Evira Guide 17012/5/uk

Food Supplement Guide
for food control officials and food business operators

Evira Guide 17012/5/uk
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Product Safety Unit

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CONTENT

1 PREFACE

Food supplements are food products, but they differ from other food products in appearance and the way they are used. Food supplements include products for the intake of vitamins, minerals, fibre and fatty acids as well as various herbal products, for example. Food supplements are in concentrated form, they are marketed in dose form and they are designed to supplement a normal diet. The ingredients used must not have medicinal effects.

In layman's terms, food supplements are referred to by many different names, such as natural health products or dietary preparations. However, all natural health products are not food supplements; the product group contains a wide variety of foodstuffs from dried plants to sweeteners. On the other hand, all food supplements are not "natural" products, even if their ingredients include substances of plant origin. Dietary preparation is a term used particularly of products used by athletes. These are not necessarily food supplements either, because they can be consumed in large portions and can sometimes even be used to replace meals. Food supplements are consumed in small doses and they supplement a balanced diet – they do not replace the diet.

Food supplements are marketed widely through various marketing channels. In addition to traditional natural health product stores and retail stores as well as pharmacies, food supplements are marketed in gyms, sporting goods stores, hairdressers, salons and erotic stores. The marketing of food supplements has undergone a strong shift to online marketing, and apart from online stores, they can be purchased through various online marketplaces and social media. Other common channels for distance selling of food supplements include network marketing as well as telemarketing and mail order marketing. The diversification of marketing channels creates challenges for both operators in the food supplement sector and control authorities, and it is therefore ever more important to be able to find information about the different regulatory requirements in an easy and collective form.

Food supplements, like other food products, are regulated through several different regulations (Figure 1). Food supplements also have many interfaces to other food products as well as to medicines and health care equipment and supplies. Thus it is important to take these different factors into account both in the in-house control of operators and in control executed by authorities.

The Food Supplement Guide is designed to be used by both food control authorities and food sector operators. The purpose of the Guide is to provide information from multiple viewpoints on regulations pertaining to food supplements, and on how they are enforced and controlled. The Guide serves as a tool for food control authorities and food sector operators, who can use it to verify that the food supplements available on the market are safe and conform to requirements. The Guide is currently only published in electronic form on Evira's website, because it is updated as necessary.

Public authority action shall be based on legislative competence conferred to the authority and be consistent with legislation. Regulatory guidelines are not, by their legal nature, binding on other authorities or operators. Issues pertaining to the application of legislative regulations are in the last instance settled by a court of law.

This Guide presents both direct quotations from legislation and interpretations on the application of legislation. Legal quotations are presented in separate paragraphs or reference is made to the regulation quoted in the text. The interpretations presented in this Guide constitute Evira's views on how legislative regulations should be applied.

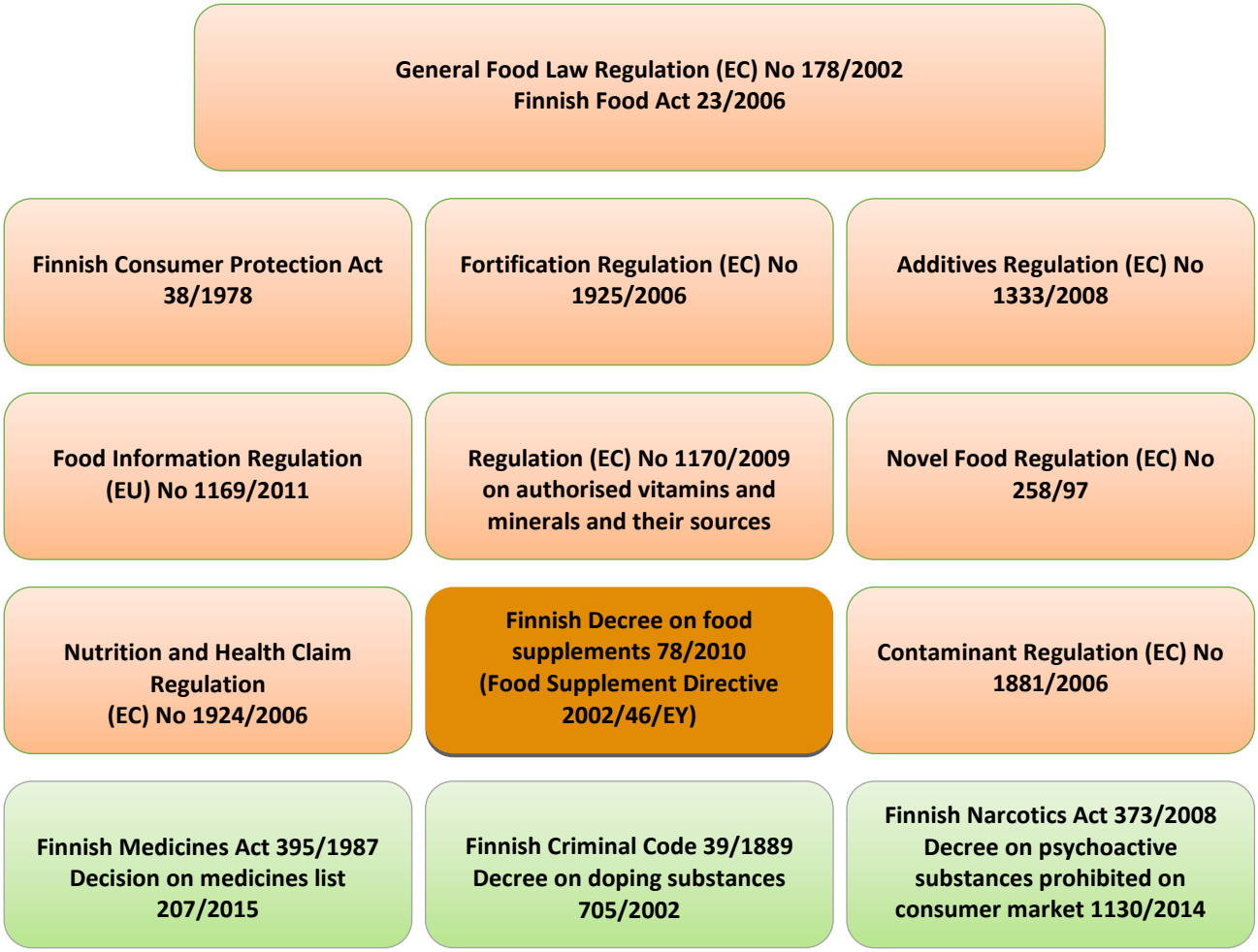

Figure 1. *Key legislation pertaining to food supplements (cf. also Section 9 Legislation and norms)*

2 DEFINITION OF FOOD SUPPLEMENT AND NOTIFICATION PROCEDURE

2.1 Definition of food supplement

In the national Decree on Food Supplements (78/2010), a food supplement is described as a pre-packed product in the form of a briquette, capsule, pastille, tablet, pill, powder, concentrate, extract or liquid, or in some other equivalent dose form, marketed as a foodstuff. Food supplements are consumed in measured small unit quantities and the amount of energy received from them has no relevance to the diet as a whole.

In Evira's view, the energy received from a food supplement when consumed according to its maximum dosage instruction is not significant in terms of energy intake, if it does not exceed 200 kJ (50 kcal) per day. A dose that is considered small is one teaspoon or tablespoon (5-15 ml) of the product, which means that the maximum volume of the daily dose of the marketed product is 100 ml.

Food supplements are concentrated sources of one or several nutrients or other substances with a nutritional or physiological effect, alone or in combination. Nutrients include vitamins and minerals. Other substances with a nutritional or

physiological effect are considered to include, for example, fatty acids, amino acids and fibres as well as various plants, chemical substances or lactic acid bacteria.

The purpose of food supplements is to supplement the normal diet. They are not designed to replace a balanced diet. Products classified as medicinal products pursuant to the Medicines Act (395/1987) are not food supplements.

2.2 Notification procedure for food supplements

Food business operators who produce or import a food supplement or have a food supplement produced shall submit a food supplement notification to Evira (23/2006, Section 8). Evira is of the view that the operator responsible for placing the food supplement on the market should submit the food supplement notification at the same time as the product is placed on the market, at the latest. A notification is also required, when the composition of the product is changed with respect to the substances that characterise the product. The requirement for the submittal of a notification to Evira of the removal of a food supplement from the market has been revoked, however, with the amendment of legislation.

If there are several operators with responsibility for the food (e.g. several importers), each shall submit the food supplement notification. The information provided in the notification shall be consistent with the labelling information. A notification is required every time the operator who produces or imports the product or has it produced changes.

Pursuant to Section 7 of the Finnish Decree on Food Supplements, the food supplement notification shall be accompanied by a model of the labelling of the product, indicating both regulatory and voluntary labelling, and if possible, also any planned illustrations for the package. If the signatory of the notification is not a representative of the company submitting the notification, but e.g. a consulting firm, a Power of Attorney shall also be attached to the notification. Other attachments to the notification may include e.g. a product brochure.

The food supplement notification is submitted via Evira's electronic service. The e-forms are available in Finnish, Swedish and English. The electronic service system is logged in with the ID used in the "Katso" identification system of the Finnish Tax Administration (http://www.vero.fi/katso).

More detailed instructions for the submission of the notification and the use of the electronic service can be found on Evira's website at: http://www.evira.fi/files/attachments/fi/evira/lomakkeet_ja_ohjeet/elintarvikkeet/erityisruokavalio_ravintolisa/ohje_ravintolisailmoituksen_tekemisesta.pdf.

When the notification has been successfully submitted, the service sends to the email address given in the notification an automatic message that the notification has been received. The notification will also be forwarded for information and control purposes to the control authorities of the municipality where the company is located. Evira also informs other relevant authorities of the notifications (such as the Regional State Administrative Agencies, the Customs and the Finnish Medicines Agency Fimea). If the food business operator is unable to submit the notification via the electronic service, the food supplement notification can also be filed using the notification form provided on Evira's website.

Evira does not assess in the notification process the conformity of the product's composition or labelling. The receipt of the notification does not

indicate that Evira has approved the notified food supplement as conforming to food laws.

The responsibility for the conformity of the product to the Decree on Food Supplements and other food regulations rests with the operator. The in-house control obligation of the operator stipulated in the Food Act also entails this.

A fee based on the Decree of the Ministry of Agriculture and Forestry on chargeable services provided by Evira (1161/2014) is charged on submitted notifications as follows:

- Notifications submitted via the electronic service EUR 42
- Notifications submitted via post or email EUR 85.

The invoice for the charged fee is sent to the address provided in the notification after the notification has been processed.

3 COMPOSITION OF FOOD SUPPLEMENTS

Food supplements comprise characteristic substances and any other substances, such as additives, as needed. A characteristic substance in a food supplement refers to a nutrient (vitamin or mineral) or some other substance with a nutritional or physiological effect. Such substances include e.g. different fibres, amino acids, dietary fats, fatty acids, carbohydrates, plants or herbs.

3.1. Vitamins and minerals

Only the vitamins and minerals listed in Annex 1 to Commission Regulation (EC) No 1170/2009 may be used in food supplements in the forms listed in Annex 2. This Regulation does not apply to natural sources of vitamins and minerals.

The Annexes to the Regulation are updated as needed and it is possible to propose new substances and compounds for addition in them. More information is provided on the website of the European Commission at: http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm.

Purity criteria

The Decree on Food Supplements does not specify purity criteria for the vitamin and mineral compounds used in food supplements. The purity criteria defined in other Community legislation are applied to vitamin and mineral compounds. For example, the purity criteria specified for L-ascorbic acid used as an additive also apply to L-ascorbic acid used to fortify foods or in food supplements. If Community level purity criteria have not been defined, it is also possible to use generally acceptable purity criteria commonly recommended by international organisations.

1. If Commission Regulation (EU) No. 231/2012 laying down specifications for food additives sets out identification and purity criteria for compounds used in food supplements, these specifications shall be applied.

   Valid regulations regarding purity criteria in the Regulations Table: http://www.evira.fi/files/attachments/fi/elintarvikkeet/tietoa_elintarvikkeista/lisaaineet/lisaaine_aromi_entsyymi_lainsaadantotaulukko.pdf

2. If the aforementioned Regulation does not contain these specifications, the identification and purity requirements recommended by the Codex Alimentarius Commission shall be applied. They are based on the identification and purity criteria of JECFA (The Joint FAO/WHO Expert Committee on Food Additives).

   The food additives for which the Codex Alimentarius Commission has recommended identification and purity criteria can be found online in CAC/MISC 6 "List of Codex advisory specifications for food additives" (http://www.codexalimentarius.org/standards/list-of-standards/en/?provide=standards&orderField=fullReference&sort=asc&num1=CAC/MISC)

   The “SIN No" indicated for each additive can be used to search for purity criteria electronically from the "Combined Compendium of Food Additive Specifications" (http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/) by entering the indicated “SIN No" of the additive in the search field "INS Number".

3. If there are no identification and purity criteria specified in EU legislation or recommended by the Codex Alimentarius Commission, other criteria defined by JECFA shall be applied

   The identification and purity criteria recommended by Codex as well as other criteria defined by JECFA can be found electronically in "Combined Compendium of Food Additive Specifications" as well as in publications FAO JECFA Monographs 1, Volume 1 - 3 (2005), FAO JECFA Monographs 3 (2006) and FAO JECFA Monographs 4 (2007), FAO, Rome.
   The determination methods used in identification and purity analyses can be found at the same web address as well as in the publication FAO JECFA Monographs 1, Volume 4 (2005), FAO, Rome.

4. In the absence of the criteria referred to in Items 1 - 3, the purity criteria recommended by the European Pharmacopoeia shall be applied.

Minimum amounts

In order for a vitamin or mineral to be considered a characteristic substance of the food supplement, its amount in the daily dose of the food supplement shall be significant. The amount is considered significant, when the daily intake of the vitamin or mineral from the food supplement is 15 percent of the daily reference intake, when consumed according to the dosage instructions, regardless of whether the food supplement is in solid or liquid form.

In other words, in order for a food supplement to be marketed as a source of a vitamin or mineral, the food supplement, when consumed according to the dosage instructions, shall provide at least 15% of the daily reference intake of the vitamin or mineral concerned.

If the food supplement is sold specifically as an excellent or good source of nutrients, or marketed as being high in vitamins or nutrients (e.g. in the name of the product), the daily intake from the food supplement, when consumed according to the dosage instructions, must be at least 30% of the daily reference intake.

The daily reference intakes (DRI/RI) of vitamins and minerals are listed in Table 1 and in Annex XIII to the Food Information Regulation (EU) No 1169/2011. The

Regulation can be found at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:FI:PDF.

Maximum amounts

So far no maximum levels have been set in the regulations for the content of vitamins and minerals in food supplements. Food business operators shall verify on the basis of their own risk assessment that the level of vitamins or minerals in the food supplement which the operator produces or has produced, imports or distributes does not cause a health hazard. This is particularly emphasised in the case of nutrients for which the difference between the recommended intake and the upper limit of safe intake (safety margin) is narrow. Nutrients with a narrow safety margin are usually considered to include vitamins D and A, niacin, folic acid and minerals. With vitamin A, for example, tripling the recommended intake is enough to reach the upper limit of safe intake.

European Food Safety Authority EFSA has, based on assessing the safety of nutrients, set daily tolerable upper intake levels (UL) for certain vitamins and minerals. The UL indicates the maximum level of the vitamin or mineral that is judged not to cause a safety risk in continuous, long-term use (Table 1).

The UL takes account of the daily intake from all sources, including regular food, fortified food products, food supplements and certain vitamin and mineral preparations classified as medicines. An exception to this is magnesium, for which the UL is based on only readily dissociable magnesium salts and MgO contained in nutritional supplements, water and fortified food products. In other words, the UL set for magnesium does not include magnesium normally present in foods and beverages.

When assessing the safety risk caused by a food supplement to the consumers, the potential targeting of the food supplement to vulnerable consumer groups, such as children, pregnant and breastfeeding women and the elderly shall be taken into account in addition to the UL.

In Evira's view, if the recommended daily dose of the food supplement contains a vitamin or a mineral in an amount that exceeds the UL, the food supplement can be judged to cause a health hazard to consumers.

In these cases the operator who produces, imports or distributes the food supplement or has it produced, shall take action to control the health hazard. The action to be taken shall be determined separately in each case based on the specific conditions. Possible actions to control the hazard include, for example, a reduction of the level of the nutrient in question in the product, a decrease in the daily dose, a warning in the labelling or some other action that will ensure the safety of the food supplement to the consumer.

Where food supplements targeted at vulnerable consumer groups are concerned, Evira considers the food supplement in that case to constitute a severe health hazard, which must result in the withdrawal of the product from the market.

More information about the withdrawal procedure is provided in Section 7 and on Evira's website at:
http://www.evira.fi/portal/fi/elintarvikkeet/valmistus_ja_myynti/takaisinvedot/.

Table 1 presents the daily reference intakes, the minimum amounts and the tolerable upper intake levels of vitamins and minerals.

Table 1. Daily reference intakes[1] and minimum amounts as well as daily tolerable upper intake levels[2] (UL) of nutrients

Nutrient	Unit	Daily reference intake	Minimum amount (15%)	UL (adults)	UL (children 1-3 yr)	UL (children 4-6 yr)	UL (children 7-10 yr)	UL (children 11-14 yr)	UL (children 15-17 yr)
Vitamin A	µg	800	120	3000	800	1100	1500	2000	2600
Vitamin D	µg	5	0.75	100	50**	50	50	100	100
Vitamin E	mg	12	1.8	300	100	120	160	220	260
Vitamin K	µg	75	11.25	-	-	-	-	-	-
Vitamin C	mg	80	12	-	-	-	-	-	-
Thiamine (B1)	mg	1.1	0.165	-	-	-	-	-	-
Riboflavin (B2)	mg	1.4	0.21	-	-	-	-	-	-
Niacin (B3)	mg	16	2.4	Nicotinic acid 10 Nicotinamide 900	Nicotinic acid 2 Nicotinamide 150	Nicotinic acid 3 Nicotinamide 220	Nicotinic acid 4 Nicotinamide 350	Nicotinic acid 6 Nicotinamide 500	Nicotinic acid 8 Nicotinamide 700
Vitamin B6	mg	1.4	0.21	25	5	7	10	15	20
Folic acid (B9)	µg	200	30	1000	200	300	400	600	800
Vitamin B12	µg	2.5	0.375	-	-	-	-	-	-
Biotin (B7)	µg	50	7.5	-	-	-	-	-	-
Pantothenic acid (B5)	mg	6	0.9	-	-	-	-	-	-
Potassium	mg	2000	300	-	-	-	-	-	-
Chloride	mg	800	120	-	-	-	-	-	-
Calcium	mg	800	120	2500	-	-	-	-	-
Phosphorus	mg	700	105	-	-	-	-	-	-
Magnesium	mg	375	56.25	250 (magnesium salts. MgO)*	-	-	-	-	-
Iron	mg	14	2.1	-	-	-	-	-	-
Zinc	mg	10	1.5	25	7	10	13	18	22
Copper	mg	1	0.15	5	1	2	3	4	4
Manganese	mg	2	0.3	-	-	-	-	-	-
Fluoride	mg	3.5	0.525	7	1.5	2.5	2.5-5	5	7
Selenium	µg	55	8.25	300	60	90	130	200	250
Chrome	µg	40	6	-	-	-	-	-	-
Molybdenum	µg	50	7.5	600	100	200	250	400	500
Iodine (µg)		150	22.5	600	200	250	300	450	500

* Only magnesium salts and MgO contained in food supplements, fortified food products and water are taken into account.
** The tolerable upper intake level of vitamin D for infants under 1 year of age is 25 µg.
[1] Regulation (EU) No 1169/2011 on the provision of food information to consumers, Annex XIII
[2] Tolerable Upper Intake Levels for Vitamins and Minerals, Scientific Committee on Food, Scientific Panel on Dietetic Products, Nutrition and Allergies, EFSA, February 2006

3.2 Other substances with nutritional or physiological effects

In addition to nutrients, other substances used in food supplements include, for example, fatty acids, amino acids, plants, plant extracts, herbs, bee products, enzymes and lactic acid bacteria. No provisions regarding other substances or their levels have so far been set out in regulations pertaining to food supplements.

However, Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to food gives the possibility to restrict or prohibit the use of some substances in foods. Article 8 of the Regulation refers to a procedure that can be followed to provide for a complete prohibition or restrictions on the use of a substance that represents a potential health risk.

Although as a rule there are no laws in Finland that would restrict the use of other substances in food supplements, it should be borne in mind that other EU member states may have lists of permitted and prohibited plants or other substances in place. These are allowed until there are Community-level regulations on the matter.

However, the general requirements specified for foodstuffs also apply to food supplements and their ingredients:

- they shall be safe in terms of their microbiological, chemical and physical quality (safety);
- they shall have been used as normal food or a food supplement to a significant degree within the Community before 15 May 1997 (novel food status);
- they may not turn the product into a medicine (medicine status).

3.3 Raw materials and products of animal origin

Raw materials of animal origin, such as reindeer horn powder or colostrum are used in some food supplements. Raw materials of animal origin fall within the scope of the Food Act (23/2006), Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, and the more specific provisions issued under them.

Importation from internal market

When raw materials or foods of animal origin are imported to Finland from EU countries within the internal market, a notification about the start of activities at the place of first arrival must be submitted to Evira's unit in charge of control of places of first arrival at ensisaapumisvalvonta@evira.fi.

More information about the control of places of first arrival is provided on Evira's website at: http://www.evira.fi/portal/fi/elintarvikkeet/tuonti+ja+vienti/eu+n+jasenmaat++norja+ja+sveitsi/ensisaapumisvalvonta/.

Importation from third countries

Raw materials of animal origin that are imported from non-EU third countries are subject to veterinary border control. For raw materials imported for the production of food supplements containing foods of animal origin or other products derived from animals, the labelling must always declare the country and establishment of origin of the product, if the products are imported from a non-EU country. Gelatine derived from cattle, sheep or goats and imported from third countries for raw material use shall be accompanied by a TSE Declaration.

When finished, processed ingredients of animal origin, such as food supplements containing fish oil, milk powder, bone meal, lactose, etc. are imported to Finland, the control of such ingredients is carried out by virtue of the Food Act.

As a rule, no requirements related to veterinary border control apply to food supplements imported from outside the EU. The products usually contain small amounts of substances of animal origin, and the assessment of the need of veterinary border control is based on the CN code referred to in Commission Decision 2007/275/EC. Based on it, veterinary border control examinations are in accordance with Annex II to the Decision not carried out, if "the food supplements packaged for the final consumer contain small amounts of animal product or include glucosamine, chondroitin or chitosan". If the level of foodstuffs of animal origin in the food supplement is judged by the border veterinarian to not be "a small amount", the food supplement shall be subject to a veterinary border control examination and in that case the import conditions set out in Evira's guidelines regarding composite food products composed of animals and plants are to be followed (http://www.evira.fi/portal/fi/elintarvikkeet/tuonti+ja+vienti/tuonti+eu+n+ulkopuolelta/elaimista+ja+kasveista+koostuvat+elintarvikesekoitukset+-ent.+yhdistelmatuotteet-/), and based on the guidelines, the batch is either subject to or exempted from border control checks.

Seal products

Trade in seal products, such as seal oil, is governed by Regulation (EC) No 1007/2009 on trade in seal products, and Regulation (EU) No 737/2010 laying down rules for its implementation. The placing of seal products on the market is only allowed provided the conditions set out in Regulation No 1007/2009/EC are fulfilled and the seal product is accompanied by the certificate referred to in Regulation No 737/2010/EU.

Trade in seal products is apart from the EU Regulations also restricted by a national act (1107/1996), which forbids the importation of raw skins and processed skins of whitecoat newborn harp seals and newborn hooded seals, as well as the importation of products manufactured from these skins. In this context, importation refers to all products brought to Finland, regardless of the manner in which they are brought, including from another EU state.

Trade in seals is in Finland controlled by the police and the Customs.

3.4. Food treatment agents

Food treatment agents refer to additives, flavourings and enzymes used in foods. Additives and enzymes are always used for some technological purpose. Flavourings are used to improve or change the aroma and/or flavour of the food.

Regulation (EC) No 1333/2008 on food additives lists the additives approved for use in the production of food supplements and the maximum amounts of these additives in Annex II, under food group 17. Food supplements are in group 17 divided into solid and liquid food supplements based on their form. The approved additives and their maximum amounts are specified for each form of food supplements. Annex III to the Regulation on food additives lists the additives that are permitted for use in additives, including carriers, in enzymes, in flavourings and in nutrients, as well as the conditions for their use.

The additives and carriers used shall comply with the specifications set out in Commission Regulation (EU) No 231/2012 as regards origin, purity criteria and other required information.

The flavourings that are permitted for use in foods (incl. food supplements) are listed in Regulation (EC) No 1334/2008 on flavourings. The enzymes that are permitted for use in foods will be listed in Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes.

Evira has prepared for the use of food authorities and food industry operators guidelines for the control of food treatment agents. The guidelines are available on Evira's website at: http://www.evira.fi/portal/fi/tietoa+evirasta/lomakkeet+ja+ohjeet/elintarvikkeet/elintarvikeparanteet/.

3.5 Novel foods

Regulation (EC) No 258/97 on novel foods defines novels foods as foods and food ingredients that have not been used for human consumption to a significant degree within the European Community before the adoption of the Regulation in May 1997. Such foods or food ingredients can include, for example, wild plants with no commonly known use in foods, exotic plants from non-EU countries, new extracts derived from a food of animal origin or a plant as well as new synthetic food ingredients.

Novel foods may not be placed on the market within the EU without a safety assessment and the novel food authorisation of the European Commission. An authorisation is also required for new production methods of foods and food ingredients (such as foods produced using nanotechnology), if the method has not been used before May 1997.

The Regulation on novel foods is applied also to food supplements. That means that the authorisation referred to in the Regulation on novel foods is required for any food supplements containing ingredients that have not been used as normal foods or food supplements within the Community before May 1997. Substances and plants with a substantiated history of use only as food supplements prior to the year 1997, on the other hand, may continue to be used in food supplements, but novel food authorisation is required should the use of the substance or plant be expanded to other food groups.

Food industry operators are under the obligation to clarify, and if necessary, to provide substantiation on the history of use as food of their products and ingredients before the year 1997. If a history of use as food cannot be demonstrated, the products are considered to be novel foods and thus fall within the scope of the Regulation on novel foods.

No comprehensive list of ingredients considered to be novel foods is available. The Novel Food Catalogue maintained by the European Commissioning contains information about the novel food status of various foods (http://ec.europa.eu/food/food/biotechnology/novelfood/novel_food_catalogue_en.htm). The Novel Food Catalogue is only indicative and the absence of a food from the list does not mean that it has a history of use as food and is not a novel food. Also, the classification of a product may change if new reliable information emerges about its history of use. Evira's website provides information on also other public sources of

data that can be used to establish the history of use of a food (http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/uuselintarvikkeet/elintarvikkeen+uuselintarvikestatuksen+selvittaminen/).

More information about novel foods can be found on Evira's website at: http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/uuselintarvikkeet/.

3.6. Medicinal and herbal medicinal products

Under Section 6 of the Medicines Act (395/1987), the Finnish Medicines Agency Fimea (hereunder referred to as Fimea) will decide whether a substance or product is considered a medicinal product. Classification is carried out specifically for each product based on an assessment of its influence and intended use, as referred to in Section 3 of the Medicines Act.

Fimea has by virtue of Section 83 of the Medicines Act compiled a list of medicinal products (207/2015), which is an indicative list of the substances and herbals that are in medicinal use in Finland (Annexes 1 and 2). The list of medicines is not exhaustive, and also substances and herbals not included in the list can be considered medicines, if they meet the definition of a medicinal product under the Medicines Act.

The salts and esters of the medicinal substances included in the list are not listed, but they are biologically comparable to medicinal substances. The medicines list also includes Annex 1A, which is a list of medicinal substance analogues and prohormones. These substances are always considered on the basis of their influence to be comparable to medicines only supplied by prescription and thus food supplements containing these substances will be classified as medicines.

Classification as a medicine is always based on an assessment of the specific product. In addition to the medicines list, also norms issued on EU level shall be taken into account in the classification procedure. As concerns products that contain plant herbals or are made from plant herbals, classification is at Fimea guided by European plant monographies and community list entries. Fimea recommends that food business operators examine the information published on the websites of the European Commission and the European Medicines Agency, if their products contain substances of plant origin, i.e. plant herbals or plant herbal products made from them (e.g. extracts, tinctures, expressed juices) as a characteristic substance.

National authorities in EU member states utilise in their classification of plant herbal preparations the scientific assessments of the Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency, as well as European plant monographies and public statements.

The community list of the European Union is valid across the EU and for its part also guides the classification of traditional plant herbal preparations at Fimea as far as substances of plant origin, plant herbal products and their compounds included in the list are concerned.

More information is available on the website of the European Medicines Agency at: http://www.ema.europa.eu/ema/index.jsp?curl=pages%2Fmedicines%2Flanding%2Fherbal_search.jsp&mid=WC0b01ac058001fa1d&searchkwByEnter=false&alreadyLoaded=true&isNewQuery=true&keyword=vaccinium&searchType=Latin+name+of+the+

genus&taxonomyPath=&treeNumber=&outcome=Herbal+-+Community+herbal+monograph&outcomeSearch=Submit
and on the website of the European Commission at:
http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm.

Food regulations do not restrict the use of substances or herbals included in the medicines list as ingredients of food supplements, as long as their use is not based on their medicinal properties. In other words, there may be on the market substances that are identical or products that are made from the same plants, but different requirements are applied to them depending on whether they are placed on the market in accordance with regulations on medicinal products or food regulations.

Evira recommends that Fimea be contacted for an assessment of the classification need, if the food supplement contains substances listed in the medicines list or herbals referred to in the medicines list are used in the production of the food supplement. Fimea may classify a product as a medicine also on its own initiative, if the product meets the criteria defined for a medicine.

The medicines list and further information about classification is provided on Fimea's website at: http://www.fimea.fi/valvonta/luokittelu.

3.7 Alcohol

Alcohol is used as an extraction solvent in the production of herbal preparations, for example, and as a result of this, food supplements may contain significant amounts of alcohol. According to the Decree on food labelling, the alcohol content of liquid foods must be declared, if it exceeds 1.2 percent by volume. Evira recommends that the alcohol content of also solid foods be declared, if it is higher than 1.8 percent by weight.

The Finnish Alcohol Act (1143/1994) defines an alcoholic substance as a substance or product which contains at least 2.8 percent of ethyl alcohol by volume. An alcoholic preparation, on the other hand, refers to an alcoholic substance which is neither an alcoholic beverage nor spirit, and which can be denatured.

Food supplements classified as alcoholic preparations may only be produced by companies that have been granted an alcoholic beverage or spirit production licence by the National Supervisory Authority for Welfare and Health Valvira (hereunder referred to as Valvira). Alcohol preparations may only be imported for commercial purposes under a wholesale licence granted by Valvira. Retail outlets do not need a licence to sell alcoholic food supplements. However, Valvira may ban or discontinue the retail sale of an alcoholic preparation with properties similar to an alcoholic beverage or used to a considerable extent as an intoxicating substance. In other words, although no licence is required for retail of alcohol, it can become subject to control measures.

More information on alcoholic preparations is available on Valvira's website at: http://www.valvira.fi/alkoholi/alkoholin_valmistus/alkoholivalmisteen_valmistus and http://www.valvira.fi/alkoholi/alkoholin_tukkumyynti/alkoholivalmisteen_tukkumyyntilupa.

3.8. Natural toxins

Some plants may inherently contain various harmful compounds, or toxins, which the plant uses as protection against the harmful effects of insects and diseases, and against perishing. When used in food, the natural toxins of plants may have adverse effects on health. The type of the toxin, the level of toxin in the edible part of the plant and the individual sensitivity of people to different substances determine whether the toxin causes any symptoms. In some cases the level of harmful substances can be influenced through appropriate processing. Some toxins, such as the gyromitrin contained in false morels, are soluble in water or volatile and will therefore decompose at a boiling temperature.

There are no specific provisions in regulations for the natural toxins of foods in regard to food supplements, but food business operators are responsible for the safety of the foods they sell and market, and for the safety of the ingredients of the foods, also with respect to any natural toxins. Food business operators who produce or market foods in which e.g. plants containing natural toxins are used shall carry out a risk assessment process to verify the safety of the food.

The European Food Safety Authority EFSA has compiled a list (EFSA Compendium) of plants known to contain naturally occurring substances of concern that are e.g. toxic, addictive or psychotropic. The purpose of the Compendium is to support risk assessment on food supplements in regard to their ingredients of plant origin, by identifying the naturally occurring compounds of concern which should be the focus of the assessment. The Compendium has been drawn up without any judgment on whether the compounds of concern can be removed from the plant through processing, for example.

Food supplements are concentrated sources of their characteristic ingredients (nutrients or other substances with a nutritional of physiological effect). As a result of this, any harmful compounds contained in a food supplement are also in a concentrated form. The potential concentration of natural toxins in the food supplement shall thus be taken into account in risk assessment.

More information on natural toxins on Evira's website at:
http://www.evira.fi/portal/fi/elintarvikkeet/tietoa+elintarvikkeista/elintarvikevaarat/elintarvikkeiden+luontaiset+myrkyt/.

The EFSA Compendium can be found on the website of EFSA at:
http://www.efsa.europa.eu/en/efsajournal/doc/2663.pdf.

3.9. Contaminants

Food contaminants refer to substances not used in the production of the food as ingredients or additives. If contaminants are present in high levels, the food may have adverse effects on human health or become unfit for consumption. Maximum levels have been set out for some contaminants occurring in foods and food business operators shall observe these levels in their in-house control. Authorities control the in-house control implemented by operators through risk-based random testing.

Contaminants, such as heavy metals or PCB compounds, may end up in foods due to e.g. environmental contamination. High levels of lead, cadmium and mercury have been found in certain food supplements, such as plant and herbal preparations.

These food supplements may increase exposure to e.g. heavy metals significantly. For this reason, maximum levels have been specified for the levels of lead, cadmium and mercury in food supplements. The maximum levels are safe and as low as reasonably achievable by following good manufacturing practices. In particular, food supplements that consist completely or primarily of dried seaweed or mussels (e.g. greed-lipped mussel) may contain high levels of cadmium, as it is naturally accumulated in seaweed and mussels. The maximum level set for cadmium is therefore higher.

When food or a food ingredient spoils, mould toxins may be produced. A mould toxin called citrinin may be found in rice fermented with red yeast (*Monascus purpureus*), for example. Because of this, some red rice preparations may contain high levels of citrinin, which can be harmful to e.g. the kidneys. A maximum level has therefore been set also for the citrinin content of red rice preparations.

Regulations related to food contaminants (Commission Regulation (EC) No 1881/2006 and amendments to it) are under constant development, also with respect to food supplements. As a result of this, food business operators need to monitor changes in regulations and at all times apply in their in-house control the valid maximum levels of different contaminants.

Raw materials with contaminant levels that exceed the maximum levels set in regulations may not be used as ingredients in foods, including food supplements.

Table 2. Examples of possible contaminants in different types of food supplements, and maximum levels of the contaminants (applicable to marketed food supplements)

Contaminant	Maximum level	Type of food supplement
Dioxins	1.75 pg/g of fat	Food supplements containing marine oil
Dioxins and dioxin-like PBC compounds, total	6.0 pg/g of fat	
Non-dioxin-like PCB compounds	200 ng/g of fat	
Lead	3.0 mg/kg	All food supplements
Cadmium	1.0 mg/kg	All food supplements
	3.0 mg/kg	Food supplements that consist completely or primarily of seaweed or products derived from seaweed or dried mussels.
Mercury	0.10 mg/kg	All food supplements
Citrinin	2000 µg/kg	Food supplements containing red rice
PAH compounds:		Food supplements containing substances of plant origin and preparations derived from them, and food supplements containing propolis, royal jelly or spirulina algae, or preparations derived from them
Benzo(a)pyrene	10.0 µg/kg	
Sum of benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene	50.0 µg/kg	

3.10 Residues of plant protection products

Plant protection products, or pesticides, refer to products used in plant production to e.g. ward off weeds, protect crops from insects and other pests, prevent plant diseases, regulate plant growth or improve the preservability of the products after

harvest. When pesticides are used in plant production, it is possible that residues of these products are found in foods. Maximum pesticide residue levels have been set for various foodstuffs (foods of both plant and animal origin) and food business operators must observe these in their in-house control. Authorities control the in-house control implemented by operators through risk-based random testing.

Raw materials with pesticide residue levels that exceed the maximum levels may not be used as ingredients in foods, including food supplements. Analyses carried out by authorities have shown pesticide residues in e.g. food supplements that contain oils or herbs.

Regulation (EC) No 396/2005 of the European Parliament and of the Council provides for the maximum pesticide residue levels in foods of plant and animal origin.

3.11 Prohibited substances

Although in Finland there is no specific list of substances that may not be used in food supplements, the use of some substances is prohibited in food in general based on other regulations.

Substances referred to in Article 8 of Regulation (EC) No 1925/2006 (Fortification Regulation)

Article 8 of the Fortification Regulation provides for a procedure to be followed to prohibit or restrict the use of certain other substances in food across the EU, if they cause a health hazard. So far this procedure has been followed to prohibit the food use of the *Ephedra* herb and preparations derived from species of the *Ephedra* family.

More information is provided on the website of the European Commission at: http://ec.europa.eu/food/food/labellingnutrition/vitamins/index_en.htm.

Hormones and doping substances

The use of hormones and other doping substances is prohibited in food supplements just like in all other food products.

Doping refers to the enhancement of athletic performance by methods alien to the human body, such as medicines. Doping may improve athletic performance, but it may also severely damage the athlete's health.

Under the Finnish Criminal Code (39/1889), Chapter 44, Section 6, doping offences include the preparation, import and dissemination of doping substances.

Section 16 of Chapter 44 of the Criminal Code lists the following as doping substances

- synthetic anabolic steroids and their derivatives
- testosterone and its derivatives
- growth hormones
- chemical substances that increase the production of the aforementioned hormones in the human body.

Government Decree (705/2002) defines the substances to be considered doping substances as referred to in Section 16 of Chapter 44 of the Criminal Code.

The Finnish Antidoping Agency FINADA publishes every year the list "Prohibited Substances and Methods in Sports". The number of substances defined as doping substances is much higher in this list than in the Criminal Code. In other words, the sports industry has stipulated rules that are more stringent than the Criminal Code.

Narcotic and psychotropic substances

Pursuant to Article 2 of the Food Law Regulation (EC) No 178/2002, the definition of food does not include 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. Their use is thus strictly prohibited in food (incl. food supplements).

Substances used solely for purposes of intoxication, or designer drugs, are controlled under the Narcotics Act (373/2008). Designer drugs are in the Narcotics Act defined as psychotropic substances prohibited on the consumer market. According to the Narcotics Act, these substances are used for intoxication purposes and they are potentially dangerous to health. The psychotropic substances referred to are listed in Government Decree (1130/2014). The Decree prohibits the production, importation to Finland, storage, keeping for sale and giving to another person of psychotropic substances prohibited on the consumer market.

Endangered species in violation of CITES Convention

Endangered species in violation of the CITES Convention may not be used as ingredients for food supplements. CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora, 1973) regulates international trade in about 30 000 endangered species of plants and animals (e.g. whales, certain species of sharks). The CITES Convention has been ratified by more than 160 countries. In Finland, the Convention was adopted in 1976.

EU states have implemented regulations on international trade in endangered plants and animals that are stricter than the CITES Convention: Basic Regulation (Council Regulation (EC) No 338/97); Commission Amending Regulation (EU) No 1320/2014 with updated lists of species for the Annexes to the Basic Regulation; and Commission Implementing Regulation (EC) No 865/2006 with more detailed information on e.g. licensing procedures and licensing criteria. EU has further banned the importation of certain CITES species to the EU area. A list of the species is provided in Regulation (EU) No 888/2014.

Trade is mainly controlled by means of import and export restrictions of varying degrees, depending on how endangered the species is and the degree to which the stock can be exploited. In practice, trade is controlled based on written permits that are issued by the environmental authorities of the countries (Finnish Environment Institute in Finland) and need to be presented to the Customs.

More information about the CITES Convention, related licences and regulations can be found at: http://www.ymparisto.fi/fi-fi/asiointi_luvat_ja_ymparistovaikutusten_arviointi/Luvat_ilmoitukset_ja_rekisterointi/Uhanalaisten_lajien_kansainvalinen_ja_EUn_sisainen_kauppa_ja_sita_koskevat_luvat_CITES.

4 INFORMATION TO BE PROVIDED ON FOOD SUPPLEMENTS

Pursuant to Section 9 of the Food Act (23/2006), the labelling, presentation, advertising or other marketing of a food product:

- must give truthful and sufficient information about food;
- must not give misleading information about food;
- must not present food as having properties related to prevention, treatment or curing of human diseases or refer to such information unless otherwise provided elsewhere by law.

Pursuant to Article 8 of Food Information Regulation (EU) No 1169/2011, the food business operator responsible for the food information is the operator under whose name or business name the food, such as a food supplement, is marketed or, if that operator is not established in the European Union, the importer into the Union market.

According to the Food Information Regulation, food information, particularly warnings, shall be marked in such a way as to be easily visible, in sufficiently large print, clearly legible, understandable and indelible. Labelling information must not be untrue or misleading. As a rule, labelling on food supplements must be in Finnish and in Swedish (Decree 834/2014 of the Ministry of Agriculture and Forestry on the provision of food information to consumers). Exceptions to this include food supplements sold locally in a monolingual area, where labelling shall be at least in the language of the area. However, food supplements sold through distance selling shall always bear labelling in both Finnish and Swedish.

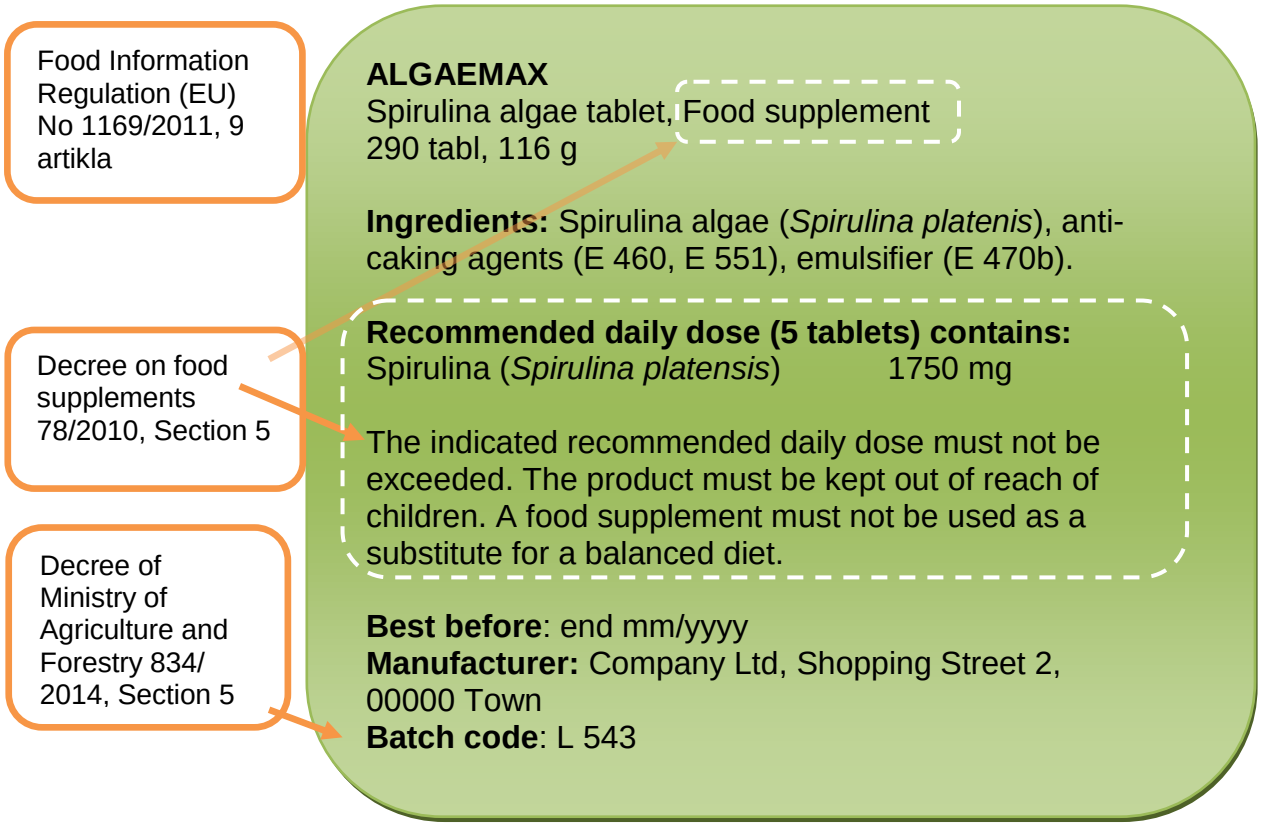

Figure 2. *Example of provisions laying down criteria for labelling of food supplements.*

4.1 General labelling

According to general labelling provisions, food packaging (incl. food supplements) must contain the following basic information:

- **Name of product**
  - The name states briefly and accurately the food product contained in the packaging (e.g. calcium tablet, oat shoot extract). The term "food supplement", which must also be shown, is not in itself sufficient as a name. A trademark or trade name cannot be used to replace the name of the food product. The trade name of the food supplement or part of the name must not be the same as the name of a medicinal product.
- **Quantity of content**
- **Name or business name and address of the operator responsible for food information**
- **List of ingredients**
  - An ingredient means a substance or product, including additives, that has been used in the manufacture of a food product and that remains in the final food product in some form. All ingredients must be listed by weight in descending order in accordance with the formula, except for e.g. water and other volatile substances, which are listed in order of their weight in the finished product.
  - Evira recommends that vitamins and minerals be indicated in the labelling using the names listed in Annex XIII to the Food Information Regulation (Table 1). Listing nutrients in the list of ingredients and in the list of characteristic substances in a uniform manner ensures that it is easier for the consumer to recognise the ingredients of the product. The name of the nutrient can also be supplemented with the name of the nutrient compound, e.g. vitamin C (l-Ascorbic Acid).
  - Evira recommends the use of the Finnish names of plants in the list of ingredients, if available (for example, using the Finnish name "pakurikääpä" for *Inonotus obliquus* fungus instead of the name "chaga" which is of Russian origin), or some other names established in Finland (for example, the *Lycium barbarum* plant can be referred to by the Finnish name "pukinpensas" or the established name "goji"). If no Finnish name is available, it is advisable to use the full scientific name of the plant (*plant family + species*, e.g. *Griffonia simplicifolia*).
  - The indication of ingredients causing allergies and intolerances, and preparations made out of them, is always mandatory, even when they have not been used as ingredients of the food product as such, but have ended up in the food product in some other way (e.g. additive carriers). Moreover, they shall be emphasised in the list of ingredients by using e.g. a different font size or style or a background colour. Mandatory indication applies to the following ingredients and products causing allergies and intolerances (Food Information Regulation, Annex III):
    - Cereals containing gluten (wheat, rye, barley, oats, spelt, kamut) and products thereof
    - crustaceans and products thereof
    - eggs and products thereof
    - fish and products thereof
    - peanuts and products thereof
    - soy and products thereof
    - milk and products thereof (incl. lactose)
    - nuts and products thereof
    - celery and products thereof

        - mustard and products thereof
        - sesame seeds and products thereof
        - sulphur dioxide and sulphite (at concentrations of more than 10 mg/kg or 10 mg/l)
        - lupin and products thereof
        - molluscs and products thereof

    - Additives shall be indicated in the list of ingredients by the name of the category indicating their purpose of use, supplemented by their own name or number code (E code). Additives made of the aforesaid ingredients or products causing allergies and intolerances shall be indicated by their real names (e.g. soy lecithin) instead of E codes.
    - The amount of the ingredient must be indicated, if the ingredient is emphasised in the labelling.

- **Best before or use by date**
    - If the date of minimum durability is not given as an indication of the day, the following form of indication shall be used: "Best before end …" (e.g. "Best before end 12/2018").
- **Country of origin or place of provenance as provided for in the Food Information Regulation or in provisions issued by virtue of it, or in other provisions**
- **Instructions for use** (cf. also Section 5.2)
    - Warnings are also part of instructions for use
    - Producers of food supplements shall establish if the products produced by them are suited to all consumers, or if warnings or restrictions of use should be provided in the labelling.
- **Any special storage conditions and/or conditions of use, if necessary**
- **If necessary, the alcohol content of beverages (for solid foods on a voluntary basis)**
- **The code of the food batch** (Decree of Ministry of Agriculture and Forestry 834/2014)
    - Instead of the food batch code, an indication based on the date of minimum durability or the use-by date can be used, provided it is given as an indication of at least the day and the month (Figure 3).

Contrary to other foods, the requirement for a nutrition declaration set out in the Food Information Regulation is not applied to food supplements.

Evira recommends that for food supplements designed to be stored and used in an inner packaging, the labelling provided on the inner packaging contain indications that are necessary to protect the health and the economic interests of the user, such as "name of food product", "best before" date / "use by" date, any required storage conditions and instructions for use (for example, the recommended daily dose and any warnings).

The size of the labelling used on foods, including food supplements, is provided for in the Food Information Regulation. Particulars that are mandatory for food supplements shall be printed on the packaging or on the label using a font size where the x-height is equal to or greater than 1.2 mm. In case of packaging the largest surface of which has an area of less than 80 cm^2, the x-height shall be equal to or greater than 0.9 mm. If the mandatory particulars are printed in capital letters, the x-height shall be 1.2 mm.

More information about the general labelling provisions can be found in Evira's Guide on food information (Evira Guide 17068/41) as well as on Evira's website at: http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/pakkausmerkinnat/.

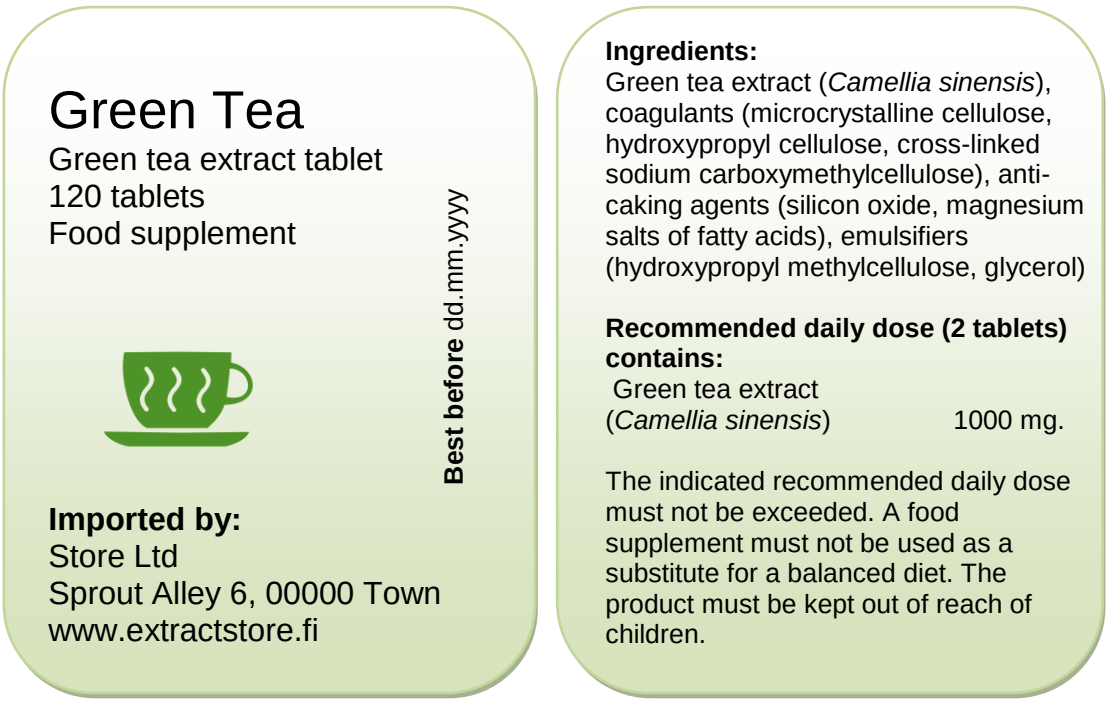

Figure 3. *Example of labelling on a plant extract product.*

4.2 Labelling pursuant to Decree on food supplements (78/2010)

Pursuant to the Decree on food supplements, the labelling of food supplements must provide the following information in addition to general labelling information:

- **The term "food supplement" ("ravintolisä" in Finnish, "kosttillskott" in Swedish)**
- **The names of the categories of characteristic nutrients or substances or an indication of the nature of these nutrients or substances**
  - A category of characteristic nutrients refers to the group in which the characteristic substance of the food supplement can be classified. Such categories include vitamins, minerals, fibres, flavonoids, amino acids, fatty acids or plant or herbal extracts. The category or the nature can be expressed in the food product's name (e.g. lactic acid bacteria preparation or chewable vitamin tablet).
- **The amount of characteristic substances of the food supplement in the daily dose**
  - The amounts of the characteristic substances of the food supplement must be indicated in the labelling in numerical form as the daily dose of the product recommended by the manufacturer. The units used for vitamins and minerals are stipulated in Annex 1 to Commission Regulation (EC) No 1170/2009. The values given are averages based on an analysis of the product made by the manufacturer. The capsule or the binding agent of the preparation must be taken into account in the indicated nutrient amount. The amount of the characteristic substances of the food supplement must always be expressed as percentage of the daily reference intake, if the reference intake is available

for the substance in question. The reference intakes of vitamins and minerals are presented in Annex XIII to Food Information Regulation (EU) No 1169/2011.

- In the case of vitamins and minerals, the vitamin activity of the compounds must also be taken into account and indicated for the characteristic substances as the proportion with physiological activity (e.g. thiamine hydrochloride must be indicated as free-form thiamine). Carotenoid correspondence coefficients (indicating vitamin A) can be found on Evira's website at http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/pakkausmerkinnat/ravintoarvomerkinnat/a-vitamiinin+ilmoittaminen/.
- For vitamins and minerals contained in food supplements, the deviations indicated in Table 3 are permitted; they include the uncertainty involved in the measured value. If claims are used in the marketing of the food supplement, the content of the vitamin or mineral referred to in the claim may not be less than the indicated amount by more than the measurement uncertainty of the method. The deviations are based on EU's guidance document on tolerances (http://www.evira.fi/files/attachments/fi/elintarvikkeet/valmistus_ja_myynti/pakkausmerkinnat/ravintoarvomerkinta_toleranssiohje_12.2012..pdf).

  If analyses repeatedly produce results on the extreme limits of the permitted tolerance, in-house control efforts should be intensified and the required changes introduced in the production process or in the labelling.

  Foods in which the labelled nutrient levels deviate repeatedly from the tolerance limits given are not acceptable and should not be marketed.

  More information about permitted deviations is provided on Evira's website at: http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/pakkausmerkinnat/ravintoarvomerkinnat/ravintoaineiden+sallitut+poikkeamat/.

Table 3. Permitted deviations for food supplements (incl. measurement uncertainty) when no claims are used.

Nutrient	Permitted deviations for food supplements (incl. measurement uncertainty)
Vitamins	+50% ** -20%
Minerals	+45% - 20%

** for vitamin C in liquids, higher upper tolerance values can be accepted

- **Recommended daily dose**
- **The recommended daily dose must not be exceeded**
- **A food supplement must not be used as a substitute for a balanced diet**
- **The product must be kept out of reach of children**

Evira recommends that the above phrases be used in warnings and indications in the labelling.

The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet does not provide adequate amounts of nutrients in general. Neither may they attribute to food supplements properties of preventing, treating or curing a human disease, or refer to such properties. On certain conditions, however, nutrition claims or health claims may be made on food supplements (cf. Section 5.4), but such claims may not mislead consumers.

CALCIUM

Vitamin-mineral preparation
Food supplement, 30 tablets 42 g
Calcium and vitamin D promote maintenance of normal bones.

Ingredients: Calcium carbonate, bulking agents (E463, E468), emulsifiers (E464, E422), colouring (E171), anti-caking agents (E 551, 470b), cholecalciferol.

Recommended daily dose: 1 tablet

1 tablet contains		**% RI***
Calcium	500 mg	62,5
Vitamin D3	5 µg	100

* Reference intake

The indicated recommended daily dose must not be exceeded.
A food supplement must not be used as a substitute for a balanced and varied diet and a healthy lifestyle.
The product must be kept out of reach of children.
Best before: 11.12.2017
Manufacturer: Company Ltd, Address Road 1, 23456 Town

Figure 4. *Example of labelling on a mineral preparation.*

4.3 Other labelling provisions

Labelling provisions based on other acts and regulations shall also be taken into account in the labelling of food supplements, for example:

- **Genetically modified ingredients**
  - Regulation (EC) No 1829/2003 stipulates that consumers shall be informed of any genetically modified ingredients used in a food supplement. The words "genetically modified" or, for example, "produced from genetically modified soy", shall appear in the labelling in the list of ingredients immediately following the ingredient concerned. More information about the labelling of genetically modified products is provided on Evira's website at: http://www.evira.fi/portal/fi/tietoa+evirasta/asiakokonaisuudet/muuntogeenisetuotteet+/pakkausmerkinnat/.

- **Irradiation**
  - If the dried spice herbs, spices or spice plants contained in a food supplement have been irradiated to improve their microbiological quality, this must be indicated in the labelling (Decree 852/2000 of the Ministry of Trade and Industry on treatment of food with ionizing radiation). Irradiation may only be carried out at facilities approved by the European Community.
  - **Note.** If the ingredient has not been irradiated at a facility approved by the EU, or if the food supplement contains an irradiated ingredient for which

irradiation is not allowed, this constitutes a major error which requires immediate withdrawal of the product from the market (cf. Table 5).

- **Labelling referring to an organic production method**
  - Labelling referring to an organic production method may only be used provided the operator is included within the scope of a control system as referred to in Regulation (EC) No 834/2007/EC on organic production.
  - The labelling of a product is considered to refer to an organic production method, if the product and/or an ingredient of the product is in labelling, advertising material and/or commercial documents described using phrases suggesting to the purchaser that the product and/or its ingredients have been produced in accordance with provisions pertaining to organic production.
  - More information about the use of labelling referring to an organic production method is provided in Evira guidelines 18222/3 (Guidelines for organic production 3 – Foodstuffs, http://www.evira.fi/files/attachments/fi/evira/lomakkeet_ja_ohjeet/luomu/luomuohje_3_elintarviketuotannon_ehdot_3_painos_04-03-2014_netti_tp.pdf).

- **Labelling pertaining to use of sweeteners**
  - If the food supplement contains sweeteners, the statement "with sweetener(s)" shall be included in the name of the food or accompany the name.
  - If the food supplement contains both sugar and sweeteners, the statement "with sugar(s) and sweetener(s)" shall be included in the name of the food or accompany the name.
  - If the food supplement is sweetened with aspartame/aspartame-acesulfame salt, the statement "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. The statement "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.
  - If the recommended daily dose of the food supplement contains more that 10% of added polyols, the statement "excessive consumption may produce laxative effects" shall be provided on the packaging.

- **Labelling pertaining to seaweed preparations**
  - Seaweeds may contain high levels of naturally occurring iodine and it is therefore recommended that food supplements containing seaweed indicate the iodine content and, if necessary, a warning about high iodine content.

- **Lactose-free and gluten-free products**
  - If the product is marketed as lactose-free or gluten-free, the product shall meet the criteria related to these claims.

- **Labelling pertaining to caffeine**
  - If the food supplement contains, as a characteristic substance, caffeine or an ingredient containing caffeine, the statement "Contains caffeine. Not recommended for children or pregnant women" shall appear on the label. The statement shall be followed by a reference in brackets to the caffeine content expressed in mg per recommended daily dose. The statement shall be placed in the same field of vision as the name of the food.
  - Evira recommends the use of caffeine warnings; more information on these warnings is provided on Evira's website at: (http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/pakkausmerki

nnat/varoitusmerkinnat+ja+kayttoohjeet/kofeiinia+sisaltavien+elintarvikkeiden+varoitus-+ja+kayttoohjemerkinnat).

4.4 Marketing

Pursuant to Section 9 of the Food Act, the information given about food in food packaging, presentation and advertising, or in some other way in connection with marketing must be truthful and sufficient. The provision of misleading information is prohibited. This applies to all forms of marketing, including also Internet sites, network marketing and oral marketing.

The Consumer Protection Act (38/1978) also applies to the marketing of food products. The Act prohibits marketing procedures that violate good practice or are otherwise inappropriate from the consumers' point of view. Marketing that does not contain information necessary to the consumers' health or economic safety is always inappropriate.

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods stipulates on nutrition and health claims used in the packaging, presentation and advertising of foodstuffs. The Regulation defines the conditions on which foodstuffs may be promoted with nutrition and health claims and thus determines common rules and approval procedures for the use of such claims in all EU states.

The basic requirement for the use of health claims is that they are based on and substantiated by commonly accepted scientific evidence. Pre-approval shall be obtained for the scientific evidence before the claim can be used. As concerns the marketing of food supplements, only claims included in the list of authorised claims in the EU may be used, and for substances of plant origin, only those health claims are currently authorised on which the assessment procedure of the European Food Safety Authority EFSA is still ongoing and/or on which the Commission has not yet issued a decision. The use of all other health claims is prohibited.

The following claims, for example, are not allowed either

- claims making reference to recommendations of individual doctors or health professionals
- claims making reference to the rate or amount of weight loss
- claims suggesting that health could be affected by not consuming the product
- claims giving rise to doubt about the safety or adequacy of other foods
- claims encouraging excess consumption of the product
- claims making reference to changes in bodily functions which could give rise to fear in the consumers.

As claims shall be based on commonly accepted scientific evidence, the use of individual consumer experiences in the marketing of food supplements can be considered to be misleading. In Evira's opinion, an individual consumer, actor or celebrity can appear in an advertisement to tell about a claim, provided the claim has been authorised. In this context it is acceptable to state that the person in question has found the food or an ingredient of the food to have the effects referred to.

More information about claims can be found on Evira's website at:
http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/pakkausmerkinnat/ravitsemus-+ja+terveysvaitteet/

The list of authorised health claims is provided on the website of the European Commission at: http://ec.europa.eu/nuhclaims/.

More information about the control of marketing of medicines can be found on Fimea's website at:
http://www.fimea.fi/valvonta/markkinoinnin_valvonta

4.4.1 Medicinal claims

The Food Act and the Decree on food supplements both stipulate that properties relating to the prevention, treatment or curing of human diseases must not be presented or referred to in the labelling, brochures or advertising of food supplements or in any other way.

A medicinal impression must not be conveyed of the effects of the products, for instance by using medical terminology or by referring to changes, symptoms, ailments or pains caused by diseases in such a way that marketing attributes to the food product properties relating to the prevention, treatment or curing of diseases.

Only medicinal products, herbal medicinal products and traditional herbal medicinal products as well as homeopathic and anthroposophic preparations may be presented as having medicinal purposes. Marketing authorisation has to be applied for these products from Fimea, which assesses e.g. the quality, effectiveness and safety of the product.

Examples of claims that may not be used on food supplements

- suitable for milk allergy sufferers and lactose intolerants
- protects against bacteria and viruses
- helps hypertension sufferers
- Mrs. X's arteriosclerosis disappeared when she used preparation Y
- for anaemia
- using the word medicine, medicinal herb, or drug in the name of the food supplement (also in other languages)

4.4.2 Health claim

According to the EU Regulation on nutrition and health claims, a health claim is any claim that states, suggests or implies that a relationship exists between a food category, a food, or one of its constituents and health. A pictorial, graphic or symbolic representation in any form can also be considered a claim.

Health claims include e.g. the following

- Calcium is crucial for maintenance of normal bones. Iodine promotes normal energy metabolism
- Vitamin C helps reduce tiredness and fatigue
- Glucomannan when consumed with a low energy diet promotes weight loss
- Calcium and vitamin D help reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor in the development of osteoporotic bone fractures.

Only authorised health claims included in the list of authorised health claims may be used in the marketing of foods, provided the product meets the criteria defined for the use of health claims with respect to e.g. composition.

The list of authorised health claims is provided on the website of the European Commission at: http://ec.europa.eu/nuhclaims/

For substances of plant origin, only those health claims may currently be used on which the scientific assessment procedure of the European Food Safety Authority EFSA is still ongoing; they may be used until the assessment procedure has been completed and the Standing Committee of the European Commission has made a decision to either authorise or reject them. The use of all other claims is prohibited.

EFSA maintains a register of questions in which health claims regarding substances of plant origin can be searched by the Latin name of the plant. The Register can be found on EFSA's website at: http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?0&panel=NDA&foodsectorarea=26

Health claims are divided into:

1. **claims referring to normal body functions**

    a. role of nutrient or other substance in growth, development and body functions

    b. psychological and behavioural functions

    c. slimming, weight control, reduction in the sense of hunger or increase in the sense of satiety, or reduction of available energy from the diet

2. **claims referring to reduction of disease risk**

3. **claims referring to children's development or health**

Claims used on products specifically designed for children are always considered to be claims referring to children's development or health.

Health claims shall only be permitted, if certain additional information is included in the labelling, or if no such labelling exists, in presentation and advertising. Such additional information includes:

- the amount of the substance referred to in the claim in the daily dose
- a statement indicating the importance of a balanced and varied 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, and an appropriate warning for products that are likely to present a health risk if consumed in excess
- where a claim referring to the reduction of disease risk is used, the following statement shall be added: "*The disease has multiple risk factors and altering one of these may or may not have a beneficial effect*".

***** As the statement "*a food supplement must not be used as a substitute for a balanced diet*" is required also under the Decree on food supplements, Evira is of the view that the mandatory labelling according to both the Claims Regulation and the Decree on food supplements can be combined with the following sentence: "*A food supplement is not a substitute for a varied and balanced diet and a healthy lifestyle*."

4.4.3 Nutrition claims

According to the Claims Regulation, a nutrition claim is any claim which states, suggests or implies that a food has particular beneficial nutritional properties with regard to nutrients or other substances it contains, contains in reduced or increased proportions, or does not contain.

Only the health claims listed in the Annex to the Regulation may be used, and then only if they conform to the requirements specified in the Regulation. The minimum quantity of the nutrient required in the food for the nutrition claim to be used is defined in the Regulation.

Nutrition claims may concern e.g. energy, amino acids, fat and nutritional fibre as well as vitamins and minerals. If such claims are made on a food supplement, the food business operator must have evidence to substantiate the claims.

Nutrition claims include e.g. the following

- high-fibre or a source of fibre
- high vitamin or mineral content
- a source of omega-3 fatty acids

4.5 Information to be provided on food supplements in distance selling

Distance selling refers to marketing using a means of distance communication. ***Means of distance communication*** means any means which, without the simultaneous physical presence of the supplier and the consumer, may be used for the conclusion of a contract between those parties (Regulation (EC) No 1169/2011, Article 2). Distance selling covers e.g. sales by internet and telephone, mail order sales and teleshopping.

Pursuant to Article 14 of the Food Information Regulation, almost the same mandatory information shall be available to consumer on foods offered for sale by means of distance communication as on foods marketed through normal channels, with the exception of the minimum durability date and the "use by" date. The mandatory particulars are defined in Article 9 of the Food Information Regulation. The information shall be available **before the purchase is concluded** without the operator charging supplementary costs. All mandatory particulars shall be available at the moment of delivery. The mandatory information shall be provided in both Finnish and Swedish on food supplements sold through distance selling.

5 INTERFACES OF FOOD SUPPLEMENTS

Food supplements are foods that differ from other food categories in terms of their physical form and purpose of use. Food supplements may be very similar to some other food category, making it difficult to distinguish between different products. Food

supplements can also resemble medicinal products in their form and purpose of use, in some cases even in their composition. Interfaces between food supplements and other products are discussed in the following Sections.

5.1 Distinction from normal food products

Food supplements are foods that, as a rule, differ from other food categories in terms of their physical form and purpose of use. However, with some products it is more challenging to make a distinction, as a food supplement and a normal food can be identical in terms of their form, for example. Fibre preparations are an example of this; they can be marketed as normal foods to be added in e.g. porridge or yogurt in a desired amount or according to instructions for use. A fibre preparation can also be marketed as a food supplement for use as a concentrated source of fibre, if it is to be consumed in small unit quantities. This means that the food category of the product is determined based on its purpose of use, i.e. the purpose for which the food is marketed. A product that meets the criteria defined for a food supplement (cf. 3.1. Definition of food supplement) can be placed on the market as a food supplement, provided the labelling information referred to in regulations pertaining to food supplements is provided on the product and a food supplement notification has been submitted to Evira regarding the product (cf. Section 3.2).

Classification of confectionery and chewing gums

In Evira's view, confectionery and chewing gums are, as a rule, normal foods, or possibly fortified foods if vitamins or minerals have been added in them. However, based on their form, confectionery and chewing gums also meet the definition presented in the Decree on food supplements and they can be classified as food supplements, if their purpose of use is clearly characteristic of that of food supplements. Factors supporting classification as a food supplement also include, for example, a container provided with a child-proof lid or the product being clearly marketed as a food supplement and not as confectionery or a chewing gum.

Products marketed to athletes

Depending on their content, formulation and purpose of use, foods marketed to athletes are either

- dietary products (sports nutrition powders, bars, drinks)
- food supplements (e.g. tablets, capsules, powders consumed in small unit quantities)
- fortified foods (e.g. yogurt drinks, quarks and smoothies fortified with vitamins), or
- normal foods (e.g. cottage cheese, quark)

Protein, amino acid and carbohydrate powders, bars and drinks marketed to athletes are in most cases dietary products for athletes. Their composition must be suitable for athletes and fulfil the criteria set out in food laws.

Some foods marketed to athletes are classified as food supplements based on their purpose and manner of use as well as their energy content. Sports nutrition products classified as food supplements differ from other food products in their formulation, i.e. they are pills, capsules, powders or herb extracts, for instance. Products intended for use as a source of e.g. vitamins, minerals, amino acids, fibre, fatty acids and lecithin as well as various plant extract preparations are food supplements. The essential thing is that the amount of energy received from food supplements is low, whereas

normal foods designed for athletes contain high levels of energy and can even be used to replace a meal or a part of a meal. Food supplements are consumed in small unit quantities and because of this, drink-type products designed for athletes do not meet the definition of a food supplement.

Evira is of the view that if the amount of energy derived from the food supplement is not greater than 200 kJ (50 kcal) per day in the maximum indicated daily dose, it is of no significance in terms of the daily energy intake. A teaspoon or a table spoon (5-15 ml) of the product is considered a small unit quantity, provided however, that the volume of the daily dose of the marketed product is no more than 100 ml.

5.2 Distinction from fortified food products

The distinction between food supplements and fortified foods is not clear in all parts at present, and no common guidelines have been issued on EU level. Fortified foods refer to foods in which nutrients, most commonly vitamins or minerals, have been added. Fortified foods and food supplements share the same purpose of use: to supplement the diet. However, fortified foods are in terms of their physical form more similar to normal foods than to food supplements. Fortified foods include, for example, milk (fortified with vitamin D), sodas (fortified with vitamins and minerals), energy drinks (containing caffeine / guarana and vitamins of group B), juice drinks (fortified with vitamin C), and even bread in which vitamin D has been added. Fortified foods are also consumed in larger quantities than food supplements and often the amount of energy derived from them plays a significant role in the diet. Food supplements are consumed in small unit quantities and not designed to provide a significant amount of energy.

5.3 Distinction from foods for particular nutritional uses

Foods for particular nutritional uses are intended for vulnerable consumer groups and are often used to replace all of the daily meals. These groups of foodstuffs for which specific provisions have been set out regarding their composition and labelling include infant formulae and follow-on formulae, foods for special medical purposes and total diet replacements for weight control.

Foods for particular nutritional uses can be the sole sources of nutrition for their users, or at least cover part of the daily food intake. As a rule, foods for particular nutritional uses are not produced in the form of pills or capsules; foods in these forms are considered to be food supplements.

5.4 Distinction from medicinal products

According to Section 3 of the Medicines Act, a medicinal product is a product or substance intended for internal or external use to cure, alleviate or prevent a disease or its symptoms in humans or animals. Products or substances to be taken internally or externally for the purposes of establishing the state of health or the cause of a disease, or for restoring, correcting or modifying physiological functions in humans or animals are also considered to be medicinal products. Products marketed as medicinal products must always have a marketing authorisation from or be registered by Fimea.

Under the Medicines Act, Fimea is the authority who decides, when necessary, whether a substance or product is to be considered a medicinal product. Each product is classified specifically. Products are classified into medicinal products or non-medicinal products. The classification is based both on the composition and the effect of the product, as well as on its intended purpose of use. Products used in accordance with the definition of a medicinal product (Medicines Act, Section 3) have a medicinal use and are thus medicinal products. Instructions for the filing of a classification application are provided on Fimea's website.

Products classified as medicinal products may not be marketed as foods. The operator is responsible for the marketing of their product and for the selection of the correct sales channel, as well as for removing from the market any products classified as medicinal products (Food Act, Section 16).

Medicines list

Fimea has confirmed and issued a decision on a list of medicines (207/2015), which includes three Annexes. The decision includes a list of the substances and herbals that are in medicinal use in Finland (Annexes 1 and 2), as well as a list of medicinal substance analogs and prohormones (Annex 1 A), which based on their effect are always considered comparable to medicinal products supplied by prescription only. The list of medicines is not exhaustive. All substances and herbals that meet the definition of a medicinal product under the Medicines Act are considered medicinal products.

According to the decision, medicinal products include the substances listed in Annex 1 to the list of medicines, and the salts and esters of those substances; the doping substances listed in the valid Government Decree on doping substances as referred to in Chapter 44, Section 16 (1) of the Criminal Code of Finland; and the substances listed in Annex 1 A.

Medicinal products also comprise the following substances or products insofar as they are used in accordance with Section 3 of the Medicines Act:

- the herbals listed in Annex 2 to Fimea's decision and the active substances derived from them which include herbal preparations (e.g. extracts, tinctures, expressed juices) and comparable active substances of animal origin, as well as medicinal products manufactured from them;
- certain products or substances that deviate from normal medicinal products in form, composition, method of manufacture or mechanism of action, such as radioactive medicinal products, allergen products, vaccines and medicinal gases, medicinal products used in advanced therapies as well as medicinal products derived from human blood and plasma; and
- vitamins and mineral products.

In some cases, products containing substances included in the list of medicines and/or herbals (e.g. Echinacea purpurea) may be marketed as food products. In such a case the use of the product must be based on something other than the medicinal effect of the product or of a substance or plant contained in it (cf. definition of a food supplement, Section 3.1). In other words, there may in some cases be on the market substances that are identical or products that are made from the same plants, but different requirements are applied to them depending on whether they are placed on the market in accordance with regulations on medicinal products or food regulations.

Evira recommends that Fimea be contacted for an assessment of the classification need, if the food supplement contains substances listed in the medicines list or

herbals. Fimea may classify a product as a medicine also on its own initiative, if the product meets the criteria defined for a medicine.

The list of medicines can be found on Fimea's website at:
http://www.fimea.fi/valvonta/luokittelu/laakeluettelo

Herbal medicinal products and homeopathic products

Herbal medicinal products are divided into three categories depending on the product: herbal medicinal products, traditional herbal medicinal products and anthroposophic products. Fimea controls all herbal medicinal products.

Herbal medicinal products are medicinal products that contain herbal substances or herbal preparations or a combination of these as their active agents.

A traditional herbal substance refers to a medicinal product for human use that contains herbal substances, herbal preparations or a combination of these as its active agents. In addition, it must fulfil the criteria for registration set out in Section 22 (1) of the Medicines Act. A traditional herbal medicinal product may also contain vitamins or minerals, if they promote the effect of the herbal active agents.

A homeopathic preparation is defined as a medicinal product that has been manufactured from homeopathic stocks using the homeopathic manufacturing procedure described in the European Pharmacopoeia. Anthroposophic preparations are considered to be such products. Homeopathic and anthroposophic products may be subject to a marketing authorisation or registration.

The labelling of a food supplement is distinctly different from that of an herbal medicinal product (cf. Figure 5). The labelling on herbal medicinal products is determined on the basis of the Medicines Act. For example, the labelling of a traditional herbal medicinal product shall contain the statement (in Finnish and in Swedish) "*TRADITIONAL HERBAL MEDICINAL PRODUCT*" and "*Consult a doctor if the symptoms persist or if adverse effects occur during the use of the product*". The labelling shall also indicate the registration number (R xxx FIN)".

The labelling of homeopathic and anthroposophic products, both licensed and registered, shall include the statement (in Finnish and in Swedish) "HOMEOPATHIC PRODUCT" or "*ANTHROPOSOPHIC PRODUCT*" and the registration number (H xxx FIN).

More information about herbal medicinal products and homeopathic products can be found on Fimea's website at:
http://www.fimea.fi/myyntiluvat/kasvirohdoslaakkeet_ja_homeopaattiset_valmisteet.

Figure 5. *An example of the label of an herbal medicinal product.*

Fimea controls medicinal products, their manufacture, distribution, marketing and sales. Medicinal products may only be sold to the public from pharmacies, subsidiary pharmacies or licensed medicine chests. As far as herbal medicinal products and homeopathic or anthroposophic products are concerned, a grocery store may also act as a sales channel. Fimea determines the sales outlets for products in connection with the granting of a marketing authorisation or registration.

In order to make a clear difference between food and medicinal products and to eliminate the possibility of misunderstanding among consumers, Evira finds that medicinal products and food must be clearly differentiated from each other in advertising. They must not be marketed in a misleading manner using the same material and common advertisements. Pursuant to Section 9 of the Food Act (23/2006), the information given about food in food packaging, presentation and advertising, or in some other way in connection with marketing must be truthful and sufficient. It is also prohibited to provide misleading information on foods. Article 16 of the General Food Law Regulation also lays down provisions on the prohibition of misleading information. Section 25b of the Decree on Medicines (693/1987) also stipulates that in marketing medicinal products to the public, advertisements must make it clear that they are advertisements marketing medicinal products.

Table 4. Foodstuffs and medicinal products are subject to different criteria for entering the market and to separate control systems.

	FOOD PRODUCTS			**MEDICINAL PRODUCTS**
Products	Conventional food	Novel food	***Food supplements*** Some foods for particular nutritional uses Fortified food	Medicinal products: – ordinary medicinal products – traditional herbal medicinal products – herbal medicinal products – Homeopathic and anthroposophic products
Criteria for entering market	No advance control	Authorisation procedure	Notification procedure	Authorisation procedure or registration
Authorising or notification authority		Evira EU Commission	Evira	Fimea European Medicines Agency EMA
Control	• In-house control • Food control authorities in municipalities and Regional State Administrative Agencies • Customs (imports and internal market trade) • Evira/ Veterinary border control and first destination control • Evira			Fimea

5.5 Distinction from health care equipment and supplies

Pursuant to the Finnish Medical Devices Act (629/2010), health care equipment and supplies refer to an instrument, equipment, device, software, material or some other devices or supplies used alone or as a combination or software necessary for their proper operation, which according to the manufacturer are intended to be used

a) to diagnose, prevent, monitor, treat or alleviate disease,
b) to diagnose, monitor, treat, alleviate or compensate an injury or handicap,
c) to investigate, replace or modify the human body or a physiological process; or
d) as a contraceptive.

The operation of the aforementioned devices and supplies can be promoted by pharmacological, immunological and metabolic means, provided their primary intended effect is not produced by those means.

Devices and supplies for health care purposes shall be designed, manufactured, packaged and labelled in such a manner that they are suitable for the purpose intended by the manufacturer. The manufacturer is responsible for

- the conformity of the product to the essential requirements applied to it
- the product achieving the performance defined for it
- the product not endangering the safety of the patient, the user or any other person.

The manufacturer must specify the intended use of the product as referred to in the definition of health care equipment and supplies.

Health care equipment and supplies placed on the market shall be given a CE marking, excluding some exceptions. The CE marking constitutes the manufacturer's

warranty that the equipment or supplies meet the essential requirements applied to them.

In some cases also a preparation for oral consumption can be considered to be a device, if its intended use and effect mechanism meet the criteria of health care equipment and it fulfils the essential requirements applied to the equipment.

More information about health care equipment and supplies is provided on Valvira's website at:
https://www.valvira.fi/terveydenhuolto/terveysteknologia/tuotteen_markkinoille_saattaminen/terveydenhuollon_laitteet_ja_tarvikkeet.

6 NOTIFICATIONS REQUIRED OF FOOD BUSINESS OPERATORS

6.1 Notification of a food establishment

Food supplements are foodstuffs that, as a rule, may only be manufactured, stored, marketed, served or otherwise handled in food establishments. A food establishment refers to any building or premises or part thereof or other outdoor or indoor space in which food intended for sale or conveyance is prepared, stored, transported, marketed, served or otherwise handled, excluding, however, places of primary production.

A written application for approval of setting up or using a food establishment is to be submitted to the municipal food control authorities in good time before starting operation. The notification referred to in Section 13 of the Food Act must also be submitted, if essential changes take place in operation. A notification to the municipal food control authorities is also required in case of discontinuation or end of the operation of the food establishment or change of operator.

The aforesaid also applies to e.g. pharmacies, gyms, sports goods stores, sports departments of department stores, care establishments, hairdressers or erotic stores selling food supplements, or to establishments set up for distance selling (e.g. warehouses), such as mail order sales, network marketing and online marketing.

Operation carried out without an actual physical food establishment is also subject to a notification to the municipal food control authorities (***notification of a virtual food establishment***). Such operation includes agency operation as well as various forms of distance selling, such as online and telemarketing, mail order sales and network marketing of food supplements.

Even if operation connected to food supplements is on a small scale, it cannot be considered to be low-risk operation due to the associated product safety risks. Because of this, a notification shall always be submitted to the municipal control authorities of any operation involving food supplements.

Municipal authorities provide instructions and information on what the notification must contain. An in-house control plan is also required of the operator of a food establishment (cf. Section 7.1.1).

Food establishments handling uncooked, unprocessed raw materials of animal origin, such as raw milk, raw meat or fish before they are delivered for retail sales, shall apply for an approval from the appropriate control authorities before the beginning of

operations or any substantial change in operations (establishment). A written in-house control plan shall be presented to the control authorities with the application (cf. Section 7.1.1).

6.2 Food supplement notification

Pursuant to Section 8 of the Food Act, food business operators who manufacture or import (from the internal market or third countries) food supplements or have food supplements manufactured, must submit a notification of this operation to Evira. The matter is discussed in more detail in Section 3.2.

Instructions for submitting the notification are provided on Evira's website in Finnish, Swedish and English at: http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/ravintolisat/ravintolisailmoitus/.

7 CONTROL

7.1 In-house control

In-house control as referred to in the Food Act requires that each operator have adequate and valid information on the food supplements they produce, process, manufacture, import, export, package, market, serve or distribute as food.

In addition to the food product itself, in-house control focuses on controlling the conditions of its manufacture, processing, transport, storage and marketing to the extent that the operator is involved in the chain.

In the manufacture and marketing of food supplements, every operator in the chain is responsible for its own operation. Information on the ingredients used must be traceable from raw materials to the final product. Operators must be prepared to trace a defect found in a food supplement upstream in the production chain. In case a product has to be withdrawn, the destination where defective products have been sent must be known.

In-house control consists of identification, monitoring and written documentation of risks and so-called critical control points. In-house control also includes an up-to-date plan for action in case a food supplement proves to be in violation of regulations.

The conformity of products can be monitored in the in-house control procedure through certificates obtained from suppliers of raw materials and through verification of the validity of the formula. The conformity of labelling must also be checked. In some cases in-house control samples have to be taken and examined. Where necessary, analyses are carried out to monitor e.g. the microbiological quality of raw materials and products, the composition of food supplements, for instance vitamin and mineral levels, and the amounts of other characteristic substances or the presence of GMO substances.

Operators shall prepare the in-house control plan and implement it in their operations. Municipal food control authorities will provide advice on the preparation of the plan.

7.1.1 In-house control plan

Pursuant to Section 20 of the Food Act, food business operators are required to prepare a written plan for in-house control, and to maintain it up-to-date, comply with it and keep records of the implementation of the plan. The in-house control plan shall describe the critical points associated with the operations and the management of the associated risks (known as critical control points). The in-house control plan shall be adequate in relation to the operations and shall provide an appropriate description of the operations of the food business operator. If necessary, a sampling and analysis plan shall be attached to the in-house control plan as well as information about the laboratories used for the analysis of the samples taken as part of in-house control.

The in-house control plan referred to in the Food Act is required also of food business operators who do not have a physical food establishment (so-called virtual establishments). The in-house control plans of notified food establishments are not submitted to the municipal control authorities for approval, but an in-house control plan that meets the requirements set out for in-house control shall be available for presentation to the municipal control authorities in the first inspection, at the latest. Although no decision is made on the approval of the in-house control plan, control authorities may order the operator to supplement or correct the plan.

More information about in-house control is provided on Evira's website at: http://www.evira.fi/portal/fi/tietoa+evirasta/asiakokonaisuudet/omavalvonta/elintarvikkeet/.

7.1.2 Product defects and withdrawals

If e.g. in-house control or a complaint from a consumer (e.g. adverse reaction report) gives the food business operator cause to believe or suspect that a food the operator has imported, produced, processed, manufactured or distributed is not in conformity with food safety requirements or causes a health hazard, the operator shall immediately take action to investigate the matter and contact food control authorities of the municipality concerned (in practice the health inspector). The operator may also be informed by authorities of any suspicions regarding the safety or conformity of the food supplement (Figure 6).

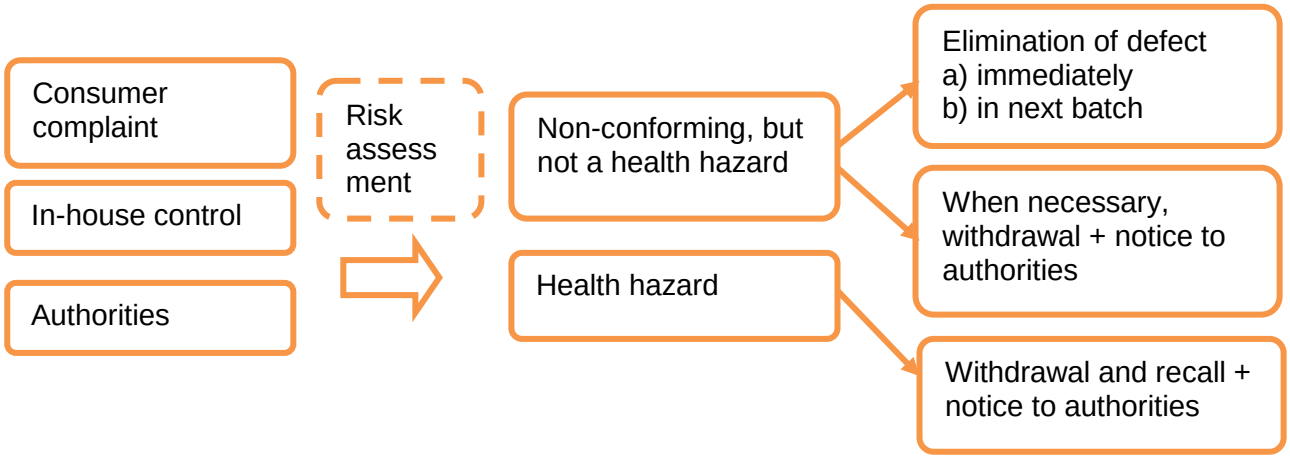

Figure 6. *An example of action in case a product defect is identified*

When suspicion arises, the operator must immediately start a risk assessment process to assess the nature and severity of the defect. In case of a suspected adverse reaction related to a food supplement placed on the market, the operator shall assess the possible link between the food supplement and the adverse reaction, as well as the required action to eliminate the adverse reaction and to prevent recurrence of similar adverse reactions. Municipal food control authorities evaluate the adequacy of the operator's risk assessment process, and if necessary, steer the actions. The operator shall include the risk assessment process in the in-house control plan.

If a food supplement proves to have adverse effects on health and thus not be in conformity with regulations on the safety of food, the food business operator must without delay start procedures to withdraw the food supplement from the market and notify the food control authorities (withdrawal notice to the municipal authorities and to Evira). The information to be submitted to the authorities shall include information about the defective product, the nature of the defect, the traceability of the product (where the product has been acquired and where it has been delivered), the number of defective products and actions that have already been implemented. It is important that all the applicable points of the withdrawal notice are filled out explicitly and with care.

Consumers must also be informed of the withdrawal, if the product has already reached them (EC/178/2002, Article 19). The operator shall announce the reason for the recall using effective and appropriate means of communication and, if necessary, give advice to the consumers on how to return the defective product.

The in-house control plan of the operator shall include a withdrawal plan.

More information about withdrawal and the obligations of the operator is provided on Evira's website at:
http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/takaisinvedot/.

Tips for in-house control to operators who manufacture or import food supplements or have them manufactured

It shall be verified that

- only authorised vitamins, minerals and compounds of them are used in the food supplement
- the microbiological quality of raw materials and finished food supplements is good
- raw materials do not contain hormones or doping substances or any other prohibited substances (cf. Section 3.11)
- only authorised additives, aromas and enzymes are used and their conditions for use are fulfilled (cf. Section 3.4)
- the history of use as food of the ingredients of the food supplement prior to May 1997 has been verified and the food supplement does not contain novel food ingredients not authorised in EU (cf. Section 3.5)
- the food supplement does not contain medicinal products as referred to in Section 3 of the Medicines Act. If the food supplement contains substances included in the list of medicinal products, the operator is advised to apply for a classification from Fimea (cf. Section 3.6)
- food supplements and their raw materials do not contain contaminants in amounts exceeding the limit values (cf. Section 3.9)
- the raw materials of food supplements do not contain pesticide residues in excess of the permitted maximum levels (cf. Section 3.10)

- the safety and suitability of packaging materials and other food contact materials has been verified
- labelling matches the composition
- labelling is correctly executed (cf. Section 4)
- any irradiation of dried spice herbs, spices and spice plants is indicated in the labelling in accordance with regulations (cf. Section 4.3)
    - Note. The irradiation of other ingredients is not allowed (Decree 852/2000 of the Ministry of Trade and Industry on treatment of foodstuffs with ionizing irradiation)
- appropriate information is provided in labelling on genetically modified ingredients (cf. Section 4.3)
- food supplements marketed as organic products (organic, bio, eco, etc.) meet the criteria set out in the Regulation on organic products and the labelling presents appropriate information (cf. Section 4.3)
- the necessary restrictions on use and warnings are shown, taking potential risk groups into account
- marketing efforts comply with regulations and good practice (cf. Section 4.4)
- the food supplement notification has been submitted to Evira, it is up-to-date and available for presentation on request (cf. Section 2.2)
- the traceability of food supplements can be verified on the basis of documents (e.g. supplier's delivery notes, invoices or other stock records). It shall also be possible to trace food supplements not delivered directly to consumers.

Tips for in-house control of food supplements to distributors

Operators selling food supplements must verify from the suppliers that

- the food supplement notification has been submitted to Evira (cf. Section 2.2)
- the mandatory labelling on food supplements is presented in Finnish and Swedish
- labelling information is legible and easily visible
- the food supplement or any ingredient of it is not a medicinal product and does not contain prohibited substances, such as hormones or doping substances (cf. Sections 3.9 and 3.11)
- any genetically modified ingredients of the food supplement are indicated in the labelling (cf. Section 4.3)
- the labelling of food supplements marketed as organic products (organic, bio, eco, etc.) indicates that the product is subject to organic control, i.e. the code number of the organic control body (cf. Section 4.3)
- no medicinal claims are made in the labelling of the food supplement or in its marketing and the claims made on the product are truthful (cf. Section 4.4)
- the supplier and the food supplement are traceable.

The condition of the products should be inspected when they are received. In-house control also includes the monitoring of shelf life and correct storage temperatures, for example.

7.2 Regulatory control

Food supplements are primarily controlled by the food control authorities in the municipalities of manufacture and importation, but all municipalities carry out market control on food supplements. The Customs control food supplements imported from third countries, and through random tests as part of market control also food supplements imported from EU Member States. The border control unit of Evira

controls raw materials of animal origin imported from third countries for the manufacture of food supplements. Evira steers control activities across the country.

7.2.1 Finnish Food Safety Authority Evira

Evira plans and steers food control also on food supplements through guides and advisory letters, and by providing information and training.

Food supplement notifications are submitted to Evira. The operator who manufactures or imports food supplements or has them manufactured must submit a notification, including the required enclosures, on a food supplement to be placed on the market or on any changes made in the composition of a food supplement. The matter is discussed in more detail in Section 2.2. Evira does not control the conformity of food supplements when it processes the notifications, but forwards the notifications to municipalities for information and for control purposes. A summary of the data provided in the notifications is sent to the Regional State Administrative Agencies, Fimea, the Customs, and if necessary, to other authorities. The municipalities and the Customs control the validity of food supplement notifications in connection with inspection visits and analysis activities, or by means of projects, if necessary.

Evira can include a national control project regarding food supplements in its plans and annual control programmes. Such projects may focus on certain sites (such as gyms), certain food supplement groups (such as calcium preparations) or marketing (nutrition and health claims).

Evira and the Customs Laboratory have agreed that Evira will forward the analysis findings of the Laboratory and any actions taken by the Customs to municipalities four times a year for information. Moreover, if the Customs suspect that defective food supplements have entered the domestic market, Evira will ask the municipal authorities to verify through control action that the operator has taken adequate efforts to rectify the defects and, if necessary, has started a withdrawal procedure regarding the defective food supplements.

If necessary, Evira together with the State Regional Administrative Agencies and municipal authorities can make inspection visits to manufacturing facilities of food supplements and to warehouses of importers or packagers.

7.2.2 State Regional Administrative Agencies

State Regional Administrative Agencies plan and guide the control of food supplements and control compliance with laws in their respective regions. They get summary information on food supplement notifications submitted to Evira and forwarded to municipalities for purposes of control. The Agencies monitor and supervise municipal control on food supplements, e.g. actions taken by municipalities on the basis of the analysis findings of the Customs.

The Agencies plan and implement together with Evira, the municipal control authorities and the Customs the market control projects targeted at food supplements which are included in the control programme. Representatives of the Agencies make inspection visits to control sites together with municipal control authorities on request or on their own initiative, e.g. in connection with control projects. The Agencies also train and instruct municipal authorities and on request provide interpretations on provisions related to food supplements.

7.2.3 Municipal control authorities

Municipal food control authorities enforce food control in practice and provide advice to food business operators, when necessary. In the case of food supplements, control focuses primarily on manufacturers, packagers, importers and wholesalers.

Food establishments

Like other foodstuffs, as a rule food supplements may only be manufactured, stored, marketed or otherwise handled in food establishments. The objective of control authorities must be to include all companies involved in food supplement business under their control. This also applies to e.g. pharmacies, gyms, sports goods stores, sports departments of department stores and hairdressers selling food supplements, or warehouses set up for mail order sales, network marketing or online marketing. The food establishment notifications of the operators are submitted to the municipality concerned (cf. Section 6.1).

The municipal food control authorities assess the risks involved in the operation covered by the notification and prepare a preliminary control plan. Based on the risk assessment, the first inspection is carried out within one, three or six months of the start of the food establishment operation. The first inspection is the inspection referred to in the control plan and it is subject to a fee.

The control of food establishments is mainly focused on verifying that the operation carried out in the establishment and the scope of the operation are consistent with the information provided in the notification of the food establishment. If it is found that operations of which no notification has been submitted are carried out in the food establishment, the operator shall be advised to submit a notification to ensure that the operations are known to the control authorities and covered by control actions. Where the scale of operations exceeds the scale described in the notification, the inspector will assess if the capacity of the food establishment is sufficient to ensure such a production scale without food safety risks, and will take control actions to have the operator rectify the situation.

More information about the control of food establishments is available in Evira Guide 16025/3 (Guide on food hygiene in food establishments subject to a notification) and in Evira guide 16043/1 (Risk-based control of in-house control in food establishments), which can be found on Evira's website at: http://www.evira.fi/portal/fi/tietoa+evirasta/lomakkeet+ja+ohjeet/elintarvikkeet/elintarvikehuoneistot/.

Product control and control of in-house control

The responsibility for the composition, labelling and marketing of the product rests with the food business operator operating in Finland, who is indicated in the labelling, or some other Finnish distributor of the product. It is important to inspect the effectiveness of the in-house control of the food business operator responsible for the product. Therefore the product control carried out by the municipal authorities focuses mainly on controlling the effectiveness of the in-house control of the food business operator (cf. Section 7.1). Product control is implemented in accordance with the Oiva inspection instructions (link to the instructions: https://www.oivahymy.fi/portal/fi/yrityksille/tarkastusohjeet/

Inspections that particularly concern criteria set out for food supplements consist of random inspections of 1-3 products, paying attention to e.g. the following issues:

- the food supplement meets the criteria set out in the definition of a food supplement,
- the food supplement is not a medicinal product and does not contain hormones or doping substances,
- the composition of the food supplement with respect to characteristic substances and their amounts is consistent with the labelling information,
- the food supplement only contains authorised vitamins and minerals and their compounds,
- the compounds of vitamins and/or minerals used in the product meet the purity criteria set out for them (applies to operators who manufacture food supplements or have them manufactured),
- the vitamin and/or mineral that is the characteristic substance of the food supplement is contained in the finished product in a significant amount (at least 15% of the daily reference intake in the recommended daily dose),
- the characteristic substance or the amount of the substance does not present a hazard to health,
- the amounts of characteristic substances are appropriately indicated,
- the labelling of the food supplements provides the mandatory information referred to in the Decree on food supplements,
- a notification of the food supplement has been submitted to Evira.

The product control of food supplements may cover also other areas, such as issues related to labelling and marketing, or issues related to the history of use, purity or traceability of the ingredients, for example.

If the product labelling does not indicate the name of a Finnish food business operator, the distributor of the product must nevertheless know who the supplier of the product is. The General Food Law Regulation of the EU (178/2002) stipulates that responsibility for products and their traceability is transferred from one operator to the next in the product chain.

7.2.4 The Customs

The Customs have a nationwide sampling and control network in place for the control of imported food. The Product Safety Unit of the Customs is in charge of regulatory operations and the Customs Laboratory carries out the analyses.

The responsibility for the control of food supplements manufactured within the **internal market of EU** rests primarily with the control authorities of the country of manufacture. According to EU food control regulations, however, samples may be taken at all stages of production, distribution and marketing. The purpose of this random sampling is to verify that control is effective in the country of origin and the required labelling information is provided on food supplements also in Finnish and in Swedish.

The Customs control food supplements imported from the internal market through random tests of samples taken in the importers' warehouses. This control is based on the annual control plan of the Customs. Since these are internal market samples, the products are not banned pending the analyses. The holder of the goods receives a report of the analyses carried out. The fee laid down in the Decree of the Ministry of Finance is charged for the analyses. If non-conforming products are found, the Customs will ban the marketing of the goods still in stock. If there is an obvious health

hazard, the goods already on the market will also have to be withdrawn by the operator (cf. Section 7.1.2). The Customs inform Evira about the matter, and Evira sends a request to municipal food control authorities to verify that the operator has implemented withdrawal, and to take any other action as required.

Food supplements are also imported to Finland from **countries outside the EU.** The control of these products falls within the scope of responsibility of the Customs. The Customs carry out an assessment of the need to take samples on the basis of the Customs' control plan in connection with the clearance of the goods. The distribution of goods of which samples are taken is discontinued pending the analyses. When the analyses have been completed, the clearance of conforming products is continued. Non-conforming food supplements may, if deemed appropriate and with permission of the control authorities, be returned to the foreign distributor or manufacturer, removed from the country, destroyed under the supervision of the Customs or modified so as to comply with regulations. The fee laid down by the Ministry of Finance is charged for the control. Evira forwards information on control carried out by the Customs to municipalities for the control of the in-house control implemented by importers of food supplements.

The classification of preparations as medicinal products is in other countries markedly different from the classification system applied in Finland. In case of doubt, the Customs always consult Fimea for a classification of the product before taking control action.

7.2.5 Unit for import and marketing control at Evira

Control of places of first arrival

Responsibility for the control of places of first arrival has been assigned to the state, with Evira as the competent authority. Control is based on Decree 118/2006 of the Ministry of Agriculture and Forestry on activities at places of first arrival under the Food Act. As the control of places of first arrival is assigned to state level, the associated inspections are always carried out in the same manner regardless of the municipality where the activities stipulated for the place of first arrival are carried out by the operator.

Veterinary border control

The Act on Veterinary Border Inspection (1192/1996) lays down requirements for food and other products of animal origin imported from outside the EU. As far as food supplements are concerned, these requirements (approved country and establishment of origin, and health certificate) usually only apply to raw materials imported for the manufacture of food supplements. Thus import requirements for food and other products of animal origin do not apply to food supplements packed e.g. in capsule or tablet form and ready for distribution to end users (e.g. colostrum capsules, royal jelly tablets). The food or other product of animal origin is in such food supplements part of the ingredient content of the food supplement, and in this case the final product, i.e. the food supplement ready for consumption is not defined as a food product of animal origin.

A special import licence is required for the importation of some raw materials. Apart from import requirements, valid legislation stipulates that a veterinary border examination be carried out on raw materials imported for the manufacture of food supplements, when they are imported to the EC area. Veterinary border control applies to raw materials with a CN code listed in the Annex to Commission Decision

2002/349/EC. The CN code of the product to be imported must be checked with the Customs before importation. As concerns raw materials that contain a substance of animal origin and are to be imported from outside the EU for the manufacture of food supplements, the border veterinarians control the fulfilment of import requirements.

An advance notification must be made to the relevant border control post, if raw materials subject to veterinary border control are to be imported for the manufacture of food supplements. The notification shall be submitted one working day before the importation during the opening hours of the border control post. The notification must be submitted electronically using the TRACES information system.

More information about veterinary border control is provided on Evira's website at: http://www.evira.fi/portal/fi/elintarvikkeet/tuonti+ja+vienti/tuonti+eu+n+ulkopuolelta/elainlaakinnallinen+rajatarkastus/.

7.3 Coercive mechanisms and sanctions

Control actions are on food supplements implemented by virtue of the Food Act.

The food control authorities may make a request which is more lenient than an order or a prohibition, in cases which do not involve an actual health hazard or intentional misleading. The request for corrective action should, however, always be given in writing and a deadline should be set for complying with the request. A temporary prohibition may be used if, for instance, the labelling of the food supplement must be corrected or a notification of a food supplement has not been made to Evira despite a request to do so. A periodic penalty payment is imposed in situations, which involve repeated violation of provisions and orders of the control authorities, or when the severity of the situation warrants a periodic penalty payment to enforce the decision issued. Municipal food control authorities may under the Food Act request executive assistance from the police, if necessary.

In addition to coercive mechanisms, the Food Act defines the cases in which the municipal food control authorities are under an obligation to request the police to conduct a pretrial investigation. This obligation arises, for example, in cases where the operator has either intentionally or due to negligence provided misleading information about the food or the properties of the food, and the act is not minor.

Table 5. Indicative examples of action taken by control authorities in various situations.

Example 1. A food supplement notification has not been submitted. A notification must be submitted to Evira when a food supplement is placed on the market.	
Authorities in municipality of manufacture or importation	Issue a written request to submit a notification and set a deadline. If a notification is not submitted to Evira within the deadline, the control authorities issue an order which in addition to the requirement for a food supplement notification orders that the sales/placing on the market of food supplements shall be discontinued until a food supplement notification has been submitted to Evira.
The Customs	Issue a written warning about the matter.
Example 2. Food supplements are marketed/imported without labelling in Finnish and in Swedish.	
Authorities in municipality of manufacture or importation or marketing	Issue an order prohibiting the placing on the market of the food supplements until the labelling has been corrected.
The Customs	Prohibit the importation or placing on the market of the food supplements until the labelling has been corrected.
Example 3. The food supplement contains a substance listed in Annex 1 or 1A to the List of Medicines or an herbal listed in Annex 2.	
Authorities in municipality of manufacture or importation	Request to see the classification decision of Fimea. In the absence of a decision, instruct the operator to acquire one or to contact Fimea for an assessment of the classification need.
The Customs	Request to see the classification decision of Fimea. In the absence of a decision, prohibit the importation of the food supplement until the operator has acquired a decision or contacted Fimea for an assessment of the classification need. In internal market control, issue a written warning to the operator.
Example 4. A food supplement classified as a medicinal product is for sale in retail stores. Products classified by Fimea as medicinal products may not be marketed as food.	
Authorities in municipality of manufacture or importation or marketing	Inform Fimea about the matter directly or inform Evira, who forwards the information to Fimea. Fimea is under the Medicines Act authorised to take action.
Example 5. The food supplement is suspected of causing/having caused adverse health effects.	
Municipal control authorities, primarily in municipality of manufacture or importation	Impose a marketing ban on products in stock and contact Evira. Instruct the food business operator to withdraw the product from the market and to inform consumers, if necessary.
The Customs *Evira/Border veterinarian*	Prohibit the importation or placing on the market of the product and contact Evira.
Evira	Implements action on national level, if necessary, and submits the RASFF (Rapid Alert System for Food and Feed) notification to the Commission.
Example 6. The food supplement is marketed using medicinal claims.	
Municipal control authorities	Issue an order prohibiting the sales/marketing of food supplements until medicinal claims have been removed from labelling. Instruct the operator to discontinue medicinal marketing in forms other than labelling. If the operator fails to obey, Evira is informed about the matter and Evira prohibits marketing, imposing a periodic penalty payment to enforce the prohibition, if necessary.
The Customs	Prohibit the importation or placing on the market of the food supplements until medicinal claims have been removed from labelling.
Evira	Prohibits medicinal marketing in forms other than labelling. Imposes a periodic penalty payment to enforce the prohibition, if necessary.
Example 7. The distributor of a food supplement has no in-house control plan or the plan is deficient.	
Control authorities in municipality of marketing	Order the food business operator to draw up or supplement an in-house control plan within a deadline.

Example 8. The manufacturer, packager or importer of a food supplement has no in-house control plan or the plan is deficient.	
Control authorities in municipality of manufacture, packaging or importation	Order the food business operator to draw up or supplement an in-house control plan within a deadline.
Example 9. The composition of a food supplement is not consistent with labelling but there is no health hazard involved.	
Control authorities in municipality of manufacture, packaging or importation	Assess if the error is major or minor. If, for instance, the product is sold as a source of substance "x" and the product does not contain the said substance or only contains it in very low levels, the error is considered to be major (misleading of consumers). False labelling information on additives, ingredients missing from the list, distinct deviations in nutrient quantities etc. are also major errors. The sales/marketing of the product is ordered to be discontinued and the operator is instructed to correct either the composition or the labelling within a deadline and, if necessary, to submit a new food supplement notification to Evira. In the case of a labelling error that could cause a health hazard (e.g. an allergen is not indicated), the procedure described in Example 5 is followed.
The Customs	In the case of a major error, prohibit the importation or placing on the market of the food supplement until the labelling information has been corrected. In the case of a minor error, instruct the importer to correct the labelling before importing the next batch.
Example 10. Genetically modified soy is used in the food supplement, but this is not indicated in labelling.	
Authorities in municipality of manufacture or importation	Instruct the operator to correct the labelling or to change the raw material within a deadline. An operator who is found to repeat the same error is ordered to discontinue the marketing of food supplements until the labelling has been corrected.
The Customs	Prohibit the importation or placing on the market of the food supplement until an indication of genetically modified ingredients has been added in the labelling of products in the importer's warehouse.
Example 11. A food supplement with adverse health effects is marketed online.	
Municipal control authorities	Establish contact information for the distributor. In case of a Finnish online distributor with a warehouse in Finland, forward the matter to the distributor's municipality of domicile and to Evira for information and for action. In case of a foreign online distributor carrying out marketing in Finnish, forward the matter to Evira for information and for action.
Evira	Reports the matter to the control authorities of the country concerned for information and for control action.
Example 12. The food supplement contains an irradiated component not included in the list of components permitted for irradiation in Decree 852/2000 of the Ministry of Trade and Industry, or the component has been irradiated at a facility not approved by the EU.	
Municipal control authorities	Impose a marketing ban on products in stock and contact Evira. Instruct the food business operator to withdraw the product from the market and to inform consumers, if necessary.
The Customs *Evira/Border veterinarian*	Prohibit the importation of the products and contact Evira.
Evira	Implements action on national level, if necessary, and submits the RASFF (Rapid Alert System for Food and Feed) notification.

8 LEGISLATION AND NORMS

The list of Acts and Regulations below lists the referred Acts and Regulations and indicates in parentheses the shorter form of the name of the Act or Regulation used in this Guide.

Food laws

- Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- Finnish Food Act 23/2006
- Decree 78/2010 of the Ministry of Agriculture and Forestry on food supplements
- Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements
- Commission Regulation No 1170/2009/EC on the list of vitamins and minerals and their forms that can be added to foods, including food supplements
- Decree 1161/2014 of the Ministry of Agriculture and Forestry on chargeable services provided by the Finnish Food Safety Authority
- Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods
- Decree 121/2010 of the Ministry of Agriculture and Forestry on foods for particular nutritional uses
- Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council on additives
- Commission Regulation (EU) No 231/2012 laying down specifications for food additives
- Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods
- Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes
- Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients
- Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs
- Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers
- Decree 834/2014 of the Ministry of Agriculture and Forestry on the provision of food information to consumers
- Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed
- Council Regulation (EC) No 834/2007 on organic production and labelling of organic products

- Decree 852/2000 of the Ministry of Trade and Industry on treatment of foodstuffs with ionizing irradiation
- Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin
- Decree 118/2006 of the Ministry of Agriculture and Forestry on activities at places of first arrivals
- Finnish Act on veterinary border inspection 1192/1996
- Commission Decision 2002/349/EC laying down the list of products to be examined at border inspection points
- Commission Decision 2007/275/EC concerning the lists of animals and products to be subject to controls at border inspection posts

Laws on medicinal products

- Finnish Medicines Act 395/1987
- Decision 207/2015 of the Finnish Medicines Agency Fimea on medicinal products list
- Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use
- Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use

Other laws

- Finnish Alcohol Act 1143/1994
- Finnish Criminal Code 39/1889
- Government Decree 705/2002 on doping substances as referred to in Chapter 44, Section 16 (1) of the Criminal Code
- Finnish Narcotics Act 373/2008
- Government Decree 1130/2014 on psychoactive substances banned on the consumer market
- Finnish Act on health care equipment and supplies 629/2010
- Finnish Consumer Protection Act 38/1978
- Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein
- Council Regulation (EC) No 1320/2014 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein
- Council Regulation (EC) No 865/2006 laying down detailed rules concerning the implementation of Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein
- Commission Implementing Regulation (EU) No 888/2014 prohibiting the introduction into the Union of specimens of certain species of wild fauna and flora
- Regulation (EC) No 1007/2009 of the European Parliament and of the Council on trade in seal products
- Commission Regulation (EU) No 737/2010 laying down detailed rules for the implementation of Regulation (EC) No 1007/2009 of the European Parliament and of the council on trade in seal products
- Finnish Act 1107/1996 on the protection of whales and arctic seals

Evira guidelines:

- Guide to food control officials and food business operators on provision of food information (Evira Guide 17068/1)
- Nutrition and Health Claim Guide for food supervisors and food business operators (Evira Guide 17052/3)
- Guide for the control of food treatment agents – additives, flavourings and enzymes (Evira Guide 17054/4)
- Guide on food hygiene in food establishments subject to a notification (Evira Guide 16025/3)
- Risk-based control of in-house control in food establishments (Evira Guide 16043/1)
- Guidelines for organic production 3 – Foodstuffs (Evira Guide 18222/3)

9 USEFUL LINKS:

Legislation:

- Finnish legislation, www.finlex.fi
- EU Regulations, http://eur-lex.europa.eu/fi/index.htm

Evira: http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/

- Food supplements:
  http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/ravintolisat/
  - Food supplement notification:
    http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/ravintolisat/ravintolisailmoitus/
  - Food Supplement Guide:
    http://www.evira.fi/portal/fi/tietoa+evirasta/julkaisut/?a=view&productId=126
- Labelling
  http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/pakkausmerkinnat/
  - Food Information Guide
    http://www.evira.fi/portal/fi/tietoa+evirasta/julkaisut/?a=view&productId=385
- Nutrition and health claims
  http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/pakkausmerkinnat/ravitsemus-+ja+terveysvaitteet/
  - Nutrition and Health Claim Guide
    http://www.evira.fi/portal/fi/tietoa+evirasta/julkaisut/?a=view&productId=393
- Novel foods
  http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/uuselintarvikkeet/
- Food treatment agents (additives, flavourings and enzymes)
  http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/elintarvikeparanteet/
- Genetically modified food
  http://www.evira.fi/portal/fi/elintarvikkeet/tietoa+elintarvikkeista/tuotantotapoja/muuntogeeniset+elintarvikkeet/
- Withdrawal procedure
  http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/takaisinvedot/

European Commission: http://ec.europa.eu/food/safety/index_en.htm

- Food supplements
  http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm

EFSA: http://www.efsa.europa.eu/

- Compendium
  http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2663.pdf
- Tolerable Upper Intake Levels (UL)
  http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf

Fimea, http://www.fimea.fi/

- List of medicinal products: http://www.fimea.fi/valvonta/luokittelu/laakeluettelo
- Classification: http://www.fimea.fi/valvonta/luokittelu
- Herbal medicinal products:
  http://www.fimea.fi/myyntiluvat/kasvirohdoslaakkeet_ja_homeopaattiset_valmisteet.
- Anthroposophic and homeopathic products:
  http://www.fimea.fi/myyntiluvat/kasvirohdoslaakkeet_ja_homeopaattiset_valmisteet/homeopaattiset_ja_antroposofiset_valmisteet
- Marketing control: http://www.fimea.fi/valvonta/markkinoinnin_valvonta

The Customs, http://www.tulli.fi/fi/

- Food control by the Customs:
  http://www.tulli.fi/fi/yrityksille/tuonti/valvonta/index.jsp

National Supervisory Authority for Welfare and Health, Valvira, www.valvira.fi

- Health care equipment and supplies:
  http://www.valvira.fi/terveydenhuolto/terveysteknologia/tuotteen_markkinoille_saattaminen/terveydenhuollon_laitteet_ja_tarvikkeet
- Alcohol products: http://www.valvira.fi/alkoholi

Finnish Competition and Consumer Authority, http://www.kkv.fi/

- Information on e.g. marketing and advertising: http://www.kkv.fi/Tietoa-ja-ohjeita/Markkinointi-ja-mainonta/

Finnish Antidoping Agency FINADA, www.antidoping.fi

ANNEX: EXAMPLE OF LABELLING ON A FOOD SUPPLEMENT

(the regulatory basis for the various labelling requirements is indicated by means of colour codes)

Decree on food supplements 78/2010

Food Information Regulation (EU) No 1169/2011

Decree on provision of food information to consumers 834/2014

Regulation (EC) No 1829/2003 on genetically modified food and feed

Claims Regulation (EC) No 1924/2006

Food supplement. Contains caffeine. Not recommended for children or pregnant women.
Recommended daily dose: 1 tablet

The recommended daily dose must not be exceeded. A food supplement must not be used as a substitute for a balanced and varied diet and a healthy lifestyle. To be kept out of reach of children.

Manufacturer: Energy Company, Factory Road 1, 23450 Town

100 capsules 54 g
Best before: end 12/2018
Batch: L 345

NUTRITIONPLUS

Vitamin-mineral preparation

Helps to cope!

Vitamin C helps reduce fatigue.

1 capsule contains		%RI *
Vitamin C	160 mg	200
Soy extract	120 mg	-
Maidenhair tree extract	120 mg	-
Caffeine	80 mg	-
Coenzyme Q10	30 mg	-
Zinc	15 mg	150

Ingredients: Vitamin C (l-ascorbic acid), **soy** extract** (*Glycine max L.*), Maidenhair tree extract (*Gingko biloba*), coenzyme Q10, caffeine, zinc (zinc oxide), anti-caking agent (E470 b), flavouring (caffeine), capsule (fish gelatin)
*reference intake
** genetically modified

Marketing name

Caffeine statement

Recommended daily dose

Mandatory warnings

Additional statement on significance of varied and balanced diet and healthy lifestyle, if a health claim is used

Quantity of content (volume/unit of weight)

Category or nature of characteristic substances

Amount of characteristic substances in recommended daily dose

Food supplement. Contains caffeine. Not recommended for children or pregnant women.
Recommended daily dose: 1 tablet

The recommended daily dose must not be exceeded. A foc supplement must not be use as a substitute for a balance and varied diet and a healthy lifestyle. To be kept out of reach of children.

Contact information

Manufacturer: Energy Company, Factory Road 1, 23450 Town

Durability

100 capsules 54 g
Best before: end 12/2018
Batch: L 345

Batch number

NUTRITIONPLUS

Food name

Vitamin-mineral preparation

Helps to cope!

Unspecific, general claim

List of ingredients in descending order

Vitamin C helps reduce fatigue.

More specific, authorised health claim

1 capsule contains		%RI *
Vitamin C	160 mg	200
Soy extract	120 mg	
Maidenhair tree extract	120 mg	
Caffeine	80 mg	-
Coenzyme Q10	30 mg	-
Zinc	15 mg	150

Daily reference intakes

Ingredients: Vitamin C acid), **soy** extract** (*Glycine max L.*), Mai extract (*Gingko biloba*), Q10, caffeine, zinc (zinc anti-caking agent (E470 flavouring (caffeine), ca gelatin)
*reference intake
** genetically modified

Allergens emphasised

Group names of additives

Quinine/ Caffeine statement

GMO statement

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