REPUBLIC OF ESTONIA
VETERINARY AND FOOD BOARD

GUIDELINE FOR THE ASSESSMENT OF COMPLIANCE OF FOOD SUPPLEMENTS

Drafted: June 2017

Last update: March 2020

Companies handling food (including food supplements) are obliged to ensure that their products are compliant and safe for consumers.

The purpose of this guideline is to provide instructions to food business operators to ensure the compliance of food supplements and handling thereof.

Contents

1. Vitamins and minerals

Only vitamins and minerals listed in Table 1 can be used in food supplements. For example, it is not permitted to use vanadium, lithium, germanium, tin, or silver in food supplements.

Table 1. Vitamins and minerals authorized in food supplements

Vitamin	Unit	Mineral	Unit
Vitamin A	µg RE*	Calcium	mg
Vitamin D	µg	Magnesium	mg
Vitamin E	mg α-TE*	Iron	mg
Vitamin K	µg	Copper	µg
Vitamin B1	mg	Iodine	µg
Vitamin B2	mg	Zinc	mg
Niacin (vitamin B3)	mg NE*	Manganese	mg
Pantothenic acid (vitamin B5)	mg	Sodium	mg
Vitamin B6	mg	Potassium	mg
Folic acid (vitamin B9)	µg	Selenium	µg
Vitamin B12	µg	Chromium	µg
Biotin	µg	Molybdenum	µg
Vitamin C	mg	Fluoride	mg
		Chloride	mg
		Phosphorus	mg
		Boron	mg
		Silicon	mg

* RE = retinol equivalent = 3.33 IU = 1 µg of retinol = 6 µg β-Carotene
α-TE = D-α-tocopherol equivalent, 1 mg α-TE = 1.49 IU = 1 mg D-α-tocopherol
NE = niacin equivalent = 1 mg niacin = 60 mg tryptophan

2. Substances of vitamins and minerals

The use of vitamins and minerals in food supplements is permitted **only** in the form of certain substances. The list of authorised substances can be found here.
Any substances, which are not included in the referred list, cannot not be used in food supplements.
For example, it is not permitted to use magnesium threonate, iron oxide, or chromium chelate in food supplements.
The list does not apply to vitamins and minerals from natural sources, such as vitamin C from sea-buckthorn powder.

3. Minimum and maximum levels for vitamins and minerals

Minimum and maximum levels for vitamins and minerals in food supplements have not been established in the European Union.
In Estonia, the applied maximum levels are based on the tolerable upper intake levels established by the European Food Safety Authority (EFSA).
Guideline on the maximum amounts of vitamins and minerals in Estonia can be found here (in Estonian).
If a product is claimed to be a source of a specific vitamin/mineral, the minimum quantity must be at least 15% of the daily nutrient reference value (established by Regulation 1169/2011).

4. Tolerances on the labelling of vitamins and minerals

Tolerances for vitamins and minerals on the labelling are permitted according to the European Commission's guideline. These values also include the laboratory measurement uncertainty.

Table 2. Tolerances for vitamins and minerals indicated on the labelling of food supplements

	Minimum	Maximum
Vitamins	-20%	+50% for vitamin C in liquids, higher upper tolerance values could be accepted
Minerals	-20%	+45%

5. Plants

The use of plants in food supplements is not regulated neither in the European Union nor in Estonia.
Two plants are prohibited in food under the so-called fortification regulation:

- plants of the *Ephedra* family and
- yohimbe (*Pausinystalia johimbe*) bark.

Products, which contain plants with medicinal properties and are on the list of the Agency of Medicines, may be prohibited in food if products are classified as medicines.
Products, which include plants from above-mentioned list, are not automatically classified as medicines. In order to find out whether or not a product is a medicine, the State Agency of Medicines should be asked to classify the product.
Plants with medicinal properties are, for example, ginkgo (*Ginkgo biloba*), common Saint John's wort (*Hypericum perforatum*), saw palmetto (*Serenoa repens*), and milk thistle (*Silybum marianum*).

Plants, which are unauthorized novel foods, are prohibited (see section 13).

Other plants are subject to the general requirement that they must be safe for human consumption.

Plants that may pose a risk to human health are listed in the EFSA's database of botanicals.
Plants included in that database are not explicitly prohibited in food supplements but it indicates that these plants may be unsafe and the food business operators must be able to demonstrate that the food supplements marketed by them are safe for human consumption.

As using plants in food supplements is not regulated in the EU level, several EU Member States have nationally enforced their own legislation for prohibited/authorised plants or restricted their use in food or food supplements (e.g. Belgium).

6. Other substances

There are no specific legislation in the European Union or in Estonia, establishing a list of authorised or prohibited substances in food supplements.

However, certain substances are prohibited in foods (including food supplements) under other legislation:

- unauthorized novel foods, such as agmatine sulphate, cannabidiols (CBD), 5-HTP (5-hydroxytryptophan);
- substances used in medicinal products (e.g. sildenafil, tadalafil, sibutramine) authorised only in medicinal products (in food, they would be unauthorized novel foods);
- products, which contain substances with a medicinal properties and they are classified as medicines by the State Agency of Medicines.
  The Register of Medicinal Products can be used to check which substances are used as active ingredients in medicinal products.
- For example, glucosamine, melatonin, caffeine and alpha lipoic acid are used in medicinal products. Products containing medical substances are not automatically medicines, it depends on the concentration of the substance whether the product is a medicine or a food supplement.
- hormones and doping sagent (Anti-doping convention, Estonian Anti-doping Agency);
- narcotic and psychotropic substances (Regulation no. 73 of the Minister of Social Affairs);
- endangered plants and animal species (CITES- the Convention on International Trade in Endangered Species of Wild Fauna and Flora).

When other substances are used, the product must comply with the general requirement that food must be safe and the food business operator must be able to demonstrate that the product marketed by them is safe for consumers.

7. Additives, enzymes, flavourings

The use of food additives in food supplements is authorized in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council.
Information about using additives can also be found from the European Commission's database of food additives.

The use of enzymes in food is regulated by Regulation (EC) No 1332/2008 of the European Parliament and of the Council and use of flavourings must comply with the requirements of Regulation (EC) No 1334/2008 of the European Parliament and of the Council.

8. Microbiology

No microbiological requirements for food supplements have been established by legislation. However, both the raw material and the final product must be of such high microbiological quality that they do not pose a risk to human health.

Guidelines for testing microbiological parameters for the determination of shelf-life can be found in the following instructions (in Estonian):

- Determination the shelf life of a food product, part I
- Determination the shelf life of a food product, part II, microbiological parameters by food groups. Food supplements are not been specified as a separate food category

9. Contaminants

Commission Regulation (EC) No 1881/2006 sets out certain maximum limits for contaminants in food supplements. These limits are specified in Table 3.

Table 3. Maximum levels for contaminants in food supplements

Contaminant	Maximum limit	Type of food supplement
Lead	3.0 mg/kg	all food supplements
Cadmium	1.0 mg/kg	all food supplements
	3.0 mg/kg	food supplements which consist only or mainly of dried seaweed, seaweed-based products, or dried bivalve molluscs
Mercury	0.10 mg/kg	all food supplements
Citrinin	2,000 µg/kg	food supplements which are based on rice fermented with red yeast *Monascus purpureus*
PAHs:		
Benzo(a)pyrene	10 µg/kg	food supplements which contain botanicals or plant-based preparations and food supplements which contain beeswax, royal jelly, or spirulina or preparations thereof
Total content of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene, and chrysene	50 µg/kg	
Total dioxin content	1.75 pg per gram of fat	food supplements which contain fish oil, fish liver oil, or oils of other marine organisms
Total content of dioxins and dioxin-like PCBs	6 pg per gram of fat	
Non dioxin-like PBCs	200 ng per gram of fat	

10. Food supplements with alcohol

Food supplements with alcohol are not required to be registered in the National Alcohol Register.
There is no maximum limit for alcohol content in food supplements.
If food supplements contain alcohol, attention should be paid to alcohol excise duty. The details can be found from the website of the Tax and Customs Board (in Estonian): Imposition of excise duty on food supplements containing alcohol.

11. Organic food

References to organic farming can be made if at least 95% of the agricultural ingredients of the product originate from organic farming. The remaining 5% may be formed by agricultural ingredients, which cannot be obtained from organic farming.

The food supplements containing vitamins and minerals as chemical compounds cannot be organic products. The vitamins and minerals in organic products may only originate from natural sources (e.g. vitamin C from rose hip).

The wholesalers marketing organic food products must be approved under the Organic Farming Act.

More information about organic food can be found here.

12. Residues of plant protection products

If food supplements contain plants, which have been treated with plant protection products during growing, the raw material and products must comply with the maximum permitted levels specified in Regulation no. 396/2005.

13. Novel food

As many different substances and plants are used in food supplements, the question of novel food often arises. Novel food is food, which was not used as food for human consumption in a significant degree in the European Union prior to 15 May 1997.

Novel food may be marketed if it has been assessed as safe by the EFSA and authorised by the European Commission.

Authorised novel foods are listed in Commission Implementing Regulation (EU) 2017/2470 (as September 1, 2020).

Authorised novel foods, for example, are krill oil, chia seeds, noni juice, UV-treated baker's yeast, coriander seed oil, lactoferrin, zeaxanthin.

Under the novel food regulation, operators are obliged to determine whether the food, which they intend to market, is novel food or not.

How to determine if product is novel food or not?

There is not one good way to do it.

The following options can be used to determine whether a food is a novel food or not:

1. List of authorized novel foods (Regulation 2017/2470)
   The list includes authorised novel foods, which may be used in food / as food according to the conditions and the specifications provided in the list.
   As the legislation is regularly updated, the latest consolidated version should be checked in Eur-Lex.
2. European Commission's novel food catalogue – the catalogue includes information on the novel food status of the substances/planrs, which have been discussed between novel food specialists of the EU Member States and European Commission.
   NB! There are four different novel food statuses in the novel food catalogue:
   - is a novel food
   - is not a novel food
   - is not a novel food in a food supplements
   - novel food status is unclear

   Thus, if a plant/substance is not a novel food in food supplements (e.g. Chaga- *Inonotus obliquus*) it can be used only in food supplements. The novel food authorization is required for regular food use.
3. Submitted novel food applications and notifications
   The foods, listed on the European Commission's website, are novel foods (incl. traditional foods from third countries) and can only be marketed after the authorisation.
4. List of old novel food applications
   The list contains novel food applications, which were submitted when the previous novel food regulation was in force. The substances/plants in the list are prohibited novel foods unless they are included in the list of authorised novel foods.
5. Decisions by Member States on novel food statuses
   The European Commission website publishes decisions by the Member States on novel food statuses.
6. Belgian regulation of food supplements
   The regulation specifies the plants, which are prohibited and authorised in food supplements. Permitted plants are considered as not novel in food supplements.
7. Italian regulation of food supplements
   The regulation specifies the plants, which can be used in food supplements, and these plants are considered not novel in food supplements.
8. German list of plants
   German plant list provides novel food statuses for certain plants.
9. Belgian list of plants
   The website of the Belgian competent authority includes a list of botanicals and their novel food statuses.
10. Danish list of plants
    The website of the Denmark competent authority includes a list of botanicals and their novel food statuses.
11. The BELFRIT list of plants

A list of plants and fungi complied by Belgium, France, and Italy. The plants and fungi included in the list are considered as not novel in food supplements.

12. The EuroFIR-Nettox list of plants
    Plants on the list are considered not novel.
13. Austrian list of tea plants
    The plants included in the list are considered not novel in the composition of teas.
14. Finnish list of plants
    A list of plants commonly found in Finland and their novel food statuses.
15. Finnish list of fungi
    A list of edible fungi, which are not considered as novel food.
16. Italian list of substances
    The substances, which may be used in food supplements in Italy and which are considered as not novel in food supplements.
17. RASFF notifications
    The Rapid Alert System for Food and Feed can be used to obtain information on which non-authorised novel foods have been found from the EU market. "Novel food" should be selected as the hazard category in the search.
    It should also be noted that in the case of RASFF notifications, the novel food status may may have changed over time (e.g. the substance has been authorised or has been found not to be novel food).

If no information on plants/substances is available from these lists, they may be novel foods and the food business operator should proceed as follows:

- search for information on whether or not the plant/substance was used as/in a food in EU Member States in a significant degree prior to May 15, 1997.
  Various materials such as purchase and sales invoices, price lists, import documents, books, recipes, catalogues, date labels, FAO statistics can be used for this purpose;
- If the status of novel food is not established, an application for determining the novel status of a food can be submitted to a competent authority of the EU Member State.
- if the plants/substance turns out to be a novel food and is to be marketed, a novel food application/notification must be submitted to the European Commission.
  Novel foods may not be marketed before the authorisation has been granted.

14. Notification of food supplements

All food supplements placed on the market in Estonia must be notified to the Veterinary and Food Board. For this purpose, information about the product and the company must be provided, as well as an example(s) of the labelling.

If a specific food supplement (same product and the same manufacturer) has already been notified, the next operator placing on the market does not have to notify the product.

The notified food supplements can be found in a public database.

The website of the Veterinary and Board also includes a list of products, which have been removed from the database or rejected upon notification (with reasoning).

15. Export

Export is the marketing of food to countries outside the European Union.
Food supplements authorised in the country of destination and meeting their requirements may be exported.
If a food is prohibited in the EU but is permitted in a third country, it may be produced and marketed in Estonia in a third country under the following conditions:

- the food is transported directly to the third country, i.e. without using distributors in the EU; and
- there is a declaration from the competent authority of the country of destination that the food is authorised in their country. The country of destination must be informed of why food is banned in the EU.

16. Import

Import is marketing food to Estonia from countries outside the European Union (except Norway and Switzerland).

Only food supplements that meet the requirements in Estonia can be imported into Estonia. This does not apply to small amounts of food supplements which are not imported for marketing (e.g. for scientific research, product development, or to be used as samples) and the Veterinary and Food Board has issued a special permit to the importer based on their application.

Food supplements of non-animal origin are not subject to inspection upon importation. However, specific requirements or restrictions may apply to imports of certain products of non-animal origin.

Food supplements, which are animal origin or contain animal and non-animal ingredients, may be subject to border control upon importation. More information about the import of animal origin food can be found here.

Veterinary and Food Board cannot restrict the import of food for personal consumption. A one-year supply of food supplements for one person is considered to be personal consumption.

17. Trade in the European Union

Trade in the European Union is marketing of food between the EU Member States, Norway, and Switzerland.
When marketing food supplements to another EU Member State, the following should be noted:

- **Is the product authorised as a food supplement?**
  As the classification of medicines is not harmonised in the European Union, all Member States classify products separately, therefore one product may be a food supplement in one country and a medicinal product in another.

- **Are the ingredients permitted?**
  As the use of plants and other substances is not harmonised in the European Union, some Member States have introduced national legislation prohibiting/restricting the use of certain plants or substances in food/food supplements.

- **Is it necessary to notify marketing a food supplement?**
  In most EU Member States, it is necessary to notify marketing of food supplements. Notification is not required in the following EU countries: Sweden, the Netherlands, Austria, and Slovakia.

The website of the European Commission includes a list of competent authorities in the field of food supplements.