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Federal Department of Home Affairs FDHA
Federal Food Safety and Veterinary Office FSVO
Food and Nutrition

Questions and answers about food supplements
For establishments

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Requirements pertaining to food supplements

- **1. Which substances may be present in food supplements (FS)?**
  Art. 2 para. 3 of the FDHA Ordinance on Food Supplements (FoodSO; SR 817.022.14) regulates permissible substances in FS. The following may be present:
  a. Vitamins and minerals as specified in Part A of Annex 1 of FoodSO under the conditions stipulated there;
  b. Other substances as specified in Part B of Annex 1 of FoodSO with the restrictions stipulated there;
  c. Novel foods, provided they are authorised for FS
  d. Other foodstuffs, subject to the provisions of letters a-c.

  Substances other than those listed in Part B of Annex 1 of FoodSO may be contained in food supplements in the context of self-supervision activities, subject to fulfilment of the requirements in the foodstuffs legislation. This means that the following conditions, in particular, must be fulfilled:
  - Food safety must be ensured (Art. 7 of the Foodstuffs Act; FoodA; SR 817.0; Art. 8 of the Ordinance on Foodstuffs and Utility Articles; FSO; SR 817.02);
  - The substance and product must not fall within the scope of the legislation on therapeutic products (Art. 2 para. 4 FoodA);
  - The definition of a foodstuff must be met (Art. 4 FoodA);
  - The definition and requirements pertaining to a food supplement must be met (Art. 1 and 2 FoodSO);
  - The prohibition of deception must be observed (Art. 18 FoodA; Art. 12 FSO);
  - The provisions for “novel foods” must be fulfilled (Art. 15-19 FSO, FDHA Ordinance on Novel Foods; SR 817.022.2).

  Compliance with these requirements must be ensured and documented by self-supervision (see Information letter 2021/7.1: Self-supervision of non-regulated other substances in food supplements).

- **2. Which lists of prohibited substances apply to FS?**
  - List of prohibited substances: The listed substances are prohibited in/as foodstuffs including FS (Annex 4 AVMO, Art. 2 para. 4 FoodSO);
  - List of prohibited plants: The listed plants and plant parts and preparations and substances obtained from them may not be used in/as foodstuffs including FS (Art. 3, Annex 1 VFO).

- **3. Which vitamins and minerals are permitted in FS? What are the maximum permitted levels?**
  The permitted vitamins and minerals and their maximum levels are listed in Part A of Annex 1 of FoodSO.

  The established maximum levels are based on the need to protect health. The upper limit of the tolerance range for the declared value is therefore the maximum level (see Information letter 2021/3: Tolerances for declared nutrient values and the EU guidelines[1]).

[1]https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-vitamins_minerals-guidance_tolerances_1212_de.pdf

Further information about the maximum level model for vitamins and minerals can be found on the FSVO website.

- **4. Which combinations of vitamins and minerals are authorised?**
  The permitted combinations of vitamins and minerals are listed definitively in Annex 2 of FoodSO.

- **5. What is the situation regarding novel combinations of vitamins and minerals?**
  The use of novel combinations (e.g. organic silicon [monomethylsilanetriol], nicotinamide riboside chloride) is governed by the Ordinance on Novel Foods (SR 817.022.2). According to the Annex of the Ordinance on Novel Foods, novel foods authorised in the EU may be marketed in Switzerland without an authorisation if the conditions for use and specifications in the novel food authorisation are fulfilled. However, if the permitted maximum level of a vitamin or mineral stated in Part A of Annex 1 of FoodSO is lower than that specified in the novel food authorisation, the latter takes precedence and may not be exceeded.

- **6. What specific requirements apply to FS containing live bacterial cultures?**
  The bacterial cultures used must be suitable for food purposes and pose no risk to health. The requirements are governed by Annex 3 of FoodSO. FoodSO also contains requirements concerning minimum levels and labelling.

- **7. What is the situation regarding novel foods including CBD?**
  The provisions for novel foods must be observed (Art. 15-19 FSO, Ordinance on Novel Foods). Novel foods are foods that were not used to a significant degree for human consumption in Switzerland or in a Member State of the EU before 15 May 1997 and that fall under one of the categories listed in Art. 15 para. 1 FSO. They must be authorised in Switzerland or the EU.
  Information about novel founds can be found on the FSVO website.
  The FSVO website also provides specific information about cannabis, hemp extracts and cannabinoids.

- **8. What regulations apply to FS containing herbal substances and preparations?**
  The following legal provisions in particular must be observed for FS containing herbal substances and preparations:
  - In order for a product to be marketed as a foodstuff, it must fall within the definition of foodstuffs stated in Art. 4 FoodA. Compliance with food safety rules (Art. 7 FoodA, Art. 8 FSO) and the prohibition of deception (Art. 12 FSO) as well as with the general legal provisions relating to foodstuffs (e.g. with regard to labelling) is essential for placing foodstuffs on the market. Any foodstuffs designated as such must also meet the requirements of the corresponding category (Art. 14 FSO).
  - As a food supplement, the product must comply with the provisions of FoodSO and all other general and specific legal requirements, in particular those concerning definition, composition, purpose, presentation and labelling.
  - The distinction between these products and therapeutic products must be ensured. In all cases an overall evaluation based on all available criteria, such as composition, dosage, purpose, labelling, presentation, claims, etc., is necessary so that a product can be correctly assigned and assessed. Further information can be found in the Report on delimitation;
  - The provisions for novel foods may need to be observed (Art. 15-19 FSO, Ordinance on Novel Foods). The novel food status of the foodstuff or ingredient (e.g. extract) must be checked and documented. The classification of a substance (plant) cannot be applied to extracts obtained from this substance. If, for example, extraction processes are used to isolate or purify components during the manufacture of a foodstuff, the composition of the product is no longer the same as the natural composition of the plant. In this case the novel status of this foodstuff must be assessed.
  - The plants and plant parts listed in Annex 1 of the FDHA Ordinance on Foodstuffs of Vegetable Origin, Fungi and Table Salt (VFO; SR 817.022.17) and preparations and substances obtained from them are not permitted in/as FS.

- The provisions governing health claims must be observed (see also Questions 12 and 13).
- Information letter 2021/4: Use of "substances" in the categories plants, fungi, lichen and algae and preparations manufactured from them as foodstuffs or ingredients in foodstuffs contains information about plants, plant parts and preparations obtained from them.

- **9. What is the situation for FS containing fungi?**
  The fruiting bodies of fungi listed in Information letter 2020/2: Marketability of fungi as foodstuffs or in Annex 4 of VFO may be used in FS; they are not considered to be novel foods. The novel food status of all products obtained from these fungi (e.g. extracts, biomass, mycelium, etc.) must be checked and documented by the manufacturer, importer or distributor before they are placed on the market. For example, the dehydrated mycelium powder of *Ganoderma lucidum* is classified as a novel food in the EU (see Novel Food status Catalogue of the EU and "Consultation process on novel food status") and must be authorised before it is placed on the market in/as a foodstuff.
  All fungi (edible fruiting bodies) which are not listed in either Annex 4 of VFO or Information letter 2020/2: Marketability of fungi as foodstuffs but which are shown in the Novel Food status Catalogue of the EU as having the status "FS" may be used in FS without authorisation (e.g. chaga, *Inonotus obliquus*). The products of this fungus mentioned in the Catalogue have a history of being used widely as a foodstuff safe for human consumption in/as a food supplement in the EU prior to 15 May 1997. However, all uses other than as/in food supplements – and all other products from these fungi – are considered to be novel and must therefore be authorised.
  For all fungi (fruiting bodies) which are not listed in either Annex 4 of VFO or Information letter 2020/2: Marketability of fungi as foodstuffs and which are not shown in the Novel Food status Catalogue of the EU as having either the status "not novel" or "FS" and all products obtained from them (e.g. extracts, biomass, mycelium, etc.), the importer or distributor must check and document the novel food status before the products are placed on the market.

- **10. Are FS permitted to contain alcohol? Can health claims be made for these products?**
  According to Art. 2 para. 3 let. d of FoodSO, FS may contain other foodstuffs, subject to the provisions of letters a-c. Food supplements may therefore contain alcohol (ethyl alcohol) as an ingredient, subject to the provisions of Art. 2 para. 3 let. a-c.
  Health claims are not permitted for beverages with an alcohol content greater than 1.2 per cent by volume (Art. 34 para. 3 FoodIO). FS are not considered to be beverages within the meaning of this paragraph. Health claims can therefore be made for these products provided the respective conditions are fulfilled.

- **11. What other provisions are important?**
  The provisions of the general and product-specific ordinances must be observed. This applies also and in particular to the provisions governing hygiene (FDHA Hygiene Ordinance; HyO; SR 817.024.1), additives (Food Additives Ordinance; FoodAO; SR 817.022.31), flavourings (Flavourings Ordinance; SR 817.022.41), technical procedures and technical auxiliaries for the treatment of foodstuffs (FDHA Ordinance on Technical Procedures and Technical Auxiliaries for the Treatment of Foodstuffs; TPAFO; SR 817.022.42) and contaminants (Contaminants Ordinance; ContO; SR 817.022.15).

Labelling and promotion

- **12. What provisions apply to the labelling of FS?**
  The general and specific labelling requirements must be observed. The general labelling requirements are based on the FSO and the Ordinance on Information on Foodstuffs (FoodIO; SR 817.022.16). The specific labelling provisions for FS are contained in FoodSO.

  The mandatory information must be shown in at least one official language of the Swiss Confederation, i.e. in German, French or Italian (Art. 36 para. 2 let. c FSO).

  The designation is: "food supplement" (Art. 3 para. 1 FoodSO).

In addition, it is vital for the following information to appear on a FS (Art. 3 para. 7 FoodSO):

- the recommended daily intake in portions of the product;
- a warning that the stated recommended daily dose should not be exceeded;
- a note that FS should not be used to replace a varied diet;
- a note that the products must be stored out of the reach of young children;
- a warning or a note referring to the specific target group or the conditions for use in accordance with Annex 1 of FoodSO;
- the names of the categories of vitamins, minerals or other substances that are characteristic of the product, or information about the nature of these vitamins, minerals or other substances.

- **13. What health claims may be used for FS?**
  Health claims may only be made if they are listed in Annex 14 of FoodIO and fulfil the requirements of Chapter 2 Section 12 FoodIO. Health claims that are not listed in Annex 14 of FoodIO require approval by the FSVO (Art. 31 para. 2 and 3 FoodIO).

  References to non-specific benefits of a nutrient or a foodstuff for health in general or health-related well-being are only permissible in conjunction with a corresponding permissible specific health claim (Art. 34 para. 2 FoodIO).

- **14. Can health claims for "botanicals,", which are "on hold" in the EU be used in Switzerland?**
  In Switzerland the provisions governing health claims on foodstuffs are regulated in the FDHA Ordinance on Information on Foodstuffs (FoodIO; SR 817.022.21). The health claims permissible in Switzerland are listed in Annex 14 of this Ordinance. Health claims that are not listed in this Annex must be approved by the Federal Food Safety and Veterinary Office (FSVO) (Art. 31 para. 3 FoodIO).
  There are no special provisions in the Swiss foodstuffs legislation for the "on hold claims" in the EU.

Food supplements for different population groups

- **15. What are the provisions governing FS for children?**
  The permissible maximum levels for vitamins, minerals and certain other substances in Annex 1 of FoodSO refer to adults. There are no specific provisions in the Swiss foodstuffs legislation for FS intended for children (toddlers). Distribution of these products is subject to self-supervision in accordance with Art. 26 FoodA.
  Breast milk and infant formula alone are sufficient to meet the needs of healthy infants. Infant formula is regulated exhaustively in the FDHA Ordinance on Foodstuffs for Persons with Special Dietary Requirements (SDRO; SR 817.022.104). It is regulated in such a way that it meets the nutritional requirements of infants in full up to the end of their fourth month of life (Art. 5 para. 1 SDRO). The legislation therefore makes no provision for supplementation of infant formula.

  A generally balanced and varied diet provides healthy children (toddlers) with the necessary vitamins and minerals. The FSVO is therefore of the opinion that food supplements are unnecessary for healthy toddlers under three years of age.

  Should special dietary requirements emerge in the first three years of an infant's or toddler's life as a result of specific genetic or health conditions, this must be investigated by a paediatrician. The correct foodstuff for special medical purposes (FSMP, see Chapter 3 SDRO) or medication will then be prescribed on the basis of the diagnosis.

  The FSVO has published information on nutrition for infants and toddlers on its website.

- **16. Why have no separate maximum levels for vitamins and minerals for special population groups been established since 1 July 2020?**
  The maximum levels of vitamins and minerals in the revised FoodSO, which came into force on 1 July 2020, are now based on the need to protect health and not on dietary requirements. It is therefore no longer possible to establish separate maximum levels for special population groups with greater requirements, e.g. pregnant and breastfeeding women, older people aged 60 and over. If the daily requirement exceeds the amount that can be provided by FS, appropriate medicinal products are available.

  Further information about the new maximum level model can be found on the FSVO website.

- **17. How should DS be distinguished from other categories of foodstuffs, such as foodstuffs for special dietary requirements (e.g. products for athletes) or enriched foodstuffs (e.g. enriched beverages)?**
  The manufacturer or distributor is fundamentally responsible for classifying their products and complying with the corresponding provisions of the foodstuffs legislation.
  Food supplements must be distinguished from foodstuffs for individuals with special dietary needs, such as foodstuffs for athletes, and enriched foodstuffs, such as enriched beverages. Each category is subject to specific requirements in terms of composition and labelling.
  Food supplements are concentrated nutrients that supplement the general diet and are placed on the market in dose form in measured small quantities (e.g. capsules, tablets, pills, sachets of powder). Their energy value is usually negligible.
  Foodstuffs for individuals with special dietary requirements (e.g. FSMP, daily rations for a weight-controlling diet, foodstuffs for athletes), on the other hand, are designed to meet the special dietary requirements of specific consumer groups. The specific requirements for this are stipulated in the SDRO. These foodstuffs differ from DS in the way in which they are supplied, their energy value and their purpose, which is usually determined by the distributor on their own responsibility.
  Foodstuffs for athletes, for example, must meet the special energy and nutrient needs of this consumer group and provide a practical source of nutrients in situations in which consumption of traditional foodstuffs is not practicable. A product must be placed on the market either as a “food supplement” or as a “foodstuff for athletes”. The designation “food supplement for athletes” can therefore not be used in Switzerland.
  The FDHA Ordinance on the Addition of Vitamins, Minerals and other Substances to Foodstuffs (AVMO; SR 817.022.32) regulates the enrichment of traditional foodstuffs.

Import and export of food supplements

- **18. Can FS from the EU be marketed in Switzerland?**
  In the EU many aspects of the provisions governing food supplements (e.g. maximum levels, lists of prohibited substances or plants) are not harmonised. Most EU Member States have national provisions.
  FS from the EU cannot automatically be marketed in Switzerland. As part of their duty to perform self-supervision activities, the importer and distributor must ensure that the product complies with the provisions of the foodstuffs legislation in Switzerland.

- **19. Can FS be approved using the Cassis de Dijon principle?**
  Since 1 May 2017, food supplements that are marketed lawfully in a Member State of the EU/EEA can also be authorised using the Cassis de Dijon (CdD) principle.
  For authorisation to be possible, there must be a technical deviation from the Swiss provisions, and the product must be marketed lawfully in the EU/EEA Member State whose regulations are referenced. CdD applications may furthermore be rejected in the interests of protecting health or preventing deception.

  Products containing very high levels of vitamins and minerals in excess of the new maximum levels in Switzerland are on the market in some EU/EEA Member States (see Question 15). Since the new

maximum level model is based on the need to protect health, products which exceed the new maximum levels for vitamins and minerals cannot be authorised using the Cassis de Dijon principle. Any applications in this category would have to be rejected.

The FSVO website provides more information about the Cassis de Dijon principle.

- **20. Can non-conforming FS be exported?**
  Foodstuffs intended for export may deviate from the provisions of the Foodstuffs Act (e.g. labelling) if the legislation or the authorities in the country of destination require or authorise something different (Art. 3 para. 2 FoodA). Foodstuffs that do not comply with Swiss foodstuffs legislation or the provisions of the country of destination may only be exported if the authorities in the country of destination consent to the import after they have been fully informed of the reasons why the foodstuffs in question may not be placed on the market in Switzerland and of the detailed circumstances (Art. 3 para. 3 FoodA).
  However, foodstuffs that are harmful to health may not be exported (Art. 3 para. 5 FoodA).
  If FS deviate from the Swiss provisions relevant to health (e.g. they exceed a Swiss maximum level based purely on health aspects), they may therefore not be exported.

More information

- **21. Is there an obligation to have FS authorised and to notify them in Switzerland?**
  In Switzerland, there is no mandatory requirement for food supplements to be authorised. However, unauthorised novel foods, unauthorised GMO and unauthorised health claims do require authorisation.
  Unlike in most EU Member States, there is also no notification obligation for FS in Switzerland. They therefore do not have to be notified prior to being placed on the market for the first time in Switzerland.
  The manufacturer, importer and distributor must therefore ensure compliance with the provisions of the foodstuffs legislation in the context of their self-supervision activities.
  Foodstuffs businesses, on the other hand, are subject to a notification obligation. Anyone who deals with foodstuffs must register their activities with the competent cantonal enforcement authority(Art. 20 FSO).

- **22. Is there a nutrivigilance system for FS in Switzerland?**
  No. In contrast to some EU Member States (e.g. France, Italy), Switzerland has not set up a surveillance system with mandatory notification of serious adverse effects by consumers, doctors, hospitals and poison information centres (nutrivigilance system).

- **23. Who controls FS?**
  Compliance with the legal requirements is monitored by the competent cantonal foodstuffs enforcement authority.

- **24. Who can provide assistance in checking the marketability of products?**
  The FSVO is unable to offer advisory services, nor is it able to determine whether a certain product can be marketed in Switzerland or not. Swiss Testing Labs lists suggested specialised consulting companies on its website. This service is subject to a fee.

- **25. Where can I find legal texts and further information?**
  The legal texts and corresponding explanations can be found on the FSVO website. The explanations of the Ordinances provide more information about and details of the legal provisions.
  The FSVO website also provides information on other topics relating to foodstuffs and nutrition.