Guidelines of Finnish Food Safety Authority Evira for submittal of food supplement notification

Public authority action shall be based on legislative competence conferred to the authority and be consistent with legislation. Authoritative 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.

These guidelines present both direct quotations from legislation and interpretations on the application of legislation. Legislative text is clearly distinguished from the rest of the text. The interpretations presented in these Guidelines constitute Evira's views on how legislative regulations should be applied.

1 Legislation

Food supplements refer to pre-packed products in the form of a briquette, capsule, pastille, tablet, pill, powder, concentrate, extract or liquid, or in some other equivalent dose form, marketed as foodstuffs to be consumed in measured small doses whereby the amount of energy received has no relevance to the diet as a whole (Decree on Food Supplements 78/2010, Section 2).

Legislation providing for food supplements

- Decree of the Ministry of Agriculture and Forestry on food supplements (78/2010)
- 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 (EC) No 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements
- Commission Regulation (EU) No. 1161/2011 amending Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No. 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No. 953/2009 as regards the lists of mineral substances that can be added to foods.
- Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods (hereunder the Health Claim Regulation).
- Decree of the Ministry of Trade and Industry on food labelling (1084/2004, hereunder the Labelling Decree)
- Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (hereunder the Food Information Regulation)
- Food Act (23/2006)

- EC legislation can be accessed at http://eur-lex.europa.eu/fi/index.htm
- National legislation can be accessed at http://www.finlex.fi/fi/.

More information:

- Food Supplement Guide, Evira's Guide 17012/4

2 Notification obligation

Under Decree 78/2010 of the Ministry of Agriculture and Forestry on Food Supplements a commercial operator who produces or imports a food supplement or has a food supplement produced with a view of placing it on the Finnish market shall submit a written notification to the Finnish Food Safety Authority Evira before marketing the new product. A notification shall also be submitted in case the composition of the product is changed with respect to the substances that characterise it. The regulations do not specify when the food supplement notification is to be submitted, but it should be done before the food supplement is placed on the market in order to enable effective control.

Evira considers the notification obligation to be fulfilled when the notification, including all the required information and attachments, is received by Evira. A model of the product labelling, presented in a clearly and legible form, is a mandatory attachment to the notification. Evira or Regional State Administrative Agencies can ask the operator to supplement the notification later.

If there are several operators with responsibility for the food (e.g. several importers), each shall submit the food supplement notification. The notification is also required in case the composition of the product is changed with respect to the substances that characterise it. A new notification shall be submitted whenever the operator who produces or imports the product or has it produced or in some other manner is responsible for placing the product on the market changes. A change in the commercial product name, the so-called brand name, also requires that the notification be submitted, even if the composition of the food supplement remains unchanged.

The responsibility for the compliance of the product with 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.

- Evira does not assess on the basis of the notification the compliance of the composition or labelling of the food supplement with regulations.
- The receipt of the notification and the sending of the acknowledgement letter do not indicate that Evira has approved the food supplement to be compliant with food laws.

A fee is charged for the processing of food supplement notifications that pertain to the placing of the product on the market or to the changing of the composition as stipulated in the Decision of the Ministry of Agriculture and Forestry on the fees charged for services produced by the Finnish Food Safety Authority.

2.1 Evira's electronic service

The notification of placing a food supplement on the market or of a change in the composition is submitted via Evira's electronic service. The e-forms are available in Finnish, Swedish and English. The electronic service system is logged in on Evira's website at:
http://www.evira.fi/portal/en/about+evira/service/electronic+service/food+supplement+and+fortified+food+notifications/

When the notification has been successfully submitted, the Finnish Food Safety Authority sends the operator a reply message to the email address indicated in the notification. Received notifications and the attachments to them are sent to the municipality and the Regional State Administrative Agencies for information and for control purposes. Evira can forward information also to other control authorities, if necessary. The reply message contains a link to the Guide for In-House Control of Food Supplements, which provides information to food business operators about matters to be taken into consideration in in-house control.

More detailed instructions for the use of Evira's electronic service can be found under the "Instructions" button in the top bar on the Electronic service page, or on Evira's website at
http://www.evira.fi/portal/en/about+evira/forms+and+instructions/food/

2.2 Notifications submitted outside electronic service

Food business operators who for some reason cannot submit notifications via the electronic service can fill in the notification on Evira's website at:
http://www.evira.fi/portal/en/food/manufacture+and+sales/food+supplements/food+supplement+notification/

Notifications that are not submitted via the electronic service shall be sent by post, complete with attachments, to Evira's Register Office: Finnish Food Safety Authority Evira, Register Office, Mustialankatu 3, FI-00790 Helsinki, Finland or by email to kirjaamo@evira.fi. The receipt process is similar to notifications received via the electronic service. The reply letter is then sent by post.

3 Information on food supplement

In addition to the information referred to in the Decree on Food Supplements, the notification form is designed for the gathering of the information referred to in the Labelling Decree or in the Food Information Regulation. The Decree on Food Supplements will be applied exclusively as of 13.12.2014.

More information about labelling requirements pertaining to food and the application of the requirements is provided in the Labelling Guide (Evira's Guide 17005/4) and in the Food Supplement Guide (Evira's Guide 17012/4) of the Finnish Food Safety Authority.

These Guides can be found in electronic form on the website of the Finnish Food Safety Authority at
http://www.evira.fi/portal/en/about+evira/publications/?a=category&cid=23

3.1 Commercial product name of food supplement

The name under which the food supplement is marketed, e.g. "Energis".

3.2 Name of food

The name of the food indicates in a concise and precise form what the food package contains, e.g. a vitamin product, a plant extract product or a fish oil capsule.

The name of the food must not be confused with its commercial product name or brand name. Commercial names and brand names are voluntary information in the labelling and do not replace the name of the food.

In addition to the name of the food, the labelling of a food supplement shall also include the marking "food supplement". Evira recommends that this marking is placed near the name of the food.

3.3 Country of origin

The labelling of origin refers to an indication made in the labelling of the food or in some other manner of the country or region of origin of the food. The country or region of origin shall be indicated if its absence could mislead the consumer as concerns the origin of the food.

3.4 Category of characteristic ingredients of food supplement or indication of the nature of these nutrients

The names of the categories in which the nutrients or other substances that are characteristic ingredients of the food supplement or an indication of the nature of such nutrients or substances shall be shown in the labelling of the product (Decree on Food Supplements 78/2010, Section 5).

The category refers to the group in which the characteristic ingredient of the food supplement can be classified.
Categories include e.g. vitamins, minerals, fibres, amino acids, fatty acids as well as plant and herbal extracts. Food supplements can be classified in several categories, if they contain characteristic ingredients of different categories. The number of lines can be increased in the e-form according to the number of categories in which the food supplement is considered to be included.

If the dropdown list in the electronic service does not include a suitable category for the characteristic ingredient, it can be classified to category "other" and provide more detailed information about the nature of the substance under "Other information".

3.5 Purpose of use and target group

The target group for which the food supplement is designed.

3.6 List of ingredients

The list of ingredients lists the ingredients used in the production of the food. The ingredients of the food are listed in full in descending order of weight at the time of production. Reference to the attached labelling model alone is not adequate.

Evira recommends that vitamins and minerals be listed in the list of ingredients using the names presented in Annex XIII to the Food Information Regulation (1169/2011).

3.7 Recommended daily dose

Pursuant to Section 5 of the Decree on Food Supplements, the daily dose of the food supplement recommended by the producer shall be indicated in the labelling of the product, e.g. 2 tablets twice a day.

3.8 Quantity of content

The quantity of content refers to the quantity of the food in the package at the time of packing, e.g. 220 g, 60 pcs. The time of packing refers to the time when the product is ready to be marketed. The weight of packaging may not be included in the indicated quantity of content. The quantity of content shall be expressed with units commonly used in Finland for solid foods. For liquid products, the quantity of content shall be expressed with units of weight or volume commonly used in Finland.

Alternatively, the labelling can indicate the number of items or the number of doses.

3.9 Characteristic ingredients of food supplement

Characteristic ingredients of food supplements refer to nutrients, such as vitamins or minerals, or some other substances with a nutritional or physiological effect.
Characteristic ingredients refer to the substances with which the product is marketed, such as vitamin C, omega-3 fatty acid, chamomile extract, Iceland moss or *Lactobacillus acidophilus* bacteria.

The characteristic ingredients used in food supplements are in the electronic service listed in dropdown lists. The selection of the category of the characteristic ingredient limits the dropdown list to substances included in that category. Plants used as characteristic ingredients can also be filled in the form under their scientific name. It is recommended that also the part of the plant that has been used is indicated. If the part of the plant is not included in the dropdown list, it can be added under "Other information".

Food supplements may contain the vitamins and minerals listed in Annex 1 to Regulation 1170/2009 of the European Commission in the forms listed in Annex 2 to the Regulation. The list of permitted compound forms is binding and other compounds of vitamins or minerals may not be used in food supplements.

As concerns substances other than vitamins and minerals, there is no legislation on substances that are permitted or prohibited in food supplements. Food business operators are responsible for the safety of the use of the product as food.

The compounds that are used shall fulfil the purity requirements specified in Community legislation. In the absence of Community specifications, generally acceptable purity criteria recommended by international bodies shall apply (Section 4). Evira's guidelines regarding the purity of compounds used as food supplements can be found on Evira's website at http://www.evira.fi/portal/en/food/manufacture+and+sales/food+supplements/instructions+on+purity+specifications+for+preparations+used+as+food+supplements/

3.10 Amount of characteristic ingredients in daily dose

The amounts of the characteristic ingredients of the food supplement shall be indicated in the labelling in numerical form, e.g. in percent, or in units of weight/volume or as the number of microbes. The indicated values shall be mean values based on an analysis made of the product by the producer. The amounts of the characteristic ingredients of the food supplement shall further always be indicated in percent of the reference intake, if the reference intake has been defined for the substance in question. The reference intake values of vitamins and minerals are presented in Annex XIII to the Food Information Regulation (1169/2011). The percentage of the reference intake may also be presented in graphical form.

The amounts of the characteristic ingredients of the food supplement are given as a daily dose of the product recommended by the producer, which is indicated in the labelling. The labelling shall indicate the whole range of the amount of the substance, e.g. 1-3 tablets contain x-y mg of zinc.

3.10 Warning statements

Pursuant to Section 5of the Decree on Food Supplements, the following mandatory warning statements shall be presented in the labelling of food supplements:

- a warning that the recommended daily dose may not be exceeded;
- a statement that the food supplement is not to be used as a substitute for a diversified diet;
- a warning that the product shall be stored out of the reach of small children.

Evira recommends that the wordings presented in Section 5 for the warnings and statements shown above be used in labelling.

3.11 Nutrition and health claims

It must not be stated or implied in the packaging, presentation and advertising of food supplements that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. Under Section 9, Item 3 of the Food Act, food must not be presented as having properties related to prevention, treatment or curing of human diseases and reference may not be made to such information. For food supplements, a prohibition to this effect is included also in Section 5 of the Decree on Food Supplements.

EU's Regulation on nutrition and health claims (1924/2006) specifies the conditions on which nutrition and health claims may be made on food supplements. A health

claim means a claim that states, presents or implies that there is a relationship between a food category, a food or its ingredient and health. More information about health claims is provided on Evira's website at http://www.evira.fi/portal/en/food/manufacture+and+sales/labelling/nutrition+and+health+claims/

4 Attachments

The notification shall be accompanied by a model of the labelling of the food, indicating both regulatory and voluntary labelling, and if possible, also the planned illustrations for the package. The labelling model shall be clear and easy to read.

If the signatory/signatories of the notification are not authorised to sign the company name, a Power of Attorney shall also be attached to the notification.

Other attachments to the notification may include e.g. a product brochure.

5 Other considerations

Food business operators are responsible for the compliance of their products with the provisions on food supplements and other regulations on foods.

Questions related to food and food labelling can be directed to municipal food control authorities. More information about food supplements is also available on Evira's website at http://www.evira.fi/portal/en/food/manufacture+and+sales/food+supplements/

More information on Evira's electronic service can be obtained from and feedback given to:
Päivi Kanerva, Senior Officer (elintarvikeilmoitukset@evira.fi, telephone +358 50 434 2203).

6 Revisions from previous version

Previous version 17006/2. The major revisions are related to the introduction of the electronic service. Legislation has also been updated.