(*OJ L 77, 20.3.2018, p. 6)

Relevant guidance documents include:

- European Commission: Details on the e-submission procedure: e-submission in accordance with the new Novel Foods regulation (europa.eu)
- EFSA has developed two guidance documents that outline the scientific information and data needed for the safety assessment of novel foods:
  - Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) No. 2015/2283. EFSA Journal (2016) 14(11):4594.
  - Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) No. 2015/2283. EFSA supporting publication (2018): EN-1381.

4.7 Medicinal Products

Pursuant to Article 2 of Regulation (EC) No. 178/2002, the definition of food specifically excludes medicinal products.

Medicinal products are defined by Directive 2001/83/EC on the Community code relating to medicinal products for human use (Article 1.2) as:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Substances and active substances are further defined in Directive 2001/83/EC:

- *A substance is any matter irrespective of origin which may be human, (e.g., human blood and human blood products); animal, (e.g., micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products); vegetable (e.g., micro-organisms, plants, parts of plants, vegetable secretions, extracts) or chemical (e.g., elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis) (Article 1.3)*
- *An active substance is any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis (Article 1.3a)*

The Health Products Regulatory Authority (HPRA) is the competent authority in Ireland for medicinal products for human use. [31] It regulates the licensing and sale of such products. Based on legislative requirements, such products shall not be marketed without prior authorisation or registration.

[31] It is also the competent authority for medicinal products for veterinary use and for medical devices.

The responsibility rests with FBOs to ensure that food supplements under their control do not contain a medicinal product. This can be challenging because there is no exhaustive list of medicinal products at European or national level. Furthermore, the classification of a product as a medicinal product may vary between EU member states. Therefore, classification needs to be conducted on a case-by-case basis. Numerous resources are available which can help 'steer' FBOs. These include:

- The HPRA Guide to the Definition of a Human Medicine
- The Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (S.I. No. 540 of 2003 as amended) which lists medicinal products which are subject to prescription control in Ireland
- The HPRA databases for medicines, traditional herbal medicines and homeopathic medicines (It should be noted that these databases are a comprehensive listing of all medicines that can be marketed in Ireland, they are not an exhaustive listing of all potential medicinal products)
- In relation to herbal substances and herbal preparations, the following information sources should also be consulted:
    - EU monographs (published by The Committee on Herbal Medicinal Products, HMPC of the European Medicines Agency (EMA). These provide information on therapeutic uses and safe conditions of well-established and/or traditional use for herbal substances and preparations[32]
    - European Union list of THMPs:[33] Commission Decision 2008/911/EC

If a FBO has any doubt/concern over the classification of a given product, it can request the opinion of the HPRA via its classification procedure, prior to placing the product on the market. In this way FBOs can obtain an authoritative opinion and avoid the risk of inadvertently breaking the law. [34] In arriving at any decision regarding classification, the HPRA must always be provided with

[32] In Ireland, herbal medicinal products must be registered or authorised by the HPRA. The registration procedure is less onerous than the authorisation procedure (i.e., the requirement for demonstration of therapeutic efficacy is reduced). The registration procedure is applicable to traditional herbal medicinal products (THMPs). All other herbal medicinal products must be authorised (same procedure as for any other medicinal product) prior to being placed on the market.
[33] Unlike EU herbal monographs, EU list entries are legally binding on applicants and national competent authorities in the Member States
[34] FBOs should also be aware in most cases the classification of a product as a medicinal product is clear in that the nature of the substance, its effects on the body, the indications for use/contraindications, its presentation and the manner of marketing are consistent with the definition of medicinal products. However, there are a growing number of products that are considered borderline, e.g., they may fall between the medicinal products sector and other sectors (e.g., food, medical device, cosmetics). Directive 2001/83/EC addresses this scenario by clarifying where doubt exists over the classification of a product the stricter medicinal products regulatory regime should apply (Article 2.2).

sufficient information about the product and its intended use. This includes not only labels, leaflets, and all advertising / promotional materials but also any websites linked to such literature.

MEDICINAL PRODUCTS – CHECKLIST

Before any food supplement is placed on the EU market, the FBO must ensure that:

- It does not contain an active substance (i.e., any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis)
- It does not carry a medicinal claim

MEDICINAL PRODUCTS – INFORMATION SOURCES

Relevant information sources include:

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311 28.11.2001, p. 67)
- The HPRA Guide to the Definition of a Human Medicine

4.8 Narcotic and psychotropic substances

Pursuant to Article 2 of Regulation (EC) No. 178/2002, the definition of food specifically excludes narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971. Thus, narcotic and psychotropic substances cannot intentionally be used in food (including food supplements). Lists of narcotic drugs and psychotropic substances are provided in the Schedules of the relevant United Nations Convention.

In recent years, the escalation of ingredients based on the **hemp plant (*Cannabis sativa*)**, has brought the discussion on narcotic and psychotropic substances into the spotlight. The following highlights the current position in Ireland:

Hemp plant / Cannabinoid	Description	Narcotic / Psychotropic substance
Hemp plant [a]	Flowers / Flowering tops [b]	Yes
	Leaves / Seeds [b, f]	No
Cannabinoids [c]	Cannabidiol (CBD) [d, f]	No
	Tetrahydrocannabinol (THC) [e]	Yes

[a] Certain varieties of hemp plant (*Cannabis sativa*) can be grown in Ireland, under license from the Department of Health and facilitated by the Health Products Regulatory Authority (HPRA).

[b] According to Article 1 of the 1961 United Nations Single Convention on Narcotic Drugs, *'Cannabis' means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated*. Thus:

- The flowering or fruiting tops of the hemp/cannabis plant are considered narcotics and thus cannot be regarded as a food in the EU.
- Other parts of the hemp/cannabis plant, such as seeds and leaves when not accompanied by the flowering or fruiting tops, are not considered narcotic and thus can be regarded as food.

[c] The hemp/cannabis plant naturally contains more than 100 cannabinoids. The two most prominent cannabinoids are cannabidiol (CBD) and tetrahydrocannabinol (THC).

[d] CBD is not considered a narcotic drug within the meaning of the 1961 United Nations Single Convention on Narcotic Drugs. This conclusion holds even if CBD is extracted from the flowering or fruiting tops of the cannabis plant. Furthermore, according to the current state of scientific knowledge, CBD does not seem to have any psychotropic effect.

[e] THC is specifically designated as a psychotropic substance in accordance with Schedules I and II of the United Nations Convention on Psychotropic Substances, 1971 and therefore is excluded from the EU definition of food. Nonetheless, maximum levels are established in EU contaminants legislation (Commission Regulation EU 2023/915) for THC in hemp seeds, hemp processed

products & hemp seed oil.[35] Furthermore, the European Food Safety Authority (EFSA) in 2015 derived an acute reference dose of 1 µg/kg body weight for Δ^9THC.[36] (NOTE: In Ireland, THC is a controlled drug in accordance with the Misuse of Drugs Act 1977, as amended).

[f] If placed on the market as a food, compliance is required with all relevant aspects of food law (e.g., novel food legislation).

NARCOTIC AND PSYCHOTROPIC SUBSTANCES – CHECKLIST

Before any food supplement is placed on the EU market, the FBO must ensure:

- It does not contain any narcotic or psychotropic substance within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971
- Where maximum levels are established in food contaminant legislation (Commission Regulation EU 2023/915), these must not be exceeded.

NARCOTIC AND PSYCHOTROPIC SUBSTANCES – INFORMATION SOURCES

Relevant information sources include:

- United Nations Single Convention on Narcotic Drugs, 1961
- United Nations Convention on Psychotropic Substances, 1971
- Commission Regulation (EU) No. 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119 5.5.2023, p. 103)
- EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin. EFSA Journal 2015;13(6):4141.
- FSAI 2020 Survey Regulatory Issues with Hemp-based Food and Food Supplements on the Irish Market
- FSAI 2019 Webinar The legal position of cannabis based food products like CBD oils

[35] Maximum levels established for Delta-9-tetrahydrocannabinol (Δ^9-THC) equivalents in hemp seeds, hemp processed products & hemp seed oil. The maximum level refers to the sum of delta-9-tetrahydrocannabinol (Δ^9-THC) and delta-9-tetrahydrocannabinolic acid (Δ^9-THCA), expressed as Δ^9-THC. A factor of 0,877 is applied to the level of Δ^9-THCA and the maximum level refers to the sum of Δ^9-THC + 0,877 × Δ^9-THCA (in case of a separate determination and quantification of Δ^9-THC and Δ^9-THCA).

[36] EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin. EFSA Journal 2015;13(6):4141, 125 pp. doi:10.2903/j.efsa.2015.4141

4.9 Substances Prohibited / Restricted / Under community Scrutiny (Regulation (EC) No. 1925/2006)

The European Commission has established harmonised rules to protect consumers against potential health risks and maintains a list of substances which are known or suspected to have adverse effects on health and the use of which is therefore controlled.

In accordance with the procedures laid down in Article 8 of Regulation (EC) No. 1925/2006, certain substances are prohibited, restricted or placed under community scrutiny if they are considered to represent a potential risk to consumers.

If a harmful effect on health has been identified, the substance and/or the ingredient containing the substance is listed in Part A, B or C of Annex III of the Regulation.

Annex III, Part A of the Regulation lists the substances and/or the ingredient containing the substance that are **prohibited**. To date, these are:

- Aloe-emodin and all preparations in which this substance is present
- Danthron and all preparations in which this substance is present
- Emodin and all preparations in which this substance is present
- Ephedra herb and its preparations originating from *Ephedra* species
- Preparations from the leaf of *Aloe* species containing hydroxyanthracene derivatives
- Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)

Annex III, Part B of the Regulation lists the substances and/or the ingredient containing the substance that are **restricted** (i.e., they are only permitted under certain conditions). To date, these are:

- Green tea extracts containing (-)- epigallocatechin-3-gallate
- Monacolins from red yeast rice
- Trans fat other than trans-fat naturally occurring in fat of animal origin

Annex III, Part C of the Regulation lists the substances and/or the ingredient containing the substance that are placed under **Community scrutiny** (i.e., the possibility of harmful effects on health is identified but scientific uncertainty persists). To date, these are:

- Green tea extracts containing (-)- epigallocatechin-3-gallate
- Monacolins from red yeast rice
- Preparations from the bark of *Rhamnus frangula* L., *Rhamnus purshiana* DC. containing hydroxyanthracene derivatives

- Preparations from the leaf or fruit of *Cassia senna* L. containing hydroxyanthracene derivatives
- Preparations from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids containing hydroxyanthracene derivatives

Once a substance is listed in Annex III, Part C of the Regulation, food businesses or other stakeholders can submit data to the European Commission supporting its safety. Within four years of a substance being listed in Annex III, Part C, a decision will be taken by the European Commission to generally allow the use of the substance or to list it in Annex III, Part A or B, as appropriate. On imperative grounds of urgency, the European Commission can act before the end of this four-year period.

SUBSTANCES PROHIBITED / RESTRICTED /UNDER COMMUNITY SCRUTINY – CHECKLIST

Before any food supplement is placed on the EU market, the FBO must:

- Ensure that it does not contain any prohibited substance (listed in Part A, Annex III, Regulation (EC) No. 1925/2006)
- Ensure that if it contains a restricted substance (listed in Part B, Annex III, Regulation (EC) No. 1925/2006), compliance is achieved with the relevant conditions of use
- Be aware that if it contains a substance under community scrutiny (listed in Part C, Annex III, Regulation (EC) No. 1925/2006), the substance may within four years of being listed in Part C be:
  - moved to Part A of the Regulation
  - moved to Part B of the Regulation
  - permitted for use (i.e., it will not be listed in any part of the Regulation)

  On imperative grounds of urgency, the European Commission can act before the end of this four-year period.

SUBSTANCES PROHIBITED / RESTRICTED /UNDER COMMUNITY SCRUTINY – INFORMATION SOURCES

Relevant information sources include:

- Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals and certain other substances to food (OJ L 404 30.12.2006, p. 26)

4.10 Contaminants

4.10.1 Chemical contaminants

Annex I in Commission Regulation (EU) No. 2023/915 of 25 April 2023 establishes maximum levels for certain contaminants in food. The contaminants for which maximum levels have been set in food supplements are listed in Table 1 (Note: This Regulation also establishes maximum levels for certain contaminants in other foods which could be used as ingredients in food supplements. Other than vegetable oils, these are not listed in this table).

Food businesses must implement appropriate control measures to ensure that their products are compliant with these maximum levels. These considerations should form part of the food businesses food safety management system based on the principles of HACCP. If the maximum level for any contaminant in a food listed in Commission Regulation (EU) No. 2023/915 is exceeded, the food must not be placed on the market. In addition, where such a maximum level for a contaminant in food is exceeded, the implicated food cannot be used as a raw material in other food or as an ingredient in other food. Furthermore, food complying with the maximum levels set out in Commission Regulation (EU) No. 2023/915 must not be mixed with food which exceeds these maximum levels.

Food business operators should also be mindful that:

- Commission Regulation (EU) No. 2023/915 on food contaminants is continually updated as new science and data emerges. As a result of this, food businesses need to monitor changes in this Regulation and ensure appropriate measures are always applied to control contaminants.
- Commission Regulation (EU) No. 2023/915 does not address other chemical substances which are the subject of more specific Union rules (e.g., pesticide residues, residues of veterinary medicines).
- Commission Regulation (EU) No. 2023/915 does not provide an exhaustive list of all maximum limits set for contaminants in food. Maximum limits for certain contaminants can be set in commodity-specific standards (vertical legislation, e.g., food of animal origin, honey, caseins and caseinates).
- Specific purity criteria (e.g., food additives), specifications (e.g., novel foods) and restrictions for undesirable substances (e.g., flavourings and food contact materials) have been set in other legal instruments and may contain maximum limits for contaminants.
- To check the compliance of a food with the maximum levels laid down in the legislation, food must be sampled and analysed in a standardised and reliable way. For this purpose,

sampling and analysis Regulations have been implemented to provide standardised approaches for each substance or substance group.

Food business operators must ensure that they are aware of and comply with all relevant legislation on contaminants which are applicable to the foods under their control.

Further details on food legislation pertaining to food contaminants can be found on the FSAI website.

Table 1: Examples of contaminants relevant to food supplements, as specified in Commission Regulation (EU) No. 2023/915

Contaminant	Food Supplement	Maximum Level
Citrinin	Food supplements based on rice fermented with red yeast *Monascus purpureus*	▪ 100 µg/kg
Pyrrolizidine alkaloids	Food supplements containing botanical preparations including extracts with the exception of pollen-based food supplements	▪ 400 µg/kg
	Pollen-based food supplements	▪ 500 µg/kg
Lead	All food supplements	▪ 3.0 mg/kg
Cadmium	Food supplements other than those listed below	▪ 1.0 mg/kg
	Food supplements consisting at least of 80% from dried seaweed, from products derived from seaweed, or from dried bivalve molluscs	▪ 3.0 mg/kg
Mercury	All food supplements	▪ 0.10 mg/kg
Tin (inorganic)	Canned food except products listed in food categories 3.5.2, 3.5.3, 3.5.4 and 3.5.5 of the Regulation	▪ 200 mg/kg
Polycyclic aromatic hydrocarbons (PAHs)	Vegetable oils used as an ingredient in food supplements: Oils and fats placed on the market for the final consumer or used as	▪ Benzo(a)pyrene: 2 µg/kg ▪ Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene: 10 ug/Kg

	an ingredient in food (except cocoa butter and coconut oil)	
	Food supplements containing botanicals and their preparations (other than those containing vegetable oil)	▪ Benzo(a)pyrene: 10.0 µg/kg ▪ Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene: 50.0 µg/kg
	Food supplements containing propolis, royal jelly, spirulina or their preparations (other than those containing vegetable oil)	
Melamine	Food except products listed in food category 6.2.2 of the Regulation	▪ 2.5 mg/kg

4.10.2 Microbiological Criteria

Microbiological hazards in foodstuffs form a major source of food-borne diseases in humans. Foodstuffs should not contain micro-organisms or their toxins or metabolites in quantities that present an unacceptable risk for human health. To contribute to the protection of public health and to prevent differing interpretations, harmonised microbiological criteria are established in European legislation, i.e., Commission Regulation (EC) No. 2073/2005.

Commission Regulation (EC) No. 2073/2005 lays down microbiological criteria (process hygiene criteria and food safety criteria) for various combinations of foods and microorganisms and the implementing rules to be complied with by food business operators. It requires food business operators to take measures as part of their procedures based on HACCP principles and good hygiene practice to ensure that:

i) the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the **process hygiene criteria** are met and

ii) that the **food safety criteria** applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.

Relevant microbiological criteria for food supplements:

To date, Commission Regulation (EC) No. 2073/2005 does not specifically mention 'food supplements'. However, the Regulation lays down food safety criteria for *Listeria monocytogenes* in three categories of 'ready-to-eat' (RTE) food, i.e.:

- RTE foods for infants & RTE foods for special medical purposes (food category 1.1)
- RTE food that is able to support the growth of L. monocytogenes (food category 1.2)

- RTE food that is unable to support the growth of L. monocytogenes (food category 1.3)

RTE food encompasses food supplements. The correct food category (i.e., 1.2, 1.2 or 1.3) for a given food supplement will depend on its characteristics and intended consumer group. The responsibility for this determination and thus compliance with the relevant criterion for *L. monocytogenes* rests with the FBO.

Sampling and testing of food supplements:
The Regulation does not lay down frequencies for sampling and testing. However, it lays down rules (with some flexibility) relating to:

- the number of samples to be taken from a production batch
- the test method that should be used by the laboratory
- how to interpret the test results
- the action that should be taken in the case of unsatisfactory results
- analysis of trends in test results
- environmental monitoring, etc

Further details on microbiological criteria, can be found on the FSAI website.

4.11 Worked Examples

WORKED EXAMPLE 1: BOTANICALS AS INGREDIENTS OF FOOD SUPPLEMENTS

Scope

This worked example addresses the use of botanicals / botanical derived preparations, as ingredients of food supplements.

Overview

Botanicals / botanical derived preparations made from plants, algae, fungi or lichens, are commonly used as ingredients in food supplements placed on the EU market. Currently there is no specific (i.e., vertical) legislation relating to botanicals / botanical derived preparations, as ingredients of food supplements (or any other food). However, general (i.e., horizontal) legislation applies, including:

- Regulation 178/2002 on General Food Law
- Regulation (EU) 2015/2283 on Novel Foods
- Regulation (EC) No 1829/2003 on Genetically Modified Foods
- Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

Key considerations

The following text box outlines some of the key questions, FBOs need to consider prior to using botanical / botanical derived preparations as ingredients of food supplements.

Other broader considerations also apply (e.g., labelling, nutrition & health claims); however, these are not addressed in this text box. These are addressed in other sections of this document.

TEXT BOX 3: Key questions, FBOs need to consider prior to using botanical / botanical derived preparations as ingredients of food supplements

Key questions INCLUDE:

Is the botanical / botanical derived ingredient a medicinal product?	Yes →	Definition of food specifically excludes medicinal products **(NOTE 1)**
Is the botanical / botanical derived ingredient a narcotic or psychotropic substance?	Yes →	Definition of food specifically excludes narcotic & psychotropic substances **(NOTE 2)**
Is the botanical / botanical derived ingredient prohibited via Regulation (EC) No 1925/2006?	Yes →	Its addition to food or its use in the manufacture of foods is prohibited **(NOTE 3)**
Is the botanical / botanical derived ingredient restricted via Regulation (EC) No 1925/2006?	Yes →	Its addition to food or its use in the manufacture of foods is only allowed under specific conditions of use **(NOTE 3)**
Is the botanical / botanical derived ingredient within the scope of Regulation (EC) No 1829/2003 on GM Food & Feed?	Yes →	Pre-market authorisation required **(NOTE 4)**
Is the botanical / botanical derived ingredient within the scope of Regulation (EU) 2015/2283 on Novel Foods?	Yes →	Pre-market authorisation required **(NOTE 5)**
Is the botanical / botanical derived ingredient safe?	Yes →	Can be used as an ingredient in food supplements **(NOTE 6)**

NOTE 1

The definition of food (Article 2 of Regulation (EC) No 178/2002) specifically excludes medicinal products within the meaning of Directive 2001/83/EC on the Community code relating to medicinal products for human use.[37]

[37] Directive 2001/83/EC lays down numerous definitions including those for medicinal product, herbal medicinal product, traditional herbal medicinal product.

The Health Products Regulatory Authority (HPRA) is the competent authority in Ireland for medicinal products for human use. [38] It regulates the licensing and sale of medicinal products for human use (based on legislative requirements, such products shall not be marketed without prior authorisation or registration). If a FBO has any doubt/concern over the classification of a given product, it can request the opinion of the HPRA via its classification procedure, prior to placing the product on the market. In this way FBOs can obtain an authoritative opinion and avoid the risk of inadvertently breaking the law

For further information on medicinal products, please see Section 4.7 of this document.

NOTE 2

The definition of food (Article 2 of Regulation (EC) No. 178/2002) specifically excludes narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971. Thus, narcotic and psychotropic substances cannot intentionally be used in food (including food supplements). Furthermore, where maximum levels are established in food contaminant legislation (Commission Regulation (EU) No. 2023/915), these must not be exceeded.

For further information on narcotic and psychotropic substances, please see Section 4.8 of this document.

NOTE 3

The European Commission has established harmonised rules to protect consumers against potential health risks and maintains a list of substances which are known or suspected to have adverse effects on health (Regulation (EC) No. 1925/2006). Under the Regulation, such substances are listed as ‘prohibited’, ‘restricted’ or ‘placed under community scrutiny’.

Further information can be found in Section 4.9 of this document.

NOTE 4

Regulation (EC) No. 1829/2003 applies to ‘genetically modified food’ (i.e., food containing, consisting of or produced from GMOs). Under this Regulation, it is not permissible to place on the market a GMO for food use or food containing / consisting of / produced from GMOs unless it is covered by an authorisation granted in accordance with the Regulation and the relevant conditions of the authorisation are satisfied.

[38] It is also the competent authority for medicinal products for veterinary use and for medical devices.

Further information on genetically modified food can be found in Section 4.5 of this document.

NOTE 5

Regulation (EU) No. 2015/2283 applies to 'novel food' (i.e., *any food that was not used for human consumption to a significant degree within the Union before 15 May 1997 and that falls under at least one of the specified categories).* Under this Regulation, it is not permissible to place on the market a novel food unless it is covered by an authorisation granted in accordance with the Regulation and the relevant conditions of the authorisation are satisfied.

Further information on novel food can be found in Section 4.6 of this document.

NOTE 6

Botanicals and botanical derived preparations which require pre-market authorisation, undergo a safety assessment by EFSA based on data submitted by the applicant. Only those which are deemed to be safe are subsequently authorised for placing on the EU market (conditions of use may be specified).

For all other botanicals and botanical derived preparations, the EU does not have a centralised authorisation procedure for their use in food. Nonetheless, the use of botanicals and derived preparations in food must comply with the general requirements of Regulation (EC) No 178/2002. This assigns primary legal responsibility for the safety of the products placed on the market to FBOs. Numerous resources are available to help FBOs assess safety.

EFSA RESOURCES

To help stakeholders assess the safety of botanicals and derived preparations which are intended for use in food supplements, EFSA has published a toolkit. The toolkit is intended for both risk assessors who want to consider the safety of a given botanical ingredient, and food manufacturers who are responsible for ensuring that the products they put on the market are safe. The toolkit is composed of:

- A guidance document identifying the data needed to assess the safety of botanicals and describing a science-based approach for the safety assessment. [39]
- A report with several examples illustrating how to apply the proposed scientific approach. [40]

[39] EFSA Scientific Committee; Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements, on request of EFSA. EFSA Journal 2009; 7(9):1249. [19 pp.]. doi:10.2093/j.efsa.2009.1249.

[40] EFSA Scientific Cooperation (ESCO) Working Group on Botanicals and Botanical Preparations; Advice on the EFSA guidance document for the safety assessment of botanicals and botanical preparations intended for use as food supplements, based on real case studies on request of EFSA. EFSA Journal 2009; 7(9):280. [104pp.]. doi:10.2903/j.efsa.2009.280.

- A Compendium of Botanicals [41] that have been reported to contain substances that may be of health concern when used in food or food supplements. This compendium has been subject to regular updates. See background information (including caveats) on the compendium .

RESOURCES FROM MEMBER STATES

In the absence of harmonised Community rules, several Member States, particularly Belgium, France and Italy, through the BELFRIT project, and other EU countries through their classification system for plants and parts of plants to be used in foods, have developed approaches to regulate or provide advice on the use of botanicals for use in food supplements. This includes implementation of legislation, such as is the case in Belgium, France and Italy, or through non-regulatory reference lists providing guidance. However, it should be noted even in the case of the BELFRIT list (which includes approximately 1,000 botanical substances), the final adoption into legislation differs in the three countries, with differing numbers of substances covered, or additional restrictions on use having been implemented.

It should be noted that the Scientific Committee of the FSAI[42] considers that the BELFRIT list(s) of botanical species is not suitable for potential adoption for regulatory risk management purposes for botanicals on the Irish market, due to a lack in transparency in the risk assessment approaches used. However, the BELFRIT list, together with other Member State's resources, in tandem with the EFSA Guidance Document and Compendium of Botanicals, are useful tools to be included in the risk assessment and management of botanicals in food supplements available on the Irish market.

WORKED EXAMPLE 2: MICRO-ORGANISMS AS INGREDIENTS OF FOOD SUPPLEMENTS

Scope

This worked example addresses placing on the market of microorganisms / microorganism derived ingredients in food supplements.

Overview

Currently, there is no specific (i.e., vertical) legislation relating to the use of microorganisms as ingredients of food supplements. However, general (i.e., horizontal) legislation applies, including:

[41] The EFSA Compendium of Botanicals
[42] FSAI. 2020. Statement of the Scientific Committee of the Food Safety Authority of Ireland. Risk management options related to the use of botanicals in food supplements.

- Regulation 178/2002 on General Food Law
- Regulation (EU) 2015/2283 on Novel Foods
- Regulation (EC) No 1829/2003 on Genetically Modified Foods
- Regulation (EC) No 1333/2008 on food additives
- Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods
- Regulation (EC) No 1332/2008 on food enzymes
- Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

Key considerations

The following text box outlines some of the key questions, FBOs need to consider prior to using microorganisms / microorganism derived ingredients in food supplements.

Other broader considerations also apply (e.g., labelling, nutrition & health claims); however, these are not addressed in this text box. These are addressed in other sections of this document.

TEXT BOX 4: Key questions, FBOs need to consider prior to using microorganisms / microorganism derived ingredients in food supplements

Key questions INCLUDE:

Is the M/O derived ingredient a medicinal product?	Yes →	Definition of food specifically excludes medicinal products **(NOTE 1)**
Is the M/O derived ingredient a narcotic or psychotropic substance?	Yes →	Definition of food specifically excludes narcotic & psychotropic substances **(NOTE 2)**
Is the M/O or M/O derived ingredient within the scope of Regulation (EC) No 1829/2003 on GM Food & Feed?	Yes →	Pre-market authorisation required **(NOTE 3)**
Is the M/O or M/O derived ingredient within the scope of FIA (*) legislation?	Yes →	Pre-market authorisation required **(NOTE 4)**
Is the M/O or M/O derived ingredient within the scope of Regulation (EU) 2015/2283 on Novel Foods?	Yes →	Pre-market authorisation required **(NOTE 5)**
Is the M/O or M/O derived ingredient safe?	Yes →	Can be used as an ingredient in food supplements **(NOTE 6)**

(*) FIA = Food Improvement Agents (Food additives, flavourings & enzymes)

NOTE 1

The definition of food (Article 2 of Regulation (EC) No 178/2002) specifically excludes medicinal products within the meaning of Directive 2001/83/EC on the Community code relating to medicinal products for human use.[43]

The Health Products Regulatory Authority (HPRA) is the competent authority in Ireland for medicinal products for human use. [44] It regulates the licensing and sale of medicinal products for human use (based on legislative requirements, such products shall not be marketed without prior authorisation or registration). If a FBO has any doubt/concern over the classification of a given product, it can request the opinion of the HPRA via its classification procedure, prior to placing the product on the market. In this way FBOs can obtain an authoritative opinion and avoid the risk of inadvertently breaking the law

For further information on medicinal products, please see Section 4.7 of this document.

NOTE 2

The definition of food (Article 2 of Regulation (EC) No 178/2002) specifically excludes narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971. Thus, narcotic and psychotropic substances cannot intentionally be used in food (including food supplements). Furthermore, where maximum levels are established in food contaminant legislation (Commission Regulation EU 2023/915), these must not be exceeded.

For further information on narcotic and psychotropic substances, please see Section 4.8 of this document.

NOTE 3

Regulation (EC) No 1829/2003 applies to ‘genetically modified food’ (i.e., food containing, consisting of or produced from GMOs). Under this Regulation, it is not permissible to place on the market a GMO for food use or food containing / consisting of / produced from GMOs unless it is covered by an authorisation granted in accordance with the Regulation and the relevant conditions of the authorisation are satisfied.

Further information on genetically modified food can be found in Section 4.5 of this document.

---

[43] Directive 2001/83/EC lays down numerous definitions including those for medicinal product, herbal medicinal product, traditional herbal medicinal product.
[44] It is also the competent authority for medicinal products for veterinary use and for medical devices.

NOTE: Where the genetically modified food is also a food improvement agent (food additive or food flavouring or food enzyme) authorisation is required for both

NOTE 4

Food improvement agents encompass food additives, food flavourings and food enzymes. It is not permissible to place on the market a food additive or food flavouring unless it is covered by an authorisation granted in accordance Regulation (EC) No 1331/2008 and the relevant conditions of the authorisation are satisfied. Regarding food enzymes, there is currently no Union list of authorised food enzymes[45]; however, Regulation (EC) No 1332/2008 lays down provisions for its establishment. As soon as the Union list of food enzymes is applicable, only food enzymes on that Union List will be allowed on the EU market. In the meantime, without prejudice to other applicable Union legislation, including Regulation (EC) No 178/2002, national provisions in force concerning the placing on the market and use of food enzymes and food produced with food enzymes continue to apply. In those Member States (including Ireland) where national rules do not exist, food enzymes can continue to be used until the Union List is established only if they are on the "Register".

Further information on food improvement agents can be found in Section 4.3 of this document.

NOTE: Where the food improvement agent (food additive or food flavouring or food enzyme) is also a genetically modified food, authorisation is required for both.

NOTE 6

Microorganisms / microorganism derived ingredients which require pre-market authorisation, undergo a safety assessment by EFSA based on data submitted by the applicant. Only those which are deemed to be safe are subsequently authorised for placing on the EU market (conditions of use may be specified). For all other microorganisms / microorganism derived ingredients, the EU does not have a centralised authorisation procedure for their use in food. Nonetheless, they must comply with the general requirements of Regulation (EC) No 178/2002. This assigns primary legal responsibility for the safety of the products placed on the market to FBOs.

Please note that the FSAI Scientific Committee is due to publish a report on the "Assessment of the safety of "probiotics" in food supplements". It will recommend safety criteria and the type of evidence required to demonstrate safety.

[45] As of November 2023

5. Technologies

When considering the technology / process used to manufacture a food supplement / ingredient, consideration should include the legislation pertaining to food irradiation and novel foods.

5.1 Irradiation

Food irradiation is the treatment of foodstuffs by a certain type of radiant energy known as ionising radiation.

Foods can only be irradiated if there is a reasonable technological need, it presents no health hazard and is carried out under the conditions proposed, it is of benefit to the consumer and it is not used as a substitute for hygiene and health practices or for good manufacturing or agricultural practice. Food irradiation may be used only for certain purposes, i.e., to reduce the incidence of food-borne disease by destroying pathogenic organisms, to reduce spoilage of foodstuffs by retarding or arresting decay processes and destroying spoilage organisms, to reduce loss of foodstuffs by premature ripening, germination or sprouting and to rid foodstuffs of organisms harmful to plant or plant products

A food supplement containing an irradiated ingredient can only be placed on the EU market, if it complies with all relevant rules. Key points include:

- EU rules regarding the manufacture, marketing and importation of foods and food ingredients are laid down in Directive 1999/2/EC.
- Only certain foods and ingredients are permitted to be treated with ionising radiation. These are listed in Directive 1999/3/EC (this Directive currently lists one category of food: dried aromatic herbs, spices and vegetable seasonings).
- Food and food ingredients may only be irradiated in EU-approved irradiation facilities.
    - The list of approved facilities in the EU is published by the Commission in the Official Journal of the European Union. [46]
    - List of approved facilities in third countries is published in the Annex of Commission Decision 2002/840/EC. Rules surrounding the importation of a foodstuff treated with ionising irradiation in a third country are laid down in Article 9 of Directive 1999/2/EC.

[46] List of approved facilities for the treatment of foods and food ingredients with ionising radiation in the Member States (OJ 37/6, 30/01/2019)

- Under Article 6 of Directive 1999/2/EC, any irradiated food or any irradiated food ingredient of a compound food must be labelled with the words: 'irradiated' or 'treated with ionising radiation'

5.2 Novel Technologies

The food supplement sector is continually evolving, and new technologies are continually emerging. Examples of emerging technologies include those focusing on optimisation of production/processing of ingredients and optimisation of delivery mechanisms (e.g., to improve bioavailability of ingredients).

Within the EU, foods produced via new technologies or processes could potentially fall within the scope of the novel foods regulation (Regulation (EU) No. 2015/2283). Within the EU, a 'novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of ten categories. Three of these categories deal specifically with foods from new 'technologies/production processes', i.e.,

Category specified in Regulation 2015/2283	Detail
(vii)	Food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances
(viii)	Food consisting of engineered nanomaterials
(ix)	Vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where: ▪ a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in category (vii) or ▪ they contain or consist of engineered nanomaterials

A food supplement / ingredient produced by a new technology or process that alters its composition, nutritional value, metabolism or level of undesirable substances may fall within the

scope of the Novel Foods Regulation. It is important to note that it is the food/ingredient produced by the new technology or process which must be authorised, rather than the technology or process itself. For example, the exposure of mushrooms to UV light causes the production of vitamin D2 within the mushroom tissues and therefore this nutritional change brings the mushroom within the scope of the novel food Regulation.

TECHNOLOGIES – CHECKLIST

Before any food supplement is placed on the EU market, the FBO must ensure that:

- If the food supplement or any of its ingredients fall within the scope of the novel food regulation on account of the technology/process used to produce it, that food supplement/ingredient must be authorised for use and included on the Union List of Novel Foods and all conditions of use must be complied with.

TECHNOLOGIES – INFORMATION SOURCES

Relevant information sources include:

- Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation (OJ L 066 13.3.1999, p. 16)
- Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation *(*OJ L 66, 13.3.1999, p. 24)
- Commission Decision 2002/840/EC. Commission Decision of 23 October 2002 adopting the list of approved facilities in third countries for the irradiation of foods (notified under document number C(2002) 3994) (OJ L 287 25.10.2002, p. 40)
- Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods (OJ L 327 11.12.2015, p. 1)

6. Labelling and food information

6.1 General introduction

Labelling and food information requirements are specified in a myriad of legislation including:

- **Regulation (EU) No. 1169/2011 on Food Information to Consumers**
  - This Regulation establishes the general requirements and responsibilities governing food information, and in particular food labelling. The Regulation applies to food

business operators at all stages of the food chain, where their activities concern the provision of food information to consumers. It applies to all foods intended for the final consumer, including food supplements.
    - 'Food information' is defined in this Regulation and means information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication.
- **Directive 2002/46 EC on Food Supplements**
    - This Directive lays down additional labelling requirements that are only applicable to food supplements.
- **Other legislative requirements**
    - Other legislative requirements may be applicable depending on the type of ingredients or the type of production/manufacturing method.

Further information is provided in the following sections.

6.2 General requirements

The general requirements regarding the provision of food information to consumers are outlined in Article 7 of Regulation (EU) No. 1169/2011. The key points are as follows:

- Food information shall not be misleading, particularly:
    - As to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production
    - By attributing to the food effects or properties which it does not possess
    - By suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients
    - By suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient.
- Food information shall be accurate, clear and easy to understand for the consumer.

- Food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties.[47]

In addition to the above general requirements, the label of a food supplement shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general (Ref: Article 7 of Directive 2002/46/EC).

6.3 General responsibilities of food business operators

General responsibilities regarding the provision of food information to consumers are outlined in Article 8 of Regulation (EU) No. 1169/2011. Responsibilities are placed on all food business operators in the supply chain. The key requirements can be summarised as follows:

- The food business operator responsible for the food information is the operator under whose name or business name the food is marketed or, if that operator is not established in the Union, the importer into the Union market.
- The food business operator responsible for the food information shall ensure the presence and accuracy of the food information in accordance with the applicable food information law and requirements of relevant national provisions.
- Food business operators which do not affect food information shall not supply food which they know or presume, based on the information in their possession as professionals, to be non-compliant with the applicable food information law and requirements of relevant national provisions.
- Food business operators, within the businesses under their control, shall not modify the information accompanying a food if such modification would mislead the final consumer or otherwise reduce the level of consumer protection and the possibilities for the final consumer to make informed choices. Food business operators are responsible for any changes they make to food information accompanying a food.

6.4 Mandatory information: food labels

6.4.1 Requirements of Regulation (EU) NO 1169/2011

According to Regulation (EU) No 1169/2011, the following mandatory information must appear on the label of all prepacked foods, including food supplements:

[47] This requirement is also specified in Article 6.2 of Directive 2002/46/EC

- The name of the food* (**see Note 1**)
- The list of ingredients (**see Note 2**)
- Any allergenic ingredient or processing aid used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form (**see Text Box 5**)
- The quantity of certain ingredients or categories of ingredients (**see Note 3**)
- The net quantity of the food* (**see Note 4**)
- The date of minimum durability or the 'use by' date (**see Note 5**)
- Any special storage conditions and/or conditions of use (**see Note 6**)
- The name or business name and address of the food business operator referred to in Article 8(1) of Regulation (EU) No. 1169/2011
- The country of origin or place of provenance where its absence may mislead the consumer as to the true origin or provenance of the food or where country of origin is specifically required under legislation (**see Note 7**)
- Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions with respect to beverages containing more than 1.2 % by volume of alcohol, the actual alcoholic strength by volume* (**see Note 8**)
- A nutrition declaration (**see Note 9**)

**This information must appear in the same field of vision*

NOTE 1	The **name of the food** must be 'food supplement'
NOTE 2	Specific rules are established in Parts A – E, Annex VII, Regulation (EU) No. 1169/2011 regarding the **indication and designation of ingredients**. ▪ PART A: Specific provisions concerning the indication of ingredients by descending order of weight ▪ PART B: Designation of certain ingredients by the name of a category rather than a specific name ▪ PART C: Designation of certain ingredients by the name of their category followed by their specific name or e number ▪ PART D: Designation of flavourings in the list of ingredients ▪ PART E: Designation of compound ingredients Text Box 6, provides further rules on the labelling of food improvement agents.

NOTE 3	Specific rules are established in Annex VIII, Regulation (EU) No 1169/2011 regarding the **quantitative indication of ingredients**.
NOTE 4	Specific rules are established in Annex IX, Regulation (EU) No 1169/2011 regarding the **net quantity declaration**. The net quantity declaration shall not be mandatory in the case of foods: a) which are subject to considerable losses in their volume or mass and which are sold by number or weighed in the presence of the purchaser; b) the net quantity of which is less than 5 g or 5 ml; however, this provision shall not apply to spices and herbs; or c) normally sold by number, provided that the number of items can clearly be seen and easily counted from the outside or, if not, is indicated on the labelling. The latter would apply to food supplements sold as capsules, tablets, etc (once the number of items is indicated on the label).
NOTE 5	The date of **minimum durability**, **or 'best before' date**, is the date until which a foodstuff retains its specific properties e.g., taste, aroma, appearance, any specific qualities which relate to the product, vitamin content etc when the product has been stored appropriately and the package unopened. In the case of foods, which from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability must be replaced by the **'use by' date**. Specific requirements regarding the presentation of the date of minimum durability are laid down in Annex X, Regulation (EU) No 1169/2011.
NOTE 6	Specific rules are established in Article 6, Regulation (EU) No 1169/2011 regarding **storage conditions**. In cases where foods require special storage conditions and/or conditions of use, those conditions shall be indicated. To enable appropriate storage or use of the food after opening the package, the storage conditions and/or time limit for consumption shall be indicated, where appropriate.
NOTE 7	Specific rules regarding designation of **country of origin** are established in Article 26 of Regulation (EU) No 1169/2011. The objective of these requirements is to inform consumers of the origin of certain ingredients

	from agricultural origin and to avoid consumers being misled in case the origin of the product is different from the origin of the primary ingredient of the product.
NOTE 8	The FSAI recommends that the **alcohol content** of solid foods is also declared if it contains more than 1.2% by weight of alcohol. These labelling requirements apply to all beverages and foods. They may be applicable to food supplements if residues of ethanol (an authorised extraction solvent) are unintentional, but technically unavoidable (further details are provided in Section 4.4).
NOTE 9	The rules on the **nutrition declaration** in Regulation (EU) No 1169/2011 do not apply to food supplements. Article 8 and 9 of Directive 2002/46/EC lays down specific requirements regarding the declaration of the nutrients or substances with a nutritional or physiological effect present in a food supplement (further details are provided in Section 6.6.1).

TEXT BOX 5:

SUBSTANCES OR PRODUCT CAUSING ALLERGIES OR INTOLERANCES

1. Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof, except:

    (a) wheat-based glucose syrups including dextrose

    (b) wheat-based maltodextrins

    (c) glucose syrups based on barley

    (d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin

2. Crustaceans and products thereof

3. Eggs and products thereof

4. Fish and products thereof, except:

    (a) fish gelatine used as carrier for vitamin or carotenoid preparations

    (b) fish gelatine or Isinglass used as fining agent in beer and wine

5. Peanuts and products thereof

6. Soybeans and products thereof, except:

(a) fully refined soybean oil and fat

(b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources

(c) vegetable oils derived phytosterols and phytosterol esters from soybean sources

(d) plant stanol ester produced from vegetable oil sterols from soybean sources

7. Milk and products thereof (including lactose), except:

(a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin

(b) lactitol

8. Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoinensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin

9. Celery and products thereof

10. Mustard and products thereof

11. Sesame seeds and products thereof

12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO_2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers

13. Lupin and products thereof

14. Molluscs and products thereof.

TEXT BOX 6:

DESIGNATION OF FOOD IMPROVEMENT AGENTS ON THE INGREDIENTS LIST

FOOD ADDITIVES & FOOD ENZYMES

Food additives & food enzymes belonging to one of the categories listed in Part C, Annex VII, Regulation (EU) No 1169/2011, must be designated in the ingredients list by:

- The name of that category, followed by their specific name (*) or, if appropriate, E number (Example: Antioxidant: Ascorbic Acid or Antioxidant: E300)
- If an ingredient belongs to > 1 category, the category appropriate to the principal function in the case of the food in question shall be indicated

The above requirements do not apply to food additives & food enzymes:

- Whose presence in the food supplements is solely because they were contained in one or more ingredients of that food supplement, in accordance with the carry-over principle (provided they serve no technological function in the final product)
- Used as processing aids

(*) According to Part A, Annex II of Regulation (EC) No 1333/2008:

- "Specific name" refers to the name used for the additive in Part A, Annex II of Regulation (EC) No 1333/2008'
- Alternatively, other specific names in Regulation (EU) No 231/2012 may be used, excluding synonyms

FOOD FLAVOURINGS

Food flavourings must be designated in the ingredients list by:

- The generic term 'flavouring(s)'
- A more specific name or description of the flavouring is permitted if the flavouring component meets one of the definitions laid down in Article 3(2) (points b-h) of Regulation (EC) No 1334/2008

The following specific rules apply to food flavourings:

- Quinine and/or caffeine used as a flavouring must be mentioned by name in the list of ingredients immediately after the term 'flavouring(s)'
- The term 'natural' for the description of flavourings must be used in accordance with Article 16 of Regulation (EC) No 1334/2008
- 'Smoke flavourings' specific rules apply for labelling; however, 'smoke flavourings' are not authorised for use in food supplements

6.4.2 Additional requirements of Directive 2002/46/EC

According to Directive 2002/46/EC, the following mandatory information must also appear on the label of food supplements:

- The names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances
- The portion of the product recommended for daily consumption
- A warning not to exceed the stated recommended daily dose
- A statement to the effect that food supplements should not be used as a substitute for a varied diet
- A statement to the effect that the products should be stored out of the reach of young children.

In addition, the label of a food supplement must not contain:

- Any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

6.4.3 Availability, placement and presentation of mandatory food information

Requirements regarding the availability, placement and presentation of mandatory information are laid down in Article 12 and 13 of Regulation (EU) No. 1169/2011. In the case of prepacked foods, mandatory food information must:

- Appear directly on the package or on a label attached to the packaging
- Be in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible
- Not be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material

Voluntary information must not be displayed to the detriment of the space available for mandatory food information.

6.4.4 Minimum font size

Requirements regarding the availability, placement and presentation of mandatory information are laid down in Article 13 of Regulation (EU) No. 1169/2011. Mandatory information must be displayed with a font size where the x-height (as defined in Annex IV) is equal to or greater than 1.2 mm. For packaging or containers with a surface area of less than 80cm^2 the x-height must be equal to or greater than 0.9 mm.

6.5 Mandatory information: distance selling

In the case of prepacked foods offered for sale by means of distance communication:

- Mandatory food information, except the date of minimum durability / use-by date, must be available before the purchase is concluded and must appear on the material supporting the distance selling or be provided through other appropriate means clearly identified by the food business operator. When other appropriate means are used, the mandatory food information shall be provided without the food business operator charging consumers supplementary costs
- All mandatory particulars shall be available at the point of delivery.

6.6 Nutrition information and label tolerances

6.6.1 Nutrition information

The rules on the nutrition information for food supplements are laid down in Article 8 of Directive 2002/46/EC, i.e.:

- The amount of the nutrient(s) or substance(s) with a nutritional or physiological effect present in the food supplements must be declared on the label in numerical form (the units specified in Annex I of Directive 2002/46/EC must be used)
- The amounts of the nutrient(s) or other substance(s) declared shall be those per portion of the product as recommended for daily consumption on the labelling
    - Information on vitamins and minerals shall also be expressed as a percentage of the daily Reference Intakes or 'nutrient reference values (NRVs)' which are expressed in Annex XIII, Part A of Regulation (EU) No. 1169/2011.

6.6.2 Label tolerances for nutrition labelling

Tolerances for nutrition labelling purposes are important as it is not possible for foods to always contain the exact nutrient levels labelled, due to natural variations and variations from production and during storage. However, the nutrient content of foods should not deviate substantially from labelled values to the extent that such deviations could lead to consumers being misled.

Tolerances for vitamins and minerals in food supplements which are laid down in an EC Guidance Document[48] are summarised below:

Nutrient	Tolerances for supplements*	
	Upper tolerance	Lower tolerance
Vitamins	+50%	-20%
Minerals	+45%	-20%

Example:

A food supplement with a nutrition declaration of folic acid of 125 µg per unit and no claim made about its folic acid content

- Apply rounding to nutrient declaration:
  - This equals to 124.5 to 125.4 µg folic acid per unit
- Apply lower label tolerance to lower value:
  - 99.6 µg per unit (i.e., 124.5ug/unit – 20%)
- Apply upper label tolerance:
  - 188.1 µg per unit (i.e., 125.4 ug/unit + 50%)
- Apply rounding to upper and lower tolerance:
  - 99.6ug – 188 ug per unit

6.7 Other Labelling Requirements

Labelling requirements specified in other pieces of legislation also apply to food supplements, for example:

Other labelling requirements relating to food ingredients[49]

Type of Food	Particulars

[48] GUIDANCE DOCUMENT FOR COMPETENT AUTHORITIES FOR THE CONTROL OF COMPLIANCE WITH EU LEGISLATION ON: Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 and Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling of foodstuffs and 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 with regard to the setting of tolerances for nutrient values declared on a label

[49] Requirement of Annex III, Regulation (EU) No 1169/2011

Foods containing a sweetener or sweeteners authorised pursuant to Regulation (EC) No 1333/2008	▪ 'with sweetener(s)' this statement shall accompany the name of the food
Foods containing both an added sugar or sugars and a sweetener or sweeteners authorised pursuant to Regulation (EC) No 1333/2008	▪ 'with sugar(s) and sweetener(s)' this statement shall accompany the name of the food
Foods containing aspartame/aspartame-acesulfame salt authorised pursuant to Regulation EC) No 1333/2008	▪ 'contains aspartame (a source of phenylalanine)' shall appear on the label in cases where aspartame/aspartame-acesulfame salt is designated in the list of ingredients only by reference to the E number ▪ 'contains a source of phenylalanine' shall appear on the label in cases where aspartame/aspartame-acesulfame salt is designated in the list of ingredients by its specific name
Foods containing more than 10 % added polyols authorised pursuant to Regulation (EC) No 1333/2008	▪ 'excessive consumption may produce laxative effects'
Foods other than beverages, where caffeine is added with a physiological purpose	▪ 'Contains caffeine. Not recommended for children or pregnant women' in the same field of vision as the name of the food, followed by a reference in brackets and in accordance with Article 13(1) of this Regulation to the caffeine content expressed in mg per 100 g/ml ▪ In the case of food supplements, the caffeine content shall be expressed per portion as

	recommended for daily consumption on the labelling
Foods or food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters	▪ 'with added plant sterols' or 'with added plant stanols' in the same field of vision as the name of the food ▪ the amount of added phytosterols, phytosterol esters, phytostanols or phytostanol esters content (expressed in % or as g of free plant sterols/plant stanols per 100 g or 100 ml of the food) shall be stated in the list of ingredients ▪ a statement that the product is not intended for people who do not need to control their blood cholesterol level ▪ a statement that patients on cholesterol lowering medication should only consume the product under medical supervision ▪ an easily visible statement that the food may not be nutritionally appropriate for pregnant or breastfeeding women and children under the age of 5 years ▪ advice that the food is to be used as part of a balanced and varied diet, including regular consumption of fruit and vegetables to help maintain carotenoid levels ▪ in the same field of vision as the statement required under point (3) above, a statement that the consumption of more than 3 g/day of added plant sterols/plant stanols should be avoided ▪ a definition of a portion of the food or food ingredient concerned (preferably in g or ml) with the amount of the plant sterol/plant stanol that each portion contains

Labelling requirements relating to Gluten[50]

Voluntary information	Particulars

[50] Requirements of Commission Implementing Regulation (EU) No 828/2014

Information on the absence or low-level presence of gluten	▪ 'gluten-free' declaration is voluntary and can only be used where the food as sold to the final consumer (either prepacked or non-prepacked) contains no more than 20 mg/kg of gluten ▪ The use of the statement 'very low gluten' is voluntary and can only be used where the food, consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties, which have been specially processed to reduce the gluten content, contains no more than 100 mg/kg of gluten in the food as sold to the consumer

Labelling requirements relating to production / manufacturing method

Production/manufacturing method	Particulars
Genetic modification[51]	▪ Labelling requirements apply to foods delivered to the final consumer which: i) contain or consist of GMOs; or ii) are produced from or contain ingredients produced from GMOs. For specific details refer to Articles 12-14 of Regulation (EU) No 1829/2003 •
Irradiation[52]	▪ Foods treated with ionising radiation shall bear one of the following indications: 'irradiated' or 'treated with ionising radiation', and other indications as per requirements of Regulation (EU) No 1169/2011 and Directive 1999/2/EC
Organic production[53]	▪ Food may only be labelled as 'organic' once it has been certified as organic by one of the certification and inspection bodies designated by the Department of Agriculture, Food and the Marine (DAFM). For further details refer to Article 30-33 of Regulation (EU) 2018/848

[51] Requirement of Regulation (EC) No 1829/2003
[52] Requirements of Regulation 1169/2011 and Directive 1999/2/EC
[53] Requirement of Regulation (EU) 2018/848

Labelling requirements relating to Authorised Novel Foods

Specific labelling requirements may be specified in the Union List for an authorised novel food. These labelling requirements must be met if the food is placed on the market.

LABELLING & FOOD INFORMATION – CHECKLIST

FBOs must ensure compliance with relevant provisions relating to food labelling and food information. These include:

- Compliance with the general requirements of Regulation (EU) No 1169/2011 and Directive 2002/46/EC
- Compliance with mandatory requirements of Regulation (EU) No 1169/2011 and Directive 2002/46/EC
- Compliance with requirements for nutrition information and label tolerances as required by Directive 2002/46/EC
- Compliance with all other labelling requirements, as required by EU legislation

LABELLING & FOOD INFORMATION – INFORMATION SOURCES

Relevant information sources include:

- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304 22.11.2011, p. 18)
- 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 (OJ L 183 12.7.2002, p. 51)
- European Commission Guidance Documents on Food Information to Consumers
- FSAI website
- FSAI Webinar: Food Labelling an Introduction
- FSAI Webinar: Food Labelling What Food Businesses Need to Know
- FSAI Webinar: Food Allergen Declaration

7. Nutrition and health claims

7.1 General introduction to nutrition and health claims

A '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 (Article 2, Regulation (EC) No. 1924/2006).

In the EU, only authorised[54] nutrition and health claims can be used in food information.

- **Authorised nutrition and health claims**, along with their conditions of use, are published in European legislation. In addition, they are published in the EU Register of Nutrition and Health Claims. This Register also lists rejected health claims and reasons for their rejection. [55] This EU Register of Nutrition and Health claims is available to the public and this ensures full transparency on authorised/rejected claims.

- **Food information** means any information concerning a food and made available to the final consumer by means of a label, accompanying material, or any other means including modern technology tools or verbal communication.

Thus, for food supplements, only authorised nutrition and health claims can be conveyed to the final consumer via food label, websites, social media, webinars, or any other means of communication. This includes trademarks and brand names.

[54] The authorisation procedure is detailed in legislation and involves submission of a detailed dossier by the applicant to the competent authority of a member state, assessment of the dossier by the EFSA and based on this, a decision by the European Commission to authorise/reject the application (this decision of the European Commission is published in European legislation and if authorised, includes details regarding the 'conditions of use').

[55] A number of submitted health claims do not appear in this EU Register:

- Health claims submitted as Article 13(1) 'function claims' but that do not qualify as such
- Health claims not related to human health which cannot consequently be used on foods
- Health claims for combination of substances where health claims are already submitted for some of the individual substances
- Some 'function claims' for which the assessment by EFSA or the consideration by the Commission is not finalised). These include health claims:
  - Referring to botanical substances
  - Under further consideration by the Commission and EU countries
- Some health claims subject to the individual authorisation procedure pending a decision

7.2 Nutrition claims

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

- the energy (calorific value) it
  - provides
  - provides at a reduced or increased rate; or
  - does not provide; and/or
- the nutrients or other substances it
  - contains
  - contains in reduced or increased proportions; or
  - does not contain

Authorised nutrition claims are listed in the Annex of Regulation (EC) No 1924/2006 and in the EU Register of Nutrition and Health Claims. Conditions of use are specified for each authorised nutrition claim and compliance with these conditions is mandatory. Three examples of permitted nutrition claims and their conditions of use are provided below:

Example of permitted nutrition claim	Conditions of use
Source of [name of vitamin/s] and/or [name of mineral/s]	A claim that a food is a source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a **significant amount** as defined in the Annex to Directive 90/496/EEC 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.
High [name of vitamin/s] and/or [name of mineral/s]	A claim that a food is high in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of 'source of [NAME OF VITAMIN/S] and/or [NAME OF MINERAL/S]'.

Contains [name of the nutrient or other substance]	A claim that a food contains a nutrient or another substance, for which specific conditions are not laid down in this Regulation, or any claim likely to have the same meaning for the consumer, 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.

7.2.1 Significant amount

- Significant amount is defined in Annex XIII (Part A, Point 2) of the Regulation on Food Information to Consumers (Regulation (EU) No 1169/2011):

- '*As a rule, the following values should be taken into consideration in deciding what constitutes a significant amount:*
  - *15% of the NRVs supplied by 100g or 100ml in the case of solids and liquids other than beverages*
  - *7.5% of the NRVs supplied by 100ml in the case of beverages, or*
  - *15% of the NRVs per portion if the package contains only a single portion for solids, liquids and beverages'*

NOTE: *NRVs (Nutrient Reference Values) are listed in Annex XIII (Part A, Point 1), Regulation (EU) No 1169/2011*

Further details regarding 'significant amount' and nutrition/health claims are provided in Recital 14 and Article 5.1 of Regulation (EC) No. 1924/2006:

- Recital 14 states: "*In order to ensure that the claims made are truthful, it is necessary that the substance that is the subject of the claim is present in the final product in quantities that are sufficient, or that the substance is absent or present in suitably reduced quantities, to produce the nutritional or physiological effect claimed. The substance should also be available to be used by the body.* ***In addition, and where appropriate, a significant amount of the substance producing the claimed nutritional or physiological effect should be provided by a quantity of the food that can reasonably be expected to be consumed****."*
- Article 5.1 states that the use of nutrition and health claims shall only be permitted if certain conditions are fulfilled. These conditions are detailed in points a-e of Article 5.1.

Based on the above:

- The 'significant amount' applicable to food supplements is 15% of the NRV
- For foods supplements it is more appropriate to consider the significant amount per portion of the product as recommended for daily consumption rather than per 100 g/100 ml (The quantity of a food supplement ingested per day is typically a few grams/mls. Determination of the significant amount using the '100g/100ml' rule only, would mean non-conformity with objective of Recital 14 and the requirements of Article 5.1)

WORKED EXAMPLE:

Scenario:

A food supplement (capsule form) makes the claim 'high calcium'. The recommended daily intake specified on the label of the food supplement is two capsules per day.

Calculation:

To make a claim 'High calcium', the daily intake of calcium in the food supplement must be at least twice the significant amount for calcium, i.e., two capsules must provide 30% of the NRV per day.

- The NRV for calcium = 800mg
- Thus, 30% of the NRV = 240mg
- Therefore, to make the claim 'high calcium' two capsules must provide at least 240mg of calcium per day

7.2.2 Comparative nutrition claims

Rules are established under Article 9 of Regulation (EC) 1924/2006 for the use of comparative nutrition claims. These claims compare the composition of the food in question with a range of foods of the same category, which do not have a composition which allows them to bear a claim, including foods of other brands. As comparative claims are only permitted for foods which do not regularly have a composition which allows them to bear a claim, they are not permitted for food supplements.

7.3 Health claims

A '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 (Article 2, Regulation 1924/2006). Types and examples of health claims are provided below:

Type of Health Claim	Example
1. Function Health Claims[56]	
a. Claims relating to the growth, development and functions of the body	*Calcium contributes to the normal function of digestive enzymes*
b. Claims referring to psychological and behavioural functions	
c. Claims on slimming or weight-control	
2. Disease Risk Reduction Claims[57]	*Supplemental folic acid intake increases maternal folate status. Low maternal folate status is a risk factor in the development of neural tube defects in the developing foetus.*
3. Claims referring to children's development[58] and health	*Iodine contributes to the normal growth of children*

Reference to general, non-specific benefits of the nutrient[59] or food for overall good health or health-related well-being may only be made if accompanied by a permitted specific health claim.

7.3.1 Mandatory requirements for the use of health claims

Health claims are only be permitted if the following information is included in the labelling:

- 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

[56] Article 13, Regulation (EC) No 1924/2006
[57] Article 14.1.a, Regulation (EC) No 1924/2006: '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
[58] Article 14.1.b, Regulation (EC) No 1924/2006
[59] Article 1.2.2, Regulation (EC) No 1924/2006: 'Nutrient' means 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

- An appropriate warning for products that are likely to present a health risk if consumed to excess
- Other statements that are mandatory according to the conditions of the specific claim

The following are not permitted:

- Recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities
- Claims which suggest that health could be affected by not consuming the food
- Claims which refer to the rate or amount of weight loss

7.3.2 Health claims relating to botanicals, probiotics and prebiotics

Health claims relating to Botanicals

Since 2012, the European Commission established an “on-hold” list of more than 2000 health claims relating to plant substances. These claims are awaiting assessment by the EFSA and a decision by the European Commission on whether to authorise or reject them. These claims are not listed on the EFSA register; however, further details can be found here.

On-hold health claims are permitted for use under transitional measures set out in article 28(5) of Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods. This means the claim can be used until the European Commission reaches a decision regarding the claim’s authorisation status. On-hold health claims must comply with the general principles and conditions of Regulation (EC) No. 1924/2006 which are outlined in the legislation preamble, Article 3 and 5.

Health claims relating to Probiotics

The term ‘probiotic’ refers to live microbes which may provide a health benefit in humans when consumed.

Applications for health claims on probiotics have been submitted to EFSA for assessment; however, to date, no application has received a positive opinion. Therefore, the European Commission has not authorised any health claim for probiotics. The probiotic claims which have been fully evaluated and rejected, are listed as non-authorised on the EU register for health claims.

Thus, FBOs should be aware that:

- The term ‘probiotic’ is considered a health claim and therefore is not permitted

- Any term which implies probiotic activity (i.e., implies that the microbes in the product may be beneficial for health) is also considered a health claim and therefore is not permitted.

Health claims relating to Prebiotics

'Prebiotic' is a term used to describe a food component that may provide a health benefit when eaten because of changes it may bring about to the gut bacterial flora.

Applications for health claims on probiotics have been submitted for evaluation to EFSA and to date, no application has received a positive opinion. Therefore, the European Commission has not authorised any health claim for prebiotics. The prebiotic claims which have been fully evaluated and rejected, are listed as non-authorised on the EU register for health claims.

Thus, FBOs should be aware that:

- The term 'prebiotic' is considered a health claim and therefore is not permitted
- Any term which implies prebiotic activity (i.e., implies that the product contains a substance that may be beneficial for health) is also considered a health claim and therefore is not permitted.

7.4 General principles and conditions for use of all nutrition and health claims

The general principles and conditions for use of nutrition and health claims are laid down in Articles 3 and 5 of Regulation (EC) No. 1924/2006.

The use of nutrition and health claims shall not:

- Be false, ambiguous or misleading
- Give rise to doubt about the safety and/or the 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

The use of nutrition and health claims are only permitted if the following conditions are fulfilled:

- The nutrient or other substance for which the claim is made, is contained in the final product at the appropriate level to produce the nutritional or physiological effect claimed[60]
- The quantity of the product that can reasonably be expected to be consumed, provides the correct quantity of the nutrient or other substance that will produce the nutritional or physiological effect claimed
- The nutrient or other substance for which the claim is made, is in a form that is available for use by the body
- The claim refers to the food ready for consumption in accordance with the manufacturer's instructions
- Nutrition labelling is provided on all products carrying a nutrition and/or health claim[61]

In addition, the FBO making an authorised claim must be able to justify its use, and if requested by the FSAI, provide all data and information supporting compliance.

7.5 Medicinal claims

A medicinal claim is a claim that a product or its constituent(s) can be used with a view to make a medical diagnosis or can treat or prevent disease, including an injury, ailment or adverse condition, whether of body or mind. Examples of terminology include ‘treats seizures’, ‘cures cancer’, ‘lowers anxiety’, ‘anti-inflammatory’.

Under EU legislation, medicinal properties/claims cannot be attributed to foods, i.e.,:

- Regulation (EU) No. 1169/2011 on the provision of food information to consumers[62]
- Regulation (EC) No.178/2002 on General Food Law[63]
- Directive 2002/46/EC on Food Supplements[64]

[60] The nutrient or other substance should be contained in the final product in a significant quantity as defined in Community legislation or where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence. If the claim is related to a reduced quantity of the nutrient or other substance, this should be established by generally accepted scientific evidence

[61] In the case of food supplements, the nutrition information shall be provided in accordance with Article 8 of Directive 2002/46/EC

[62] Recital 20, Regulation (EU) No 1169/2001 states ‘Food information law should prohibit the use of information that would mislead the consumer in particular as to the characteristics of the food, food effects or properties, or attribute medicinal properties to foods. To be effective, that prohibition should also apply to the advertising and presentation of foods’

[63] Article 2, Regulation (EC) No 178/2002 defines food. This definition states that food does not include medicinal products. Medicinal products are defined in Directive 2001/83/EC on the Community code relating to medicinal products for human use. This definition is based on two characteristics, i.e., the claims associated with the product and the composition of the product

[64] Article 6.2 states ‘The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties’.

Any product linked to a medicinal claim (i.e., verbally, on the label of a food or on associated marketing material such as websites, social media, leaflets, etc) may be a medicinal product. In Ireland, the Health Protection Regulatory Authority (HPRA) is the competent authority for human medicines.

7.6 Communications to health professionals

The European Court of Justice Ruling (Case C-19/15)[65] provides clarity on the scope of Regulation 1924/2006 on nutrition and health claims in so far as it relates to information shared with health professionals. This ECJ Ruling concluded that commercial communications[66] between food companies and health professionals falls within the scope of communications referred to and governed by Commission Regulation 1924/2006. This means that while there is provision for information pertaining to new scientific developments to be given to health professionals from food companies (including food supplement companies), all information disseminated should be factual and objective scientific information. This information, however, must not take the form of a rejected nutrition or health claim.

NUTRITION & HEALTH CLAIMS – CHECKLIST

FBOs must ensure compliance with relevant provisions relating to nutrition and health claims. These include:

- The general principles and conditions for use of all nutrition and health claims must be met
- Only authorised nutrition and health claims can be made, and all conditions of use must be met (including mandatory statements on the label)
- Recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities cannot be made
- Claims which suggest that health could be affected by not consuming the food cannot be made
- Claims which refer to the rate or amount of weight loss cannot be made
- Medicinal claims cannot be made
- All communications with health care professionals must be factual and scientific (they must not take the form of rejected nutrition or health claims)

[65] Judgement of the Court (Third Chamber) 14 July 2016, Case C-19/15
[66] Commercial communication means any form of communication designed to promote, directly or indirectly, the goods, services or image of a company, organisation or person pursuing commercial, industrial or craft activity or exercising a regulated profession (Article 2(f) Directive 2000/31/EC)

NUTRITION & HEALTH CLAIMS – INFORMATION SOURCES

Relevant information sources include:

- 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 (OJ L 404 30.12.2006, p. 9)
- EU Register of Nutrition and Health Claims
- European Commission 2007 Guidance on the Implementation of Regulation No 1925/2006 on Nutrition and Health Claims Made on Food Conclusions of the Standing Committee on the Food Chain and Animal Health
- European Commission Website Nutrition and Health Claims
- FSAI Website: Nutrition and Health claims
- FSAI 2021 Information on Nutrition and Health Claims

Food Safety Authority of Ireland
The Exchange, George's Dock, IFSC,
Dublin 1, D01 P2V6

T +353 1 817 1300
E info@fsai.ie

Join us on LinkedIn

Follow us on X

Say hi on Facebook

Visit us on Instagram

Subscribe to our Youtube channel

www.fsai.ie