RUOKAVIRASTO
Livsmedelsverket • Finnish Food Authority

Guide
6538/04.02.00.01/2021/EN

Guidelines for the control of fortified foods

Contents

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 the Finnish Food Authority's views on how legislative regulations should be applied.

2 LEGISLATION AND NORMS

The central legislation on fortified foods is:

- 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 on Fortified Foods).
    - Annex I – Vitamins and minerals which may be added to foods
    - Annex II – Vitamin formulations and mineral substances which may be added to foods
    - Annex III – Substances whose use in foods is prohibited, restricted or under Community scrutiny
- The Regulation on Fortified Foods has been amended by the following regulations:
    - 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
    - Regulation (EC) No 108/2008 of the European Parliament and of the Council amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

- The annexes to the Regulation on Fortified Foods have been complemented by the following regulations:
    - Commission Regulation (EU) 2021/468 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards botanical species containing hydroxyanthracene derivatives
    - Commission Regulation (EU) 2019/650 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille)
    - Commission Regulation (EU) 2019/649 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in fat of animal origin
    - Commission Regulation (EU) 2017/1203 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards organic silicon (monomethylsilanetriol) and calcium phosphoryl oligosaccharides (POs-Ca®) added to foods and used in the manufacture of food supplements
    - Commission Regulation (EU) 2015/403 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards Ephedra species and Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille)
    - Commission Regulation (EU) No 119/2014 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards chromium enriched yeast used for the manufacture of food supplements and chromium(III) lactate tri-hydrate added to foods
- 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
- 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
- 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.
- 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
- Decree of the Ministry of Agriculture and Forestry (754/2016) on the addition of vitamin D to skimmed homogenised milk
- Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (the Food Information Regulation)
- Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods (the Claims Regulation)
- Food Act (297/2021)
- Control Regulation (EU) No. 2017/625 of the European Parliament and of the Council

The EU legislation: https://eur-lex.europa.eu/homepage.html
The national legislation: https://www.finlex.fi/en/laki/kaannokset/

Other guidebooks related to fortified foods:
- Guidelines for submittal of notification on fortified foods (The Finnish Food Authority's guideline 6540/04.02.00.01/2021)
- Guidelines for withdrawal of fortified foods (The Finnish Food Authority's guideline 6539/04.02.00.01/2021)

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 Regulation on Fortified Foods).

At present, vitamins, minerals and certain other substances may be added to foods pursuant to the conditions of the Regulation on Fortified Foods without any specific

authorisation. However, operators in the food business are required to notify the Finnish Food Authority about the placing on the market of foods fortified with vitamins and/or minerals.

More information about the notification procedure is provided on the Food Authority's website at https://www.ruokavirasto.fi/en/companies/food-sector/production/common-requirements-for-composition/addition-of-nutrients-to-food/notification-on-bringing-to-market-fortified-foods/

The Regulation on Fortified Foods 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 (infant formula and follow-on formula, processed cereal-based foods and baby foods, dietary foods for special medical purposes and total diet replacement for weight management).

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 (Regulation on Fortified Foods, article 4).

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 https://ec.europa.eu/food/system/files/2021-01/labelling_nutrition-vitamins_minerals-comm_reg_en.pdf.

In Finland it is compulsory under the decree of the Ministry of Agriculture and Forestry (754/2016) to fortify skimmed homogenised milk with vitamin D3.

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 Regulation on Fortified Foods 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 vitamins, minerals and compounds of these permitted for use as fortification of foods are found in annexes I and II to the Regulation on Fortified Foods.

3.2 Permitted amounts

Minimum amount

The amounts of added vitamins and minerals in the final product shall not be too small or insignificant so that fortification may mislead the consumer. Fortification is adequate when the final total quantity 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 has to be at least:

1. 15% of the daily reference intake for the nutrient which is from 100 grams or 10 millilitres for products other than beverages.
2. 7.5 % of the daily reference intake, which is in 100 millilitres beverage or
3. 15% of the daily reference intake if the package contains only one dose

The reference intakes for vitamins and minerals are found in Annex XIII to the food regulation and in table 1 of this guideline.

Maximum amount

However, the amount of the added substances cannot be so large that they would exceed the daily reference intake (UL value) and cause adverse health effects. 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 place on the market in any other way (e.g. distance sales) 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 with triple the recommended intake.

The European Food Safety Authority EFSA has defined the tolerable upper intake levels (UL) for the daily intake of certain vitamins and minerals (see table 1).

The UL value indicates the overall amount of the vitamin or mineral that can be consumed daily without any health risks.

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.

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.

Table 1. Reference values for the daily intake of vitamins and minerals[1] and minimum amounts (15 % and 7.5 %) and the tolerable upper daily intake level[2] (UL values)

Vitamin/Mineral	Unit	Daily reference intake	Minimum amount 15 %	Minimum amount 7,5 % (liquids)	UL (adults)	UL children 1-3 y)	UL (children 4-6 y)	UL (children 7-10 y)	UL (children 11-14 y)	UL (children 15-17 y)
Vitamin A	µg	800	120	60	3000	800	1100	1500	2000	2600
Vitamin D	µg	5	0,75	0,375	100	50**	50	50	100	100
Vitamin E	mg	12	1,8	0,9	300	100	120	160	220	260
Vitamin K	mg	75	11,25	5,625	–	–	–	–	–	–
Vitamin C	mg	80	12	6	–	–	–	–	–	–
Thiamine (B_1)	mg	1,1	0,165	0,0825	–	–	–	–	–	–
Riboflavin (B_2)	mg	1,4	0,21	0,105	–	–	–	–	–	–
Niacin (B_3)	mg	16	2,4	1,2	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 B_6	mg	1,4	0,21	0,105	25	5	7	10		20
Folic acid	µg	200	30	15	1000	200	300	400	600	800
Vitamin B_{12}	µg	2,5	0,375	0,1875	–	–	–	–	–	–
Biotin	µg	50	7,5	3,75	–	–	–	–	–	–
Pantothenic acid (B_5)	mg	6	0,9	0,45	–	–	–	–	–	–
Potassium	mg	2000	300	150	–	–	–	–	–	–
Chloride	mg	800	120	60	–	–	–	–	–	–
Calcium	mg	800	120	60	2500	–	–	–	–	–
Phosphorus	mg	700	105	52,5	–	–	–	–	–	–
Magnesium	mg	375	56,25	28,125	250*	–	–	–	–	–
Iron	mg	14	2,1	1,05	–	–	–	–	–	–
Zinc	mg	10	1,5	0,75	25	7	10	13	18	22
Copper	mg	1	0,15	0,075	5	1	2	3	4	4
Manganese	mg	2	0,3	0,15	–	–	–	–	–	–
Fluoride	mg	3,5	0,525	0,2625	7	1,5	2,5	2,5-5	5	7
Selenium	µg	55	8,25	4,125	300	60	90	130	200	250
Chromium	µg	40	6	3	–	–	–	–	–	–
Molybdenum	µg	50	7,5	3,75	600	100	200	250	400	500
Iodine	µg	150	22,5	11,25	600	200	250	300	450	500

**Only magnesium salts and MgO from food supplements, fortified foods and water are included*

*** The UL value for vitamin D at the age of 0-6 months is 25 µg/day, at the age of 6-12 months 35 µg/day*

[1] *Regulation on the provision of food information to consumers (EU) No 1169/2011, Annex XIII*

[2] *Tolerable Upper Intake Levels for Vitamins and Minerals. Scientific Commitee on Food. Scientific Panel on Dietetic Products. Nutrition and Akkergies. EFSA February 2006.*

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 or 100 mg or the recommended dose 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 markets the food in question in any other way, 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 measures are for example:

- the reduction of the level of the nutrient in question in the product,
- changing the instructions for use so that the UL value is not exceeded in the recommended dose,
- a warning statement on the labelling, or
- some other action that will ensure the food is safe for 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 the Finnish Food Authority's website at https://www.ruokavirasto.fi/en/companies/food-sector/common-requirements-in-the-food-sector/valvonta/guidelines-on-withdrawal-of-products/

3.4 Labelling

According to article 9 in the Food Information Regulation, the mandatory requirements on food information also apply 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.

The Finnish Food Authority recommends that vitamins and minerals be indicated in the list of ingredients using the same names as 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. It is recommended that the order used in Annex XIII to the Food Information Regulation is followed in the nutrition labelling to make it easier for consumers to compare products with each other.

It is possible to add nutrition claims to fortified foods to emphasise their fortification, such as "*vitamin D added*" or "*source of vitamin D*" according to the conditions set out in the annex to the regulation on nutrition and health claims. But comparisons such as "*more vitamin C*", *50 % more calcium*", "*twice as much vitamin D*" and "*as much as*" are not permitted claims.

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

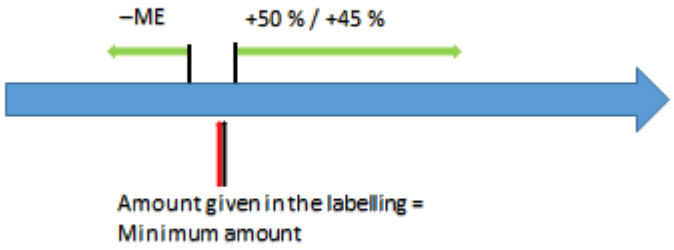
When the food is marketed as a source of nutrients (nutrition and health claims), the Finnish Food Authority recommends that the amount of each nutrient be determined by means of laboratory analyses or verified in some other reliable manner.

Tolerances in respect of the amount declared on the labelling

The European Commission has issued a guidance document with regard to the setting of tolerances for nutrient values declared on a label which is to be complied with in the member states.
https://ec.europa.eu/food/system/files/2016-10/labelling_nutrition-vitamins_minerals-guidance_tolerances_1212_en.pdf.

According to the guidance document of the Commission on tolerances (table 3), for a food that is fortified with vitamins and/or minerals the following deviations from the average values between the declared values and the result from the analysis can be accepted:

1. If the product contains the minimum amount of vitamins or minerals required



The tolerance is

- for vitamins +50 % and -the measurement uncertainty of the method of analysis
    - for vitamin C in liquids, higher upper tolerance values can be accepted
- for minerals +45 % and -the measurement uncertainty of the method of analysis

Example 1
Potassium has been added to a juice. The labelling claims that the food contains 150mg potassium per 100ml. The test result for potassium carried out by the official controls is 147mg/100ml. The measurement uncertainty for the method of analysis used is ± 4 %. Is the amount of potassium in the product within the tolerance range?

The potassium added has to affect the amount of potassium in the juice at least a significant amount. The juice must therefore contain at least a significant amount of potassium as defined in Annex XIII to the Food Information Regulation. A significant amount for liquid foods is 7.5 % of the reference intake, which means that the juice has to contain a minimum of 150mg of potassium per 100 ml.

According to the rounding rule in the EU Guidance Document for the Control of Compliance (see table 4), three significant figures are

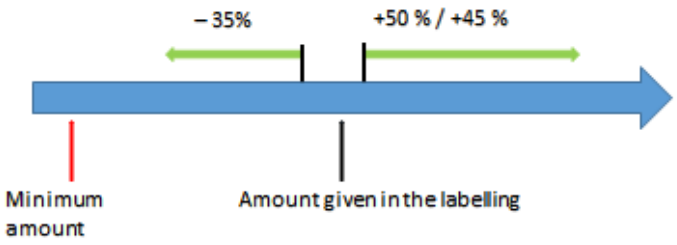
observed for potassium, so that the value 150mg/100 ml recorded on the label means that it has been rounded from the values 149.5-150.4mg/100 ml.

When controlling the conditions for the use of the claim in accordance with the Guidance Document to the lower side, meaning below the declared values of the vitamins or minerals added to foods, a tolerance that only includes the measurement uncertainty of the method of analysis is applied. When the measurement uncertainty is added to the analysed result for potassium content (147+147x0.04=152.88), we can see that the measured amount of potassium in the juice is within the tolerated range of the declared value.

Example 2
The test result for potassium in the mentioned juice carried out by the official controls is 143mg/100ml. Is the potassium content within the tolerated range?

When the measurement uncertainty is added to the analysed result for potassium content (143+143x0.04=147.72), we can see that the quantity of potassium in the juice is outside the tolerated range of the declared value. The official control authority has to assess the reasons for being outside the tolerance range in accordance with section 2.4 in the Commission Guidance Document and take further measures accordingly (guidelines, advice, requests).

2. If the product contains more vitamins or minerals than the required minimum amount



The tolerance is

- for vitamins +50 % and -35 %,
    - for vitamin C in liquids, the higher upper tolerance can be accepted

- for minerals +45 % and -35 %

The tolerances include the measurement uncertainty.

Example 3
Potassium has been added to a juice. The labelling claims the juice contains 200mg potassium per 100ml. The test result for potassium carried out by the official controls is 175mg/100ml. The measurement uncertainty for the method of analysis used is ± 4 %. Is the amount of potassium in the product within the tolerance range?

According to the rounding guidelines in the Guidance Document, three significant figures are observed for potassium, so the value 200mg/100 ml recorded on the label means that it has been rounded from the values 199.5-200.4mg/100 ml.

*In accordance with the Guidance document, when checking the limits of the declared value, the lower tolerance range is -35 % of the declared value. This also includes the measurement uncertainty. The lower tolerance is therefore 199.5 – 0.35*199.5= 129.68. Considering the rounding rule the minimum tolerance is 130 mg/100 ml.*

*The upper tolerance is +45 % from the declared value, which also includes the measurement uncertainty. The upper tolerance is 200.4+0.45*200.4=290.58. Considering the rounding rule, the upper tolerance is 291 mg/100 ml.*

If the control authority finds that the potassium content in the juice varies between 130-291 mg/100 ml, the product is considered to be within the variation tolerance. Therefore the potassium content in the juice is within the tolerated range as the value according to the analysis is 175 mg/100 ml.

If the results are repeatedly at the limits of the tolerated value, the food business operator should intensify their own-check control and carry out the necessary changes of the production process or labelling in order to rectify the situation.

When the declared nutrient content of a food repeatedly deviates from the tolerance range, it is not acceptable and the food should not be marketed.

3.6 Purity criteria for added vitamin and mineral formulations

The Regulation on Fortified Foods 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” https://www.fao.org/fao-who-codexalimentarius/codex-texts/miscellaneous/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 Regulation on Fortified Foods 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. Products containing these substances do not have to be declared.

The addition of these other substances is permitted, as a rule, if the substances are suited for human consumption and do not endanger human health. 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.

The Finnish Food Authority 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 warning labelling is provided on the Guidebook on Food Information, published by the Finnish Food Authority.

Article 8 of the Regulation on Fortified Foods 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.

These substances are included in Annex III of the Regulation on Fortified Foods in either:

- A – If the substance is prohibited
- B – If restrictions apply to the use of the substance
- C – If the substance is under Community scrutiny

Until now, the following have been prohibited by way of this procedure (A):

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

- Danthron and all preparations in which this substance is present.

Restrictions shall apply to the use of substances (B):

- Trans fat other than trans fat naturally occurring in fat of animal origin
  - Conditions of use: Maximum 2 grams per 100 grams of fat in food intended for the final consumer and food intended for supply to retail.
  - Additional requirements: Food business operators supplying other food business operators with food not intended for the final consumer or not intended for supply to retail, shall ensure that supplied food business operators are provided with information on the amount of trans fat, other than trans fat naturally occurring in fat of animal origin, where that amount exceeds 2 grams per 100 grams of fat.

Under Community scrutiny (C):

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

For more information, see the website of the European Commission at:
https://ec.europa.eu/food/safety/labelling_nutrition/vitamins_minerals_en

3.8 Is it a novel food?

If the other substance referred to in the Regulation on Fortified Foods 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 the Finnish Food Authority's website at https://www.ruokavirasto.fi/en/companies/food-sector/production/common-requirements-for-composition/novel-foods/

4 OPERATOR'S OWN-CHECK QUALITY ASSURANCE

4.1 Operator responsibility

As far as fortification of foods is concerned, responsible operators are 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 or places them on the market in any other way (for example distance sales via an on-line store)

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 own-check quality assurance.

Items that are critical with respect to food safety and food regulations shall be recorded in the operator's own-check 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 own-check 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 own-check 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 or placed on the market in any other way 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 the Finnish Food Authority's website at https://www.ruokavirasto.fi/en/companies/food-sector/common-requirements-in-the-food-sector/valvonta/guidelines-on-withdrawal-of-products/

More information about own-check is provided the Finnish Food Authority's website at https://www.ruokavirasto.fi/en/companies/food-sector/common-requirements-in-the-food-sector/own-check/

4.2 Own-check 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. 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 Own-check 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. 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 exceed the safe daily upper intake level (UL value) and does not pose a health hazard;
- 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 the Food Authority of the placing on the market of a food fortified with a vitamin or a mineral.

4.4 Own-check control implemented by operators who import or have fortified foods produced or placed on the market in any other way

Food business operators, who import or have fortified foods produced or placed on the market in any other way (i.e. distance sales), must possess sufficient and accurate information about the food they produce, process and distribute and about the legislation pertaining to it. Food business operators who import or have fortified foods produced or placed on the market in any other way are not permitted to forward products they know or have reason to suspect to be in violation of legislation.

Operators who import fortified foods or have them produced or placed on the market in any other way shall also ensure the safety of the fortified food and the accuracy of the information provided on the product through their own-check control.

- 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 added does not exceed the safe daily upper intake level (UL) and does not pose a health hazard;
- 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 the Finnish Food Authority of the placing on the market of a food fortified with a vitamin or a mineral.

The most important own-check control tools of operators who import fortified foods or have them produced or placed on the market in another way 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 Own-check 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. 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 or sell under their own name.

Operators, who apart from packing or marketing foods also produce them or have them produced or import them or place them on the market in any other way, shall implement own-check 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 (EU) 2017/625.

5.1 Risk based approach

Pursuant to Section 1 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
    - provision of information to consumers for making of choices
    - preventing the misleading of consumers (e.g. adequate / significant amount of added vitamins and minerals)

5.2 Control authorities

Municipal food control authorities 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.

The Finnish Food Authority is in charge of the planning, guiding and development of the control of fortified foods on national level.

- **The Food Authority's official veterinarians** control the effectiveness and implementation of own-check control in their own region, and also take into account requirements related to fortified foods.
- **The Food Authority's Organic Control Section** is entrusted with the control of the fortified foods pursuant to legislation on organic farming.
- **The Food Authority's Veterinary Border Control and Intra-Union Trade Section** control of the compliance of foods of animal origin imported from non-EU states (incl. fortification of foods).

The Customs control the import of food of non-animal sources from outside of EU but also from the EU.

Other control authorities (National Supervisory Authority for Welfare and Health i.e. Valvira and the Defence Forces) 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 own-check plan;
- controls of recipes, labelling and documents;
- review of practical activities;
- sampling, if necessary / if non-compliance is suspected.

Review of own-check plan and its implementation is designed to verify that

- operators manage through their own control of their activities (own-check) 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
- the products contain the declared quantity of vitamins and/or minerals within the tolerances
- the information provided on the product is accurate

Control shall focus on aspects, which operators can influence with their own activities. The content of own-check 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.

The OIVA evaluation guideline 11.2,"Fortification of foods" in the Finnish Food Authority’s food safety information publication system OIVA determines the measures to be taken when defects related to fortification 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

The Food Authority's guidelines for withdrawal of foods
https://www.ruokavirasto.fi/en/companies/food-sector/common-requirements-in-the-food-sector/valvonta/guidelines-on-withdrawal-of-products/

7 COMING INTO FORCE

This guidance has come into force on 15.11.2021 and it replaces the previous version (The Finnish Authority's guidance 17059/2, published on 25.1.2019).

Updates in this version: The guide has corrections to references to legislation, including the Food Act 297/2021 and Official Controls Regulation (EU) No. 2017/625, the European Commission's website and the updated Food Authority's guidelines.

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