Evira guideline 17059/1 en

Evira

Guidelines for control of fortified foods

Content

1. PREFACE

These guidelines are designed for food control authorities and operators within the food business.

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. The interpretations presented in these Guidelines constitute Evira's views on how legislative regulations should be applied.

2. LEGISLATION AND NORMS

- 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 (the Fortified Food Regulation).
- Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods (the Health Claim 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.
- The Decree (588/2009) of the Ministry of Agriculture and Forestry on Nutrition Labelling for Foodstuffs (the Nutrition Labelling Decree)
- 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 (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (the Food Information Regulation)

- Commission Implementing Regulation (EU) No. 307/2012 establishing implementing rules for the application of Article 8 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

3. REQUIREMENTS FOR FORTIFICATION OF FOODSTUFFS

Fortified foodstuffs are normal food to which vitamins, minerals or other substances with nutritional or physiological effects are added voluntarily in the production process. The objective of the fortification of foodstuffs is to improve nutrition level, restore nutrients lost in production or gain a competitive advantage in the food market.

Regulation (EC) No. 1925/2006 of the European Parliament and of the Council provides for the addition of vitamins and minerals and of certain other substances to foods (the Fortified Food Regulation).

Prior to the year 2007, authorisation was required for the fortification of foodstuffs. At present, vitamins, minerals and certain other substances may be added to foods pursuant to the conditions of the Fortified Food Regulation without any specific authorisation. However, operators in the food business are required to notify Finnish Food Safety Authority Evira about the placing on the market of foods fortified with vitamins and/or minerals.

More information about the notification procedure is provided 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/

The Fortified Food Regulation does not restrict the addition of e.g. vitamin or mineral compounds to food supplements or their use as food improvement agents, or the addition of nutrients as required by the composition requirements laid down for foods for particular nutritional uses.

Foods produced from raw materials that contain naturally occurring vitamins or minerals, such as calcium-containing milk, iron-containing powdered blood or fruit juice concentrates that contain vitamin C, are not considered to be fortified foodstuffs. The use of a fortified foodstuff as an ingredient in another foodstuff does not make the final product a fortified foodstuff either. For example, foods in which milk fortified with vitamin D or iodised salt has been used as an ingredient are not considered to be fortified foods. However, this may not be interpreted so that a product could contain vitamin or mineral compounds, which are not permitted in Europe.

Vitamins and minerals may not be added to unprocessed foods, such as fruit, vegetables, meat, poultry or fish. The addition of vitamins and minerals is also prohibited to beverages with an alcohol content of more than 1.2 percent by volume.

In a few EU states, national laws provide for the fortification of certain foods. More information can be found in the register maintained by the Commission, at

http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf. There are no national provisions in Finland on compulsory fortification of foods.

3.1 Permitted vitamin and mineral compounds

The principle applied to the fortification of foods is that only vitamins and minerals that occur also normally in food and are necessary to humans may be added to foods. The Fortified Food Regulation defines these vitamins and minerals as well as the permitted compounds on which a safety assessment has been conducted. The list of the permitted compound forms is binding and no other vitamin or mineral compounds may be used to fortify foods.

When importing fortified foods from outside the EU, in particular, it shall be verified that the vitamin and mineral compounds used are permitted in the EU.

The Register maintained by the Commission lists the vitamins, minerals and their compounds, which may be added in foods:
http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf

3.2 Permitted amounts

The amounts of added vitamins and minerals in the final product shall not be too small or insignificant so that fortification misleads the consumer. However, the amount of the added substances may not be so large that they could cause adverse health effects.

Fortification is adequate when the final total amount of the added vitamin or mineral is significant in the food. In other words, the total amount of vitamins or minerals derived from raw materials and from fortification shall be at least 15% of the daily reference intake for solid products. For liquid products, which are consumed in larger quantities at a time, 7.5% of the daily reference intake is adequate, as a rule.

The daily reference intakes of vitamins and minerals can be found in the Nutrition Labelling Decree and in Annex XIII to the Food Information Regulation:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF

No maximum limits have so far been laid down in regulations for added vitamins and minerals. Operators in the food business shall conduct their own safety assessments to verify that the foods they produce, have produced, import or distribute do not cause any health risks for any reasons, including excessive amounts of vitamins, minerals or other substances contained in them. This is particularly emphasised for nutrients with a narrow safety margin, for which the difference between the recommended intake and the maximum safe intake is small. Substances usually considered to be nutrients with a narrow safety margin include vitamins D and A, niacin, folic acid, vitamin B6 and minerals. With vitamin A, for example, the maximum safe intake is reached already with triple the recommended intake.

Based on a safety assessment, European Food Safety Authority EFSA has defined Tolerable Upper Intake Levels (UL) for certain vitamins and minerals. The UL value indicates the overall amount of the vitamin or mineral that can be consumed daily without any health risks (Table 1).

The UL value takes into account the daily intake from all different sources, including food for normal consumption, fortified foods, food supplements as well as vitamin and mineral products classified as medicines. An exception is magnesium: only readily degradable magnesium chlorides and MgO derived from food supplements, water and fortified foods have been considered in its UL value. In other words, magnesium that occurs inherently in normal foods and drinks is not taken into account.

Table 1. Daily Reference Intake levels and Tolerable Upper Intake Levels (UL values) of nutrients with a narrow safety margin.

Vitamin or mineral	**Daily Reference Intake** (Decree 588/2009 of Ministry of Agriculture and Forestry)	**Tolerable Upper Intake level, UL (adults)** (SCF/EFSA)
Vitamin A (µg)	800	3000
Vitamin D (µg)	5	100
Niacin (mg)	16	Nicotinic acid 10 Nicotinic amide 900
B6 (pyridoxine) (mg)	1.4	25
Folic acid (µg)	200	1000
Calcium (mg)	800	2500
Magnesium (mg)	375	250 (magnesium chlorides, MgO)*
Zinc (mg)	10	25
Iodine (µg)	150	600
Copper (mg)	1	5
Selene (µg)	55	300
Molybdenum (µg)	50	600
Fluoride (mg)	3,5	7
Boron (mg)		10

* only magnesium chlorides and MgO derived from fortified foods, food supplements and water are taken into account

In addition to the UL values, also the average level of consumption of the food as well as the targeting of the food at vulnerable consumer groups, such as children, pregnant and nursing women as well as elderly people, shall be considered in the assessment of the safety risk that the food poses to consumers.

3.3 Action required due to high levels of vitamins and minerals in fortified foods

If the content of the vitamin or mineral per 100 g of the fortified food exceeds the UL value, the food can be considered to pose a safety risk to consumers.

In this case, the food business operator, who produces the food, has it produced, or imports or distributes the food, shall take action to manage the health risk. Such action shall be considered specifically in each case depending on the circumstances. Examples of possible risk management actions include the reduction of the level of the nutrient in question in the product, adding a warning statement in the labelling, or some other action that will make the food product safe to consumers.

If the food is targeted at vulnerable consumer groups and / or the levels of consumption are high (e.g. beverages), an excessive content of a vitamin or mineral is a severe safety risk and must result in the withdrawal of the product from the market.

More information about withdrawals is provided on Evira's website at http://www.evira.fi/portal/en/food/manufacture_and_sales/guidelines_on_withdrawal_of_products/

3.4 Labelling

General labelling requirements (Decree 1084/2004 of the Ministry of Trade and Industry, and in the future, Regulation (EU) No. 1169/2011) apply also to fortified foods. The list of ingredients shall contain all the ingredients used in the production of the product, including added vitamins, minerals and other substances.

Evira recommends that vitamins and minerals be indicated in the list of ingredients using the same names as in the Nutrient Labelling Decree and in Annex XIII to the Food Information Regulation.

Vitamins and minerals can be indicated by group names. The individual vitamins and minerals shall then be listed after the group name in the order of their amount: for example, vitamins (vitamins A, D and E) and minerals (iron, calcium).

Nutrition labelling is obligatory on foods fortified with vitamins and minerals. The nutrition labelling shall indicate the total amounts of vitamins and minerals per 100 grams or 100 millilitres, i.e. for a fruit juice fortified with vitamin C, for example, the total amount of vitamin C occurring inherently in the fruits used in the juice and the vitamin C added in the juice. The percentages of the vitamins and minerals of the daily reference intake shall also be indicated, in addition to their amount.

The order used in the Food Information Regulation should be followed in the nutrition labelling to make it easier for consumers to compare products with each other.
Annex XIII to the Food Information Regulation:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF

Fortified foods can bear nutrition claims, which highlight their fortification, such as vitamin D added, according to the terms and conditions of the Claim Regulation.

The marketing of fortified foods must not mislead the consumer by e.g. misrepresenting the health benefits of fortification or by implying that a balanced and varied diet cannot provide appropriate quantities of nutrients without fortified foods.

3.5 Consideration of tolerance and measurement uncertainty of analysis method in analysis results

The amounts of vitamins and minerals declared in nutrition labelling shall be based on

- The producer's analysis of the food, or
- A calculation from the known or actual average values of the ingredients, or
- A calculation from generally established and accepted data

When the food is marketed as a source of nutrients (nutrition and health claims), Evira recommends that the amount of each nutrient be determined by means of laboratory analyses or verified in some other reliable manner.

The European Commission has issued a guidance document for the setting of tolerances for the nutrient values declared on a label; it is to be complied with in the member states as of 13 December 2014.
http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/guidance_tolerances_december_2012.pdf.

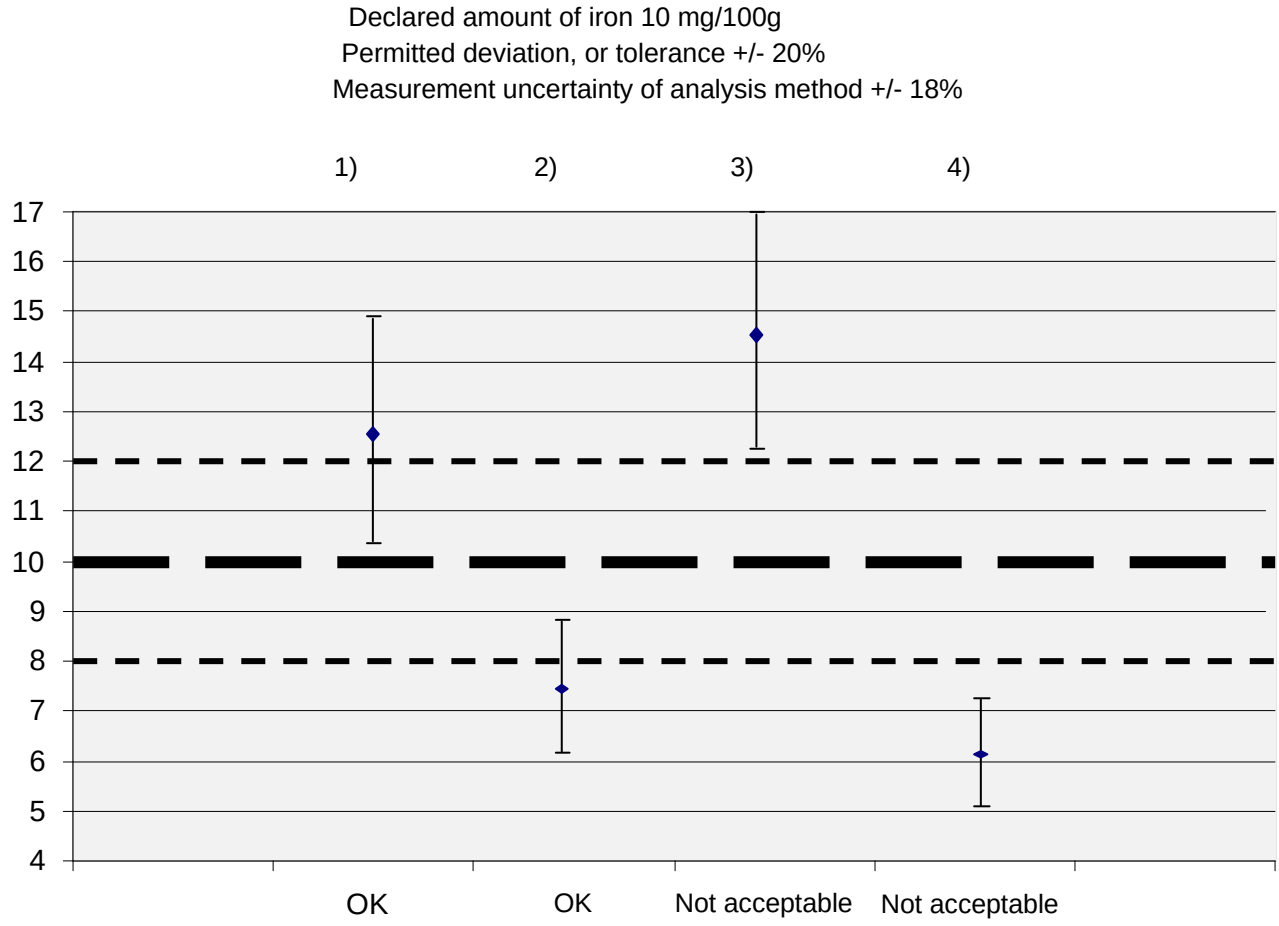
Until then, the following instructions, which are commonly used in Finland, shall be applied in control to the consideration of tolerance and the measurement uncertainty of the analysis method in analysis results.

In Evira's view, the following deviations can usually be allowed between the average value of the nutrient declared on the label and the result obtained in the control analysis:

- minerals ± 20%
- vitamin C + 100%/ - 20%
- other vitamins + 50%/ - 20%

The measurement uncertainty of the analysis method used shall also be taken into account according to the following example.

Figure 1. Example of consideration of measurement uncertainty of analysis method in measurement results



In the example, the product is on the labelling indicated to have an iron content of 10 mg/100 g. The permitted deviation in the iron content between the declared value and the analysis result is ± 20%, which means the analysed iron content must be 8-12 mg/ 100 g. The measurement uncertainty of the analysis method applied to iron content is ± 18 %.

1) The control analysis gives an iron content of 12.6 mg/ 100 mg. Taking the measurement uncertainty into account, this 12.6 mg analysis result is within 10.3-14.9 mg, i.e. it falls within the permitted tolerance range of 8-12 mg/ 100 g. The iron content indicated on the labelling is within acceptable limits according to this analysis result.

2) The control analysis gives an iron content of 7.5 mg/ 100 mg. Taking the measurement uncertainty into account, this 7.5 mg analysis result is within 6.15-8.85 mg, i.e. it falls within the permitted tolerance range of 8-12 mg/ 100 g. The iron content indicated on the labelling is within acceptable limits also according to this analysis result.

3) The control analysis gives an iron content of 14.7 mg/ 100 mg. Taking the measurement uncertainty into account, this 14.7 mg analysis result is within 12.1 mg-17.3 mg, i.e. it does NOT fall within the permitted tolerance range of 8-12 mg/ 100 g. The iron content indicated on the labelling is NOT within acceptable limits according to this analysis result.

4) The control analysis gives an iron content of 6.2 mg/ 100 mg. Taking the measurement uncertainty into account, this 6.2 mg analysis result is within 5.1 mg-7.3 mg, i.e. it does NOT fall within the permitted tolerance range of 8-12 mg/ 100 g. The iron content indicated on the labelling is NOT within acceptable limits according to this analysis result.

If the analysis results are repeatedly at the upper limits of the permitted tolerance, the food business operator must adopt more effective in-house control and make the necessary changes in the production process or the labelling.

If the indicated nutrient contents of the foodstuff deviate repeatedly from the set tolerance limits, taking the measurement uncertainty of the analysis method into account, the foodstuff is not acceptable and may not be kept for sale.

3.6 Purity criteria

The Fortified Food Regulation does not specify purity criteria for added substances. 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. If Community-level purity criteria have not been defined, it is also possible to use generally acceptable purity criteria commonly recommended by international bodies.

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

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 in CAC/MISC 6 ”List of Codex advisory specifications for food additives” http://www.codexalimentarius.net/web/standard_list.do?lang=en.
    - 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 from the "Combined Compendium of Food Additive Specifications" http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/ as well as in the 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. If the criteria referred to in Items 1 - 3 are missing, the purity criteria recommended by the European Pharmacopoeia shall be applied.

3.7 Fortification with other substances

Apart from vitamins and minerals, the Fortified Food Regulation also applies to other substances added in foods due to their nutritional of physiological effects. Such substances include e.g. amino acids, omega-3 fatty acids, caffeine, milk acid bacteria and plant extracts.

The addition of these other substances is permitted, as a rule, and no minimum or maximum amounts, permitted compound forms or specific labelling requirements have been laid down for them. However, food business operators are responsible for ensuring that also foods fortified with other substances are safe and do not cause health risks e.g. to certain consumer groups.

Evira is of the view that specific warnings for vulnerable consumer groups shall be added on the labels of foods that contain a high level of caffeine, as well as ginger tea and similar drink powders.

More information about label warnings is provided on Evira's website at:
http://www.evira.fi/portal/en/food/manufacture_and_sales/labelling/warning_labelling_and_instructions_for_use/

Article 8 of the Fortified Food Regulation provides for a procedure that can be used to impose an EU-wide prohibition or restriction on the addition of certain other substances to foods, if they represent a potential health risk. So far this procedure has not been applied to prohibit or restrict the use of other substances in foods.

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

3.8 Is it a novel food?

If the other substance referred to in the Fortified Food Regulation has no history of use as a food prior to 1997 or it has been produced with a new method, the substance is considered to be a novel food and it shall undergo the authorisation procedure referred to in the Novel Food Regulation. This also applies to new sources of vitamin and mineral compounds.

More information about novel foods is provided on Evira's website at http://www.evira.fi/portal/en/food/manufacture_and_sales/novel_foods/

4. OPERATOR'S IN-HOUSE CONTROL

4.1. Operator responsibility

As far as fortification of foods is concerned, responsible operators include, for example:

- operators who produce vitamin and mineral compounds and certain other substances designed for fortification of foods, and operators who have them produced, import them, package them or sell them
- operators who produce fortified foods, and operators who have them produced, import them, package them or sell them

Food business operators are responsible for the compliance of their products. Operators shall identify and manage the criteria laid down in legislation for these substances and their use. The verification of compliance shall be part of the operator's in-house control.

Items that are critical with respect to food safety and food regulations shall be recorded in the operator's in-house plan.

As a rule, operators shall primarily ensure the safety of the fortified food by means of instructions, documents, recipe development and good production practices incorporated in in-house control. If necessary, analyses shall be carried out on finished products, particularly if a defect related to vitamins or minerals with a narrow safety margin is suspected, and this defect could cause a safety risk. Operators shall document the verification and check measurements and analyses that they conduct.

Operators shall have a plan in place for action to be taken and the schedule to be followed, if deficiencies or defects are found in the in-house control of fortified foods.

If operators find out or are made aware of that the product they produce, is produced for them, or packed or sold by them does not meet the criteria specified for safety, they must initiate action to withdraw the product from the market and to inform consumers of the situation.

More detailed information about withdrawals and operator responsibilities is provided on Evira's website at http://www.evira.fi/portal/en/food/manufacture_and_sales/guidelines_on_withdrawal_of_products/

More information about in-house control is provided in Finnish on Evira's website at http://www.evira.fi/portal/fi/elintarvikkeet/hygieniaosaaminen/tietopaketti/omavalvonta/

4.2 In-house control implemented by operators who produce vitamin and mineral compounds or other substances, have them produced, or import or pack them

Food business operators must possess sufficient and accurate information about the food they produce, process and distribute and about the legislation pertaining to it (Food Act, Section 19). Operators may not forward products they know or have reason to suspect to be in violation of legislation.

Operators who produce vitamin and mineral compounds or other substances used to fortify foods, have them produced, or import or pack them shall ensure the safety of the compounds they deliver and the accuracy of the information provided on them.

- the vitamins, minerals and other substances used to fortify foods are safe, i.e.
  - the used vitamins and minerals and their compounds are permitted for use;
  - the purity criteria specified for the vitamin and mineral compounds are met;
- the vitamins, minerals and other substances are handled and stored according to good practices and the employees have adequate knowhow and work instructions to manage their use;
- vitamin and mineral compounds and other substances are delivered accompanied by appropriate labelling and product specifications;
- the traceability of both incoming and outgoing raw materials and products can be verified from documents, such as waybills, incoming and outgoing invoices, packing lists, stock records.

4.3 In-house control implemented by producers of fortified foods

Food business operators producing fortified foods must possess sufficient and accurate information about the food they produce, process and distribute and about the legislation pertaining to it (Food Act, Section 19). Producers may not forward products they know or have reason to suspect to be in violation of legislation.

Operators who produce fortified foods shall ensure the safety of the food and the accuracy of the information provided on the product.

- the vitamins, minerals and other substances used to fortify foods are safe, i.e.

  - the used vitamins and minerals and their compounds are permitted for use;
  - the purity criteria specified for the vitamin and mineral compounds are met;
- the final total amount of the vitamin or mineral is significant in the food (15% of the daily reference intake in solid foods and 7.5% in liquids);
- the amount of the added substance does not pose a health risk;
- the vitamins, minerals and other substances are handled and stored according to good practices and the employees have adequate knowhow and work instructions to manage their use;
- the vitamins, minerals and other substances as well as their amounts are indicated in the recipe and the amounts used in production are consistent with the amounts indicated in the recipe;
- the added vitamins, minerals and other substances are appropriately indicated in the list of ingredients;
- the added vitamins and minerals are appropriately indicated on nutrition labelling;
- references made on labelling or in advertising to the amount of fortification or its effects meet the requirements specified in claim legislation
- the labelling, presentation and advertising of foods does not state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general;
- the traceability of both incoming and outgoing raw materials and products can be verified from documents, such as waybills, incoming and outgoing invoices, packing lists, stock records;
- a notification has been submitted to Food Safety Authority Evira of the placing on the market of a food fortified with a vitamin or a mineral.

4.4 In-house control implemented by operators who import fortified foods, or have them produced

Food business operators, who import fortified foods or have them produced, must possess sufficient and accurate information about the food they produce, process and distribute and about the legislation pertaining to it (Food Act, Section 19). Operators may not forward products they know or have reason to suspect to be in violation of legislation.

Operators who import fortified foods or have them produced shall also ensure the safety of the fortified food and the accuracy of the information provided on the product.

- the vitamins, minerals and other substances used to fortify foods are safe, i.e.
  - the used vitamins and minerals and their compounds are permitted for use;
  - the purity criteria specified for the vitamin and mineral compounds are met;

- the final total amount of the vitamin or mineral is significant in the food (15% of the daily reference intake in solid foods and 7.5% in liquids);
- the amount of the added substance does not pose a health risk;
- if the food product is produced according to the recipe of the operator for whom it is produced, the vitamins, minerals and other substances as well as their amounts are indicated in the recipe;
- the added vitamins, minerals and other substances are appropriately indicated in the list of ingredients;
- the added vitamins and minerals are appropriately indicated on nutrition labelling;
- references made on labelling or in advertising to the amount of fortification or its effects meet the requirements specified in claim legislation
- the labelling, presentation and advertising of foods does not state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general;
- the traceability of both incoming and outgoing raw materials and products can be verified from documents, such as waybills, incoming and outgoing invoices, packing lists, stock records;
- a notification has been submitted to Food Safety Authority Evira of the placing on the market of a food fortified with a vitamin or a mineral.

The most important in-house control tools of operators, who import fortified foods or have them produced, are functioning work practices and work instructions regarding

- selection of material suppliers (e.g. the producer has a quality system, supplier audits)
- selection of new products (e.g. up-to-date product descriptions, specifications)
- acquisition of information about the production conditions and composition of the products
- competence of personnel, appointment of responsible persons

4.5 In-house control implemented by operators who pack and market fortified foods

Food business operators, who pack or market fortified foods, must possess sufficient and accurate information about the food they produce, process and distribute and about the legislation pertaining to it (Food Act, Section 19). Operators, who pack or market foods may also not forward products they know or have reason to suspect to be in violation of legislation. The same obligations apply to all operators, who market foods, regardless of whether the operation is limited to e.g. a food establishment, a virtual establishment, an online store or network marketing.

As concerns packed foods, the responsibility for the accuracy of labelling rests with the operator under whose name or business name the food is marketed. Consequently, operators, who pack or market fortified foods are responsible for the accuracy of labelling on foods that they

- pack
- market under their own name.

Operators, who apart from packing or marketing foods also produce them or have them produced or import them, shall implement in-house control according to the requirements laid down in Sections 4.3 and 4.4.

5. REGULATORY CONTROL

The control of fortification of foods is included in the control of foods referred to in the Food Act. Control authorities shall carry out official inspections to verify compliance with regulations on fortification of foods with vitamins, minerals and other substances in accordance with Regulation (EC) No. 882/2004
.

5.1 Risk based approach

Pursuant to Section 6 a of the Food Act, the following shall be taken into account regarding the activity carried out by the operator when implementing the obligations (operators) laid down in the Food Act and in controlling compliance with them

- extent of activity (local / national operation)
- type of activity (e.g. products designed for special consumer groups, production / import of vitamin and mineral compounds and mixtures for use by other companies)
- safety (e.g. compounds with a narrow safety margin, permitted vitamin and mineral compounds)
- consumer protection
    - o provision of information to consumers for making of choices
    - o preventing the misleading of consumers (e.g. adequate / significant amount of added vitamins and minerals)

5.2 Control authorities

Municipalities are entrusted with executing the control of fortified foods regarding operators in the area of the municipality.

Regional State Administrative Agencies, on the other hand, are responsible for the planning, guiding and supervision of the control of fortified foods and for the control of compliance with fortification regulations.

Evira is in charge of the planning, guiding and development of the control of fortified foods on national level.

Evira's inspection veterinarians control the effectiveness and implementation of in-house control in their own region, and also take into account requirements related to fortified foods. Evira's Import, Export and Organic Control Unit is entrusted with the control of the fortified foods pursuant to legislation on organic farming as well as with the control of the compliance of foods of animal origin imported from non-EU states (incl. fortification of foods).

Other control authorities (National Supervisory Authority for Welfare and Health, the Defence Forces, the Customs and border veterinarians) implement control of fortification of foods for their part.

5.3 Implementation of control

Regulatory control of fortified foods focuses on

- review of the scope, adequacy and implementation of in-house plan;
- controls of recipes, labelling and documents;
- review of practical activities;
- sampling, if necessary / if non-compliance is suspected

Review of in-house plan and its implementation is designed to verify that

- operators manage through their own control of their activities (in-house control) the compliance of the fortification of foods;
- the quality assurance procedures implemented by the operator, such as instructions and documentation, are adequate.

Reviews of recipes, labelling and documents are carried out to verify that the foods produced or distributed by the operator are

- safe and
- the information provided on the product is accurate

Control shall focus on aspects, which operators can influence with their own activities. The content of in-house control implemented by operators of different types is described in Sections 4.2-4.5. The focus of control shall be on these aspects.

6. ACTION

If control authorities find that the food operator violates valid food regulations, they shall take action as necessary to ensure compliance with the regulations. **If necessary, the administrative coercive measures referred to in the Food Act shall be implemented.**

Control instruction 8.3 "Fortification of foods" in Evira's food safety information publication system OIVA determines the measures to be taken when defects related to supplementation are found.

Reasons that will result in withdrawal include

- fortification of food with non-permitted vitamins, minerals or their compounds
- the amount of vitamin, mineral or other substance added in the food is so large that is risks the consumers' health
  (Evira's guidelines for withdrawal of fortified foods
  http://www.evira.fi/files/attachments/en/evira/forms_and_instructions/food/takaisinvetoohje_taydennetyt_17051_1_en.pdf)

Finnish Food Safety Authority Evira
Mustialankatu 3, FI-00790 Helsinki, Finland
Telephone 029 530 0400 • Fax 029 530 4350
www.evira.fi

Evira