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

Questions and Answers – Maximum Level Model for Vitamins and Minerals

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Context and Aims

- **Why has a new maximum level model been developed? What is the aim?**
  Response: The previous maximum levels in Switzerland were basically geared to the requirements. The setting of maximum levels encroaches on fundamental rights and may therefore only be justified on the basis of health protection or protection against deception.
  The new maximum level model is geared to health protection. Thus two objectives could be simultaneously achieved:
  - Health protection of the consumer (maximum level);
  - No unnecessary limitation of the market (no maximum level where not necessary).

- **What is the situation in the EU?**
  Response: At present in the EU harmonised maximum levels exist neither for enrichment nor for food supplements (FS) or foods for sportsmen or sportswomen. Individual countries in the EU have their own national provisions.

- **For which substances and product categories has the new maximum level model been developed?**
  Response: The new maximum level model has been developed for vitamins and minerals in food supplements, foods for sportsmen and sportswomen and for the enrichment of foodstuffs.

Data and allocation key

- **On which data is the maximum level model based?**
  Response: The model is based on the "Tolerable Upper Intake Level" (UL) and data on the consumption of individual nutrients in the normal daily diet. The amount (residual amount) of a vitamin or mineral which is available for an additional intake via food supplements (FS) and fortified foods corresponds to the difference between the UL and the baseline intake (intake from the usual daily diet, BI), i.e. residual amount = UL - BI.

  Data:
  The UL were obtained from the European Food Safety Authority EFSA data; where not available, from the Institute of Medicine, IOM, now the National Academy of Medicine (iron), and from WHO (chromium).
  The results of the national consumption study II from Germany[1] were used to estimate the consumption of the nutrient from conventional foodstuffs. Data from the Swiss National Nutrition Survey *menu*CH[2] could not be considered, as the analyses required for this are not yet available.

[1] MRI (2008) Max Rubner-Institut. Nationale Verzehrstudie II, Ergebnisbericht, Teil 2. Max Rubner-Institut, Bundesforschungsinstitut für Ernährung und Lebensmittel.

[2] https://www.blv.admin.ch/blv/de/home/lebensmittel-und-ernaehrung/ernaehrung/menuch/menu-ch-ergebnisse-ernaehrung.html

Data from the Consumption Study from France[3] were also examined. They are in the same order of magnitude as the data from Germany although generally lower. The data from the German consumption study were preferred, as they ensure a slightly higher safety level.

- **Which age classes and intake percentiles were considered in the consumption data?**
  Response: Basically, data were considered for men aged 14 to 80 years, 90th intake percentile. For calcium and iron the data for women aged 14 to 80 years, 90th intake percentile, were used, as principally women did not attain the recommended intake for these two nutrients. Additionally, significantly more women than men take calcium supplements. It is therefore appropriate to use consumption data for women.
  For iodine the maximum level was derived from the 50th intake percentile for women, because Switzerland is an iodine-deficient territory, and regular iodine monitoring has shown that a significant proportion of the population (particularly children and women) does not attain the daily requirement. The distribution for iodine is 1:1, so that the intake may be improved both from FS as well as from fortified foods.

- **Are high consumers taken into account?**
  Response: High consumers are taken into account, in that consumption data of the 90th percentile (P90) are used to determine the maximum levels. Furthermore, with FS a warning label is required, stating that the recommended daily dose is not to be exceeded.

- **Why is the distribution key 3:1?**
  Response: The factor 3:1 (FS : fortified foods) is used in order to emphasise that food supplements represent a concentrated form of nutrient. A recommended daily consumption level of a food supplement should consequently be allowed to contain more of a certain nutrient than a daily ration of a fortified food. On the other hand, this factor ensures that the daily ration of a fortified food contains a significant amount of a nutrient and that the amount that may be added to food supplements is not too high.

Basic principles

- **Why are separate values for specific population groups no longer defined?**
  Response: The new maximum level model is based on health protection and no longer on the requirement. Consequently, characteristic maximum levels can no longer be defined for specific population groups that have a higher requirement, e.g. pregnant and breastfeeding women, persons above 60 years old.

- **What do the maximum levels for enrichment refer to?**
  Response: The maximum levels for the daily rations were defined in accordance with Annex 7 of the FDHA Ordinance on the Addition of Vitamins, Minerals and other Substances to Foodstuffs (AVMO; SR 817.022.32). Thus, for example, a daily ration of breakfast cereal is 50 g, i.e. 250 mg calcium may be added to 50 g breakfast cereal.

- **Why are consumption data for adults used to determine the maximum levels?**
  Response: The defined maximum levels apply to adults and for this reason are calculated from consumption data for adults.

- **Why are the vitamins and minerals classified into four groups?**
  Response: The substances are classified into groups based on their risk to exceed the UL. The groups are as follows:
  - Group 1: non-critical substances; no maximum level;

[3] Anses (2017) Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail, Étude individuelle des consommations alimentaires 3 (INCA 3), Avis et rapport de l'Anses sur la troisième étude individuelle des consommations alimentaires, Anses.

- Group 2: substances with a large difference UL – BI (i.e. with high residual amounts or with a low risk of exceeding the UL);
- Group 3: substances with a small difference UL – BI (i.e. with low residual amounts or with a high risk of exceeding the UL);
- Group 4: substances, for which side effects or interactions may occur at medium-low doses, and which therefore require a warning label.

- **For which substances are maximum levels no longer set?**
  Response: Maximum levels are no longer set for the non-critical substances (group 1). The substances are as follows: Vitamin B_1, B_2, B_6, B_{12}, Biotin, pantothenic acid, silicon (in food supplements). No adverse reactions have been observed for these substances even with very high intakes for longer periods of time. Consequently, no maximum level can be justified on the grounds of health protection.

- **Which levels apply for foodstuffs for sportsmen and sportswomen?**
  Response: The maximum levels for foodstuffs for sportsmen and sportswomen are specified in Annex 11 of the FDHA Ordinance on Foodstuffs for Persons with Special Dietary Requirements (SDRO; SR 817.022.104). With the exception of sodium the same requirements as for food supplements apply to foodstuffs for sportsmen and sportswomen.

- **Why are safety factors not used when calculating the maximum levels?**
  Response: The new maximum level model considers the total intake of a nutrient via a FS or a foodstuff for sportsmen and sportswomen, and a fortified food. However, multiple exposures from e.g. two FS or one FS plus one foodstuff for sportsmen and sportswomen with the same substance on the same day are not taken into account. The FSVO does not have appropriate data in Switzerland to show or account for such a multiple exposure. The FSVO did not obtain the appropriate data in the scope of the public consultation either.

- **Which tolerances are to be taken into account?**
  Response: The defined maximum levels are based on health protection. The tolerance range of the declared level therefore ends at the maximum level (see information letter 2017/7: Tolerances for the nutrition declaration, respectively EU guidance document[4]).

Impact of the maximum level model

- **Is it still possible to enrich foodstuffs with all vitamins and minerals?**
  Response: It is fundamentally possible to enrich foodstuffs with all substances, except fluoride. Due to the intake via salt and other sources, in particular toothpaste and tea, there is no leeway for additional supplementation. Chloride and phosphate should no longer be authorised as an additive, rather only as counter ions, because they are not nutritionally relevant and are indirectly ingested (e.g. as counter ions) in sufficient quantities. Supplementation and enrichment with sodium should be excluded on grounds of public health, although sodium as a counter ion may continue to be added in FS. It may be added to other foodstuffs (as an FS) and must be listed as the salt (sodium chloride) in the nutrition declaration. Vitamin A may now only be added as beta-carotene.

- **Which nutrition claims are still possible?**
  Response:
  Solid foodstuffs
  The nutrition claims “Source of” and “Contains” [nutrient name] are still possible for all permitted substances. Note that the tolerance range ends at the permitted maximum level. As a result, for the critical case of zinc, the upper tolerance range is lower than the otherwise permitted 45% for minerals (50% for vitamins, cf. Table 1 below). In such cases the manufacturer must employ the most precise procedures in the enrichment process in order to be able to ensure that these conditions are respected.

[4] https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-vitamins_minerals-guidance_tolerances_1212_en.pdf

The nutrition claims, “High Content” and “Rich in” [name of the nutrient], are possible for all permitted substances except for zinc. There are two borderline cases: potassium and vitamin K. The claims are possible for both cases, with the proviso that the available lower tolerances are respected. Calcium does not represent a borderline case in dairy products. Although the addition of calcium in dairy products must not exceed 250 mg per 100 g, dairy products naturally contain calcium. Thus, the requirements for the calcium content may be respected for these nutrition claims.

Table 1. Borderline cases for the application of nutrition claims to “solid” foodstuffs

Substance	**Maximum level**	**Claim *contains/source of***		**Claim *high content/rich in***	
		Requirement	**Upper tolerance [level]/[%]**	**Requirement**	**Upper tolerance [level]/[%]**
Vitamin K	24 µg	11.25 µg ✓	5.75 µg/50%	22.5 µg T	1.5 µg/6.7%
Calcium (dairy products)	250 mg	120 mg ✓	54 mg/50%	240 mg ✓	10 mg/4%*
Zinc	1.8 mg	1.5 mg T	0.3 mg/20%	3 mg X	-
Potassium	750 mg	300 mg ✓	150 mg/50%	600 mg T	150 mg/25%

*Dairy products already contain calcium; the tolerance applies to the additive.

✓ permitted

X not permitted

T lower tolerance range

Beverages

In beverages, for the claims:

- “Source of” and “Contains” [name of the nutrient] only 7.5% of the significant level according to Annex 10 FoodIO and
- for the claims “High content” and “Rich in” [name of the nutrient] only 15% of the significant level according to Annex 10 FoodIO

have to be contained.

Consequently, for beverages for all permitted substances, the claims “Source of” and “Contains” [name of the nutrient] as well as the claims “High content” and “Rich in” [name of the nutrient] are permitted. There is still only one borderline case for zinc with the claim “High content” and “Rich in” [name of the nutrient] (cf. Table 2).

Table 2. Borderline case for the application of nutrition claims to beverages

		Claim *contains/source of*		**Claim *high content/rich in***	
Substance	**Maximum level**	**Requirement**	**Upper tolerance [level]/[%]**	**Requirement**	**Upper tolerance [level]/[%]**
Zinc	1.8 mg	0.75 mg ✓	0.34 mg/45%	1.5 mg T	0.3 mg/20%

✓ permitted

T lower tolerance range

- **Which compounds of vitamins and minerals are permitted?**
  Response: The permitted compounds are listed exhaustively in the corresponding ordinances. These concern Annex 5 AVMO for enrichment, Annex 2 of the FDHA Ordinance on Food Supplements (DietSO; SR 817.022.14) for food supplements, respectively Annex 12 SDRO on Foodstuffs for Sportsmen and Sportswomen.
  The addition of certain compounds (such as e.g. retinol) is no longer permitted, because the intake with the normal diet of high consumers (P90) is already above the UL.
  The use of novel compounds (e.g. organic silicon (monomethylsilane triol) is governed by Annex 1 of the FDHA Ordinance on Novel Foods (SR 817. 022. 2).

- **In enrichment, for which substances have the maximum levels become higher and for which substances have the maximum levels become lower in comparison to the previous system?**
  Response:
  - In the following Table the maximum levels for vitamins and minerals in fortified foods are listed before and after Stretto 3 came into force.

Substance	Food Law 2017		Stretto 3	
Vitamin A	800	µg	450[1]	µg
Vitamin D	15	µg	23	µg
Vitamin E	12	mg	68	mg
Vitamin C	100	mg	250	mg
Vitamin K	75	µg	24	µg
Vitamin B_1 (Thiamine)	1.1	mg	none	mg
Vitamin B_2 (Riboflavin)	1.4	mg	none	mg
Niacin (Vitamin PP)	16	mg	200	mg
Vitamin B_6	1.4	mg	5	mg
Folic acid	300	µg	250	µg
Vitamin B_{12}	3	µg	none	µg
Biotin	50	µg	none	µg
Pantothenic acid	6	mg	none	mg
Calcium	1000	mg	250 (700[2])	mg
Phosphorus	700	mg	Only as counter ion	mg
Iron	14	mg	7	mg
Magnesium	375	mg	250	mg
Zinc	10	mg	1.8	mg
Iodine	150	µg	200	µg
Selenium	60	µg	55	µg
Copper	1	mg	0.5	mg
Manganese	2	mg	1	mg
Chromium	40	µg	62	µg
Molybdenum	50	µg	100	µg
Fluoride	3.5	mg	-	mg
Potassium	2000	mg	750	mg
Chloride	800	mg	Only as counter ion	mg

  - [1]Only permitted as Beta-Carotene. Corresponds to 2.7 mg Beta-Carotene.
  - [2]Only substitute products for milk and dairy products

- **In the new maximum level model, which substances in food supplements and foodstuffs for sportsmen and sportswomen are more strictly controlled than in the previous system?**
  Response:
  - In the following Table the maximum levels for vitamins and minerals are listed before and after Stretto 3 came into force.

	DietSO				SDRO			
Substance	Food Law 2017		Stretto 3		Food Law 2017		Stretto 3	
Biotin	450	µg	none		450	µg	none	
Folic acid	600 (800[1])	µg	750	µg	600 (800[1])	µg	750	µg
Niacin Nicotinic acid and Inositol hexanicotinate (summed)	48 48	mg mg	600 10	mg mg	48 48	mg mg	600 10	mg mg
Pantothenic acid	18	mg	none		18	mg	none	
Riboflavin	4.2	mg	none		4.2	mg	none	
Thiamine	3.3	mg	none		3.3	mg	none	
Vitamin A	1600	µg	1360[2]	µg	1600	µg	1360[2]	µg
Vitamin B_6	4.2	mg	15	mg	4.2	mg	15	mg
Vitamin B_{12}	9	µg	none		9	µg	none	
Vitamin C	300	mg	750	mg	300	mg	750	mg
Vitamin D	20	µg	70	µg	20	µg	70	µg
Vitamin E	36	mg	205	mg	36	mg	205	mg
Vitamin K[3]	225	µg	225	µg	225	µg	225	µg
Boron	-		1	mg	5	mg	1	mg
Calcium	1000	mg	750	mg	1000	mg	750	mg
Chloride	800	mg	Only as counter ion	mg	800	mg	Only as counter ion	mg
Chromium	40	µg	188	µg	40	µg	188	µg
Iron	14(30[4])	mg	21	mg	14	mg	21	mg
Fluoride					3.8	mg	-	
Iodine	150(200[4])	µg	200	µg	150	µg	200	µg
Potassium	2000	mg	2250	mg	2000	mg	2250	mg
Copper	1	mg	1.6	mg	1	mg	1.6	mg
Magnesium	375	mg	375[5]	mg	375	mg	375[5]	mg
Manganese	2	mg	3	mg	2	mg	3	mg
Molybdenum	50	µg	300	µg	50	µg	300	µg
Sodium	-		-		550	mg	550/none[6]	mg
Phosphate	700	mg	Only as counter ion	mg	700	mg	Only as counter ion	mg
Selenium	60	µg	165	µg	60	µg	165	µg
Silicon	200 (10.4[7])	mg	none		200 (10.4[5])	mg	none	
Zinc	15	mg	5.3	mg	15	mg	5.3	mg

- [1]For women with desire for children and women up to the 12th week of pregnancy
- [2]Only permitted as Beta-Carotene. Corresponds to 8.2 mg Beta-Carotene.
- [3]Above a daily dose of 25 µg the following warning shall be made: *Patients who take anticoagulants should consult their physician before taking vitamin K preparations.*
- [4]For pregnant and breastfeeding women
- [5]New warning: Above 250 mg magnesium now requires a warning that the product may have a laxative effect.
- [6]Foodstuffs specifically developed for extreme endurance sports for sportsmen and sportswomen
- [7]as monomethylsilanetriol

- **What happens with products that are legally on the market in an EU or EEA Member State? Are authorisations according to the Cassis de Dijon Principle possible for FS, foodstuffs for sportsmen and sportswomen and for fortified foods?**

Response: Foodstuffs that are legally on the market in an EU or EEA Member State may also be authorised in Switzerland through the Cassis de Dijon Principle. Such applications may be rejected only for reasons of health protection or protection against misrepresentation.
At present in some EU Member States products are found on the market which have very high vitamin and mineral contents that are above the new maximum levels in Switzerland. As the new model is based on health protection and considers the total intake of a nutrient through an FS or a foodstuff for sportsmen and sportswomen and a fortified food, it may result that products, in which the new maximum levels for vitamins and minerals are exceeded, will not be granted authorisations according to the Cassis de Dijon Principle. Possible applications would have to be rejected.

Possible Amendments

- **What happens if the EU introduces a model with different maximum levels or if new scientific findings are presented?**
  Response: Provided that the model of the EU would also be attuned to health protection, then it would be highly probable that the derived maximum levels would be of the same order of magnitude as the new maximum levels in Switzerland.
  If the EU specified harmonised maximum values and e.g. used a different allocation key, Switzerland would examine the EU model and as far as possible align its own model to that of the EU so as to avoid barriers to trade.
  It is also possible that the values would have to be amended due to new scientific findings. In this case the maximum values according to Art. 7 para. 1 AVMO, Art. 6 para. 1 DietSO and Art. 41 para. 1 SDRO would be amended.

Self-supervision and Transitional Periods

- **How will compliance with protection against deception and the differentiation from therapeutic products be ensured for substances:**
  - **for which maximum levels are no longer specified or**
  - **for which the maximum levels are significantly above the daily requirement?**

  Response: Compliance with protection against deception and with the differentiation from therapeutic products would have to be ensured by the manufacturer and distributers in the context of self-supervision.
  To ensure compliance with the protection against misrepresentation, it is essential to bear in mind the content and rationale of the corresponding foodstuff category or the ordinance. The objective of enrichment is to improve the nutritional value of the foodstuff as well as peoples' health; food supplements should serve to complement the normal diet, and foodstuffs for sportswomen and sportsmen should cover their particular nutrient requirements. The target groups for these foodstuff categories are healthy adults.

- **Are there transitional periods for enriched foodstuffs, food supplements or foodstuffs for sportswomen and sportsmen which do not comply with the new legislation?**
  Response: Yes. A transitional period of 2 years has been specified for the import, manufacture and labelling of products in accordance with the old law. Finally, they may still be supplied to consumers until the stocks are cleared.

Further information

- **Where can further information be found?**
  Response: Further information and details can be found in the explanations of the relevant ordinances.
  - Explanations of AVMO (available in German, French and Italian)
  - Explanations of DietSO (available in German, French and Italian)
  - Explanations of SDRO (available in German, French and Italian)