

Placing of foods fortified with vitamins and minerals on the market, change in composition and removal from the market – guidelines for submittal of notification to Evira

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

Fortification of food refers to the adding of nutrients, most commonly one or several vitamins and/or minerals, to food in connection with the production process.

Legislation providing for fortified foods:

- 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 (hereafter the Fortified Food Regulation)
- The Decree (726/2007) of the Ministry of Trade and Industry on the national measures required by the entry into force of 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
- Regulation (EC) No. 1170/2009 of the European Commission 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 (hereafter the Health Claim Regulation)
- The Decree of the Ministry of Trade and Industry on Labelling of Foodstuffs (1084/2004, hereafter the Labelling Decree)
- The Decree of the Ministry of Agriculture and Forestry on Nutrition Labelling for Foodstuffs (588/2009, hereafter the Nutrition Labelling Decree)

Guidelines for submittal of fortification notification

- Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (hereafter the Consumer 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:

- Guidelines for Control of fortified foods, Evira's Guide 17059/1

2 Notification obligation

Under Decree 726/2007 of the Ministry of Trade and Industry a food business operator who produces or imports a food fortified with vitamins and/or minerals or has such a food produced shall submit a written notification to the Finnish Food Safety Authority Evira.

The fortification notification is required of foodstuffs that are fortified in themselves. The notification is also required, when the composition of a food changes with respect to the added vitamins and/or minerals or when the foodstuff is removed from the market. The notification is not required, on the other hand, of foodstuffs containing a fortified food as an ingredient. The regulations do not specify when the fortification notification is to be submitted, but it should be done before the food 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 labelling of the fortified food product, presented in a clearly and legible form, is a mandatory attachment to the notification. Evira 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 fortification notification. 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 fortified food remains unchanged. In this case a notification of the removal of the product from the market shall be made on the food with the old composition.

The responsibility for the compliance of the product with the Fortified Food Regulation and other food laws rests with the food business operator. The in-house control obligation of the food business operator stipulated in the Food Act also entails this.

- Evira does not assess on the basis of the notification that the composition or labelling of the food fortified with vitamins and/or minerals complies with regulations.
- The receipt of the notification does not indicate that Evira has approved the fortified food to be compliant with food laws.

Guidelines for submittal of fortification notification

A fee is charged for the processing of 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. No fee is charged for notifications of the removal of products from the market.

2.1 Evira's electronic service

The notification of placing a fortified food on the market, of a change in the composition or of removal from the market 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/>

Select in the electronic service the "Notification of a fortified food" and then select from the "Type of notification" dropdown list the notification of placing a fortified foodstuff on the market or of a change in the composition of fortified foodstuff. The notification of a change in the composition is selected, when the composition of the fortified food is to be changed with respect to the added vitamins or minerals. The date as of which the change in the composition of the product will be valid shall be indicated in the notification. A notification need not be submitted of removal from the market of the food with the old composition.

The "Notification of removal from the market" is selected, when submitting a notification of the removal of a fortified food from the market. It is recommended that the notification of the removal of the food from the market be submitted, when information about the removal of the product from the market is available. The notification shall indicate the date on which the product is removed from the market, e.g. before the best before date of the last batch.

The notifications of changes in the composition or removal from market of fortified foods can be specified to pertain to a fortified food of which a notification has been made previously ("Product being notified"). The dropdown list only shows fortified foods of which notifications have been submitted via the electronic service. If the food product to which the notification pertains is not included in the list, select "Not found" in the list.

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. Information about the received notification and the attachments to it 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 Guidelines for Control of Fortified Foods, which provides information to food business operators about matters to be taken into consideration in the in-house control of fortified foods.

More detailed instructions for the use of Evira's electronic service can be found under the "Help" 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/addition+of+nutrients+to+food/notification+on+bringing+to+market+fortified+foods/>

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.

Notifications of a change in the composition of a fortified food can only be submitted via the electronic service. Otherwise the fortified food product with changed composition with respect to vitamins or minerals is considered to be a new product and a new notification shall be submitted of it. A notification of removal from the market shall be submitted of the product with the old composition.

3 Information on fortified food

In addition to the information referred to in the Fortified Food Regulation, the notification form is designed for the gathering of the information referred to in the Labelling Decree and the Nutrition Labelling Decree or in the Food Information Regulation. The Food Information Regulation shall be applied with respect to general labelling requirements as of 13.12.2014 and with respect to nutrient labelling as of 13.12.2016, at the latest. New nutrition labelling produced during 13.12.2014-13.12.2016 shall already comply with the Food Information Regulation.

More information about requirements pertaining to the fortification of food is provided in the Guidelines for Control of fortified foods

<http://www.evira.fi/portal/en/about+evira/publications/?a=view&productId=340>

3.1 Commercial name (e.g. "Namis")

Refers to the so-called brand name of the product.

3.2 Name of foodstuff

The name specified in the legislation of the European Community shall be used for the food, or in the absence of such a name, the name stipulated for use in Finland. If no such name has been stipulated, the established name used in Finland shall be used or a name that describes the food, and if necessary, its use in such a manner that the name specifies the food explicitly and distinguishes it from foods with which it could otherwise be confused.

3.3 Food group

Foods are in the e-form divided into food groups and food categories to facilitate the search for foods. The food group in which the fortified food is included is first selected from the "Food group" dropdown list, e.g. "Fruit and vegetable juices and nectars".

Guidelines for submittal of fortification notification

3.4 Food class

The food classes are determined by the food group selected in the e-form. The proper food class is selected from a dropdown list. For example, food group "Fruit and vegetable juices and nectars" includes the food classes "Fruit juices" as well as "Mixed fruit and vegetable juices or nectars".

3.5 Food product

The foods included in the "Food product" dropdown list of the e-form are determined by the selected food class. For example, if the selected food class is "Fruit juices", the "Food product" dropdown list includes e.g. orange juice and black currant juice.

The food groups and classes are based on the FoodEx2 draft of the European Food Safety Authority EFSA. As the objective of EFSA's system has been to gather the food products most commonly used in the EU countries, it may be difficult to find there some foods generally included in the Finnish food culture or eating habits, or equivalent products. Evira can be informed of any fortified foods not found in the list (contact information is provided in Section 6 of the Guidelines).

3.6 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. In practice, the country of origin is often the country in which the food is produced.

3.7 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.

3.8 The product has been fortified in the sense of Regulation 1925/2006 with the following vitamins and minerals

Each vitamin and mineral used to fortify the food is entered in the e-form as a specific item. The selection of "+ Add vitamin/mineral" opens a field with a dropdown list from which the added vitamin/mineral is selected. The form in which the vitamin or mineral has been added can be selected from the "Chemical compound used" dropdown list. If the food has been fortified with several vitamins or minerals, information is entered on each of them by selecting "+ Add vitamin/mineral" and filling in the information.

The amounts of the vitamins and minerals added in the food are entered in the e-form under "**Nutrient declaration". Both fields shall be filled in carefully with respect to all the vitamins and minerals added in the food.

3.9 Nutrition declaration

Nutrition declaration is presented in compliance with either the Nutrition Labelling Decree or the Food Information Regulation. Nutrition declaration is compulsory on fortified foods.

Guidelines for submittal of fortification notification

In the electronic service, the operator selects if the nutritional content of the food is indicated per 100 grams (solid food) or 100 millilitres (liquid food). The e-form contains entry fields for the energy content of the food as well as for the amounts of fat, saturated fat, carbohydrates, sugars, protein and salt per 100 g or 100 ml of the product. It is also possible to provide voluntary nutritional information, e.g. regarding dietary fibre.

The amounts of all the added vitamins and minerals shall be entered. Each new vitamin/mineral is entered in the e-form by first pressing the "+" button and then selecting the added vitamin/mineral from the dropdown list and entering its amount. The e-form system automatically adds the correct unit to the amount and calculates the proportion of the added vitamin/mineral of the reference value for daily intake.

Also other substances added in the food can be entered in the e-form, in addition to vitamins and minerals. The "+" button is pressed first, and then the other substance is selected from the dropdown list. The substance can either be directly selected from the dropdown list or substances can be filtered by first selecting the class of the substance. If the substance is not included in the list, its name can be entered in the empty field by selecting "If you cannot find the substance in the list, open here". If the substance is a plant, the form of the substance is also selected from the dropdown list, e.g. powder or extract. The amount of the substance is entered per 100g or 100 ml and the correct unit is selected from the dropdown list.

A warning appears on the e-form if the other substance entered is e.g. a novel food or a medicinal substance. More information can be obtained by clicking on the warning.

Nutritional information can be provided of a food ready for consumption, if adequately detailed instructions for preparation are provided in the labelling and the information pertains to the food prepared according to these instructions. For example, it would be informative to indicate in the labelling of a juice concentrate that needs to be diluted the nutritional content of the juice when it is ready for consumption. If the nutritional information refers to food that is ready for consumption, this shall be indicated in e.g. the "Additional information" field of the e-form.

3.10 Additional information

Additional information can be provided on the fortified food, if considered necessary, such as information on any nutrition claims regarding the adding of a vitamin or mineral (e.g. "Vitamin C added") according to the Claim Regulation, or on any warnings (e.g. "Not recommended for pregnant women") or instructions for use (e.g. "No more than 5 cans a day").

More information about nutrition and health claims is provided on Evira's website at: <http://www.evira.fi/portal/en/food/manufacture+and+sales/labelling/nutrition+and+health+claims/>

More information about warnings and instructions for use is provided on Evira's website at: <http://www.evira.fi/portal/en/food/manufacture+and+sales/labelling/warning+labelling+and+instructions+for+use/>

Guidelines for submittal of fortification notification

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 fortified foods and other regulations on foods.

More information on Evira's online service can be obtained from and feedback given to:

Sanna Kiuru, Senior Officer (elintarvikeilmoitukset@evira.fi, telephone +358 40 124 5176)

6 Revisions from previous version

30.9.2013 The Guidelines have been updated in connection with the introduction of the electronic service. The major revisions in the Guidelines are related to the use of the electronic service. Legislation has also been updated.