Draft Regulation (vitamins and minerals) amending the Regulation on the addition of vitamins, minerals and certain other substances to foods

**Statutory authority:** Stipulated by the Ministry of Health and Care Services on XX XXXX 20XX, pursuant to Section 9, paragraph one, Section 10, paragraph two and Section 15 of Act No 124 of 19 December 2003 relating to food production and food safety etc. (Food Act), cf. Delegation Decision No 1790 of 19 December 2003.

**EEA reference:** The Regulation has been reported to EFTA’s surveillance authority in accordance with the requirements in Act No 101 of 17 December 2004 relating to the European notification of technical rules (EEA Hearing Act) and Annex II, Chapter XIX, no. 1 of the EEA Agreement (Directive 98/34/EC amended through Directive 98/48/EC).

**I**

The following amendments are made to Regulation No 247 of 26 February 2010 on the addition of vitamins, minerals and certain other substances to foods:

**The following paragraphs are added at the bottom of the EEA references:**

*Chapters II and IV and Annexes 1 and 2 of the Regulation have been reported to EFTA’s surveillance authority in accordance with the requirements in Act No 101 of 17 December 2004 relating to the European notification of technical rules (EEA Hearing Act) and Annex II, Chapter XIX, no. 1 of the EEA Agreement (Directive 98/34/EC amended through Directive 98/48/EC).*

**Chapter II shall be worded as follows:**

**Chapter II. Supplementary national provisions relating to the addition of vitamins and minerals to foods.**

**Section 2.** Scope of the Chapter

This Chapter contains supplementary national provisions relating to the addition of vitamins and minerals to foods. The provisions apply in addition to and supplement the provisions relating to this in Section 1, cf. Regulation (EC) No 1925/2006.

**Section 3.** Conditions for the addition of vitamins and minerals to foods.

It is only permitted to add vitamins and minerals to foods in accordance with the conditions stipulated in Annex 1.

**Section 4.** The notification requirement when adding vitamins and minerals contrary to the conditions in Annex 1.

If a food business operator wishes to add vitamins or minerals to foods and the addition is not in compliance with the conditions in Annex 1, the food business operator must notify the addition to the Norwegian Food Safety Authority. The notification must contain all the information required in Annex 2. The notification applies exclusively to the addition of the relevant vitamins and minerals to the specific food. The notification is deemed to have been submitted when the Norwegian Food Safety Authority has sent confirmation to the food business operator that all information required in Annex 2 has been received.

The food business operator may commence using the addition six months after the notification is deemed to have been submitted pursuant to paragraph one. If the notification contains data that has already been submitted, assessed and approved in another EEA country and this assessment has been sent to the Norwegian Food Safety Authority, the food business operator may use the addition three months after the notification is deemed to have been submitted pursuant to paragraph one. If required, the Norwegian Food Safety Authority may extend this period from three to six months, and must notify the food business operator of this. The notified addition can only be used in accordance with the information in the notification and provided that the Norwegian Food Safety Authority has not laid down an individual decision pursuant to paragraph three prohibiting the addition or setting other restrictions on the addition to those stipulated in the notification.

Prior to the expiration of the deadlines in paragraph two for when a notified addition can be used by the food business operator and at any time after use of the addition has commenced, the Norwegian Food Safety Authority may lay down an individual decision that prohibits or places other restrictions on the additionve to those stipulated in the notification, including time limit or restriction on use in certain food categories.

If, when processing notifications pursuant to paragraph one regarding the addition of vitamins or minerals to foods that originate within the EEA and which are legally placed on the market in another EEA state, the Norwegian Food Safety Authority finds that an individual decision must be laid down to prohibit or place restrictions on the addition in addition to those stated in the notification, the provisions in Act No 13 of 12 April 2013 relating to the free movement of goods within the EEA (EEA Goods Act), cf. Regulation (EC) No 764/2008, shall apply.

**Section 5** *Requirements for submitting information regarding the name and address of the food business operator, the name of the product, list of ingredients and nutrition declaration to the Norwegian Food Safety Authority.*

The food business operator that is responsible for the initial placing on the Norwegian market of a food that contains added vitamins or minerals in accordance with the requirements in Annex 1 must send information about the name and address of the food business operator, the name of the product, list of ingredients and nutrition declaration to the Norwegian Food Safety Authority before the food can be placed on the Norwegian market.

The food business operator that is responsible for the initial placing on the Norwegian market of a food that contains added vitamins or minerals and which was legally placed on the Norwegian market prior to XX. XXXXX 20XX (the date these new provisions enter into force), shall, by the end of XX. XXXX 20XX (six months from the date these new provisions enter into force), send the Norwegian Food Safety Authority equivalent information to that stated in paragraph one.

Subsequent changes to the information that is sent to the Norwegian Food Safety Authority pursuant to paragraphs one and two and notice of the permanent cessation of the placing of the food on the Norwegian market must also be sent to the Norwegian Food Safety Authority.

Foods that do not contain added vitamins or minerals other than sodium, chloride or potassium are exempt from the requirements in paragraphs one, two and three.

**The new Section 15 shall have the following wording:**

**Section 15** Fees for specific services

The food business operators shall pay fees pursuant to Regulation No 406 of 13 February 2004 relating to the payment of fees for specific services provided by the Norwegian Food Safety Authority, for the Norwegian Food Safety Authority’s processing of notifications pursuant to Section 4 regarding the addition of vitamins or minerals to foods.

**The new Section 16 shall have the following wording:**

**Section 16.** The Norwegian Food Safety Authority’s issuing of Regulations for amendments in Annex 1 and 2.

Immediately after having completed the processing of notifications pursuant to Section 4 regarding the addition of vitamins or minerals to foods, the Norwegian Food Safety Authority shall propose and issue Regulations that make the necessary amendments to Annex 1 and, when required, can also stipulate separate requirements for identity and purity.

If required, the Norwegian Food Safety Authority may also, at its own initiative and at any time, propose or issue Regulations that amend Annex 1 and 2.

**The new Annex 1 shall be worded as follows:**

***Annex 1 - Conditions for the addition of vitamins and minerals to foods.***

|  |  |  |
| --- | --- | --- |
| **Food category**  | **Vitamin/mineral** 1, 2 | **Maximum content per 100 g or 100 ml (as specified in the nutrition declaration)** |
| **Bread products and breakfast cereals** |  |  |
| Bread  | Vitamin D | 5 µg  |
| Breakfast cereals | Calcium Niacin Vitamin B6 Folic acid | 384 mg 11 mg 1,4 mg 133 µg |
| **Gluten free products** |  |  |
| Gluten free muesli/breakfast cereals | Niacin Vitamin B6Folic acid Iron  | 12,5 mg 1,25 mg 125 µg 5 mg |
| Gluten free and low protein bread/flour mixtures  | Niacin Vitamin B6Folic acid Iron  | 6,4 mg 0,6 mg 40 µg 8 mg  |
| Gluten-free bread, crispbread and crusts | Niacin Vitamin B6Folic acid Iron  | 4 mg 2,5 mg 40 µg 9 mg  |
| **Milk, fermented dairy products and vegetarian alternatives** |  |  |
| Milk (all types of milk sold directly to consumers) 3 | Vitamin D | 0,4 µg  |
| Milk-based beverages (fermented and/or flavoured) 3 | Vitamin DVitamin B6Niacin Vitamin CCalciumChromium | 1,9 µg 0,29 mg 3 mg 9,4 mg 19 mg5 µg  |
| Condensed milk | Vitamin D | 1,1 µg |
| Soy-, oats-, almond- and rice-based alternatives to milk-based beverages. May be flavoured. | Vitamin D Vitamin E CalciumFolic acid Iodine | 1,5 µg 1,8 mg 120 mg 23 µg 16 µg |
| Fermented dairy products such as yogurt (does not include beverages)3. May be flavoured. | Vitamin DVitamin CCalcium | 2,9 µg 26 mg 106 mg  |
| Soy-, oat-, almond- and rice-based alternatives to fermented dairy products (does not include beverages). May be flavoured. | Vitamin D Vitamin E Calcium | 0,75 µg 1,5 mg 120 mg |
| **Cheese and vegetarian alternatives** |  |  |
| White cheese  | Vitamin D Vitamin E  | 3,7 µg 38 mg  |
| Spreadable brown cheese (prim) | Vitamin D | 2,7 µg  |
| Brown cheese and prim products for children  | Iron | 10 mg  |
| Vegetable alternatives to cheese | Calcium | 664 mg |
| **Spreadable fats and oils** |  |  |
| Margarine, other types of spreadable fats (liquid and solid) | Vitamin AVitamin D | 900 µg 10 µg  |
| Butter  | Vitamin D | 10 µg  |
| Cooking oil | Vitamin DVitamin E | 10 µg 13 mg  |
| **Fishery products and products derived from fishery products** |  |  |
| Caviar in tube | Vitamin D Vitamin E | 9,5 µg 4,7 mg  |
| **Meat and meat products** |  |  |
| Liver pâté  | Vitamin D Vitamin E | 2,5 µg 2,5 mg  |
| **Beverages** |  |  |
| Fruit juices, vegetable juices, nectars, smoothies etc. | Vitamin D Vitamin EVitamin CNiacinVitamin B6Magnesium | 2,5 µg1,8 mg 47 mg 1,8 mg0,2 mg45 mg |
| Soft drinks and other water-based, non-alcoholic beverages, both carbonated and non-carbonated. 4 | Vitamin D Vitamin E Niacin Vitamin B6 Folic acid Vitamin C CalciumMagnesiumSelenium | 0,89 µg 2,9 mg 8 mg 0,6 mg 24,4 µg 40 mg 6,3 mg 0,7 mg 0,15 mg  |
| Energy drinks and other water-based non-alcoholic, carbonated and non-carbonated beverages with added caffeine of a quantity exceeding 15 mg/100 ml 4. | Vitamin D Vitamin E Niacin Vitamin B6Folic acid Vitamin C Magnesium | 0,8 µg 4 mg 47 mg 1,2 mg 24,4 µg 24 mg 30 mg  |
| Shots/drinking ampoules 4,5 (water-based, non-alcoholic, carbonated and non-carbonated beverages) portioned in smaller units.  | NiacinVitamin B6Folic acid | 1,5 mg 2,3 mg 1,3 µg  |
| Sports drinks (Category I) 4, 5, 6 (carbohydrate-electrolyte drinks)  | Vitamin AVitamin DVitamin EVitamin CNiacinVitamin B6Folic acidCalciumMagnesiumIronZincSeleniumCopperPhosphorusManganeseIodineMolybdenumChromium | 290 µg2,5 µg4,5 mg35 mg7,5 mg0,75 mg82 µg180 mg60 mg3 mg2,7 µg8,5 µg0,2 mg150 mg0,4 mg23 µg17 µg20 µg |
| Sports Drinks (Category II) (carbohydrate-electrolyte drinks which also contain protein/fat 4, 5, 7 of which the protein content is at least 20% of the energy content of the product and the energy content is at least 420 kJ/100 ml (100 kcal/100 ml)). | Vitamin AVitamin DVitamin EVitamin CNiacinVitamin B6Folic acidCalciumMagnesiumIronZincSeleniumCopperPhosphorusManganeseIodineMolybdenum | 125 µg 2 µg1,9 µg32 mg2,5 mg0,6 mg35 µg210 mg60 mg2,6 mg1,7 µg8,5 µg0,3 mg175 mg0,3 mg23 µg17 µg |
| Sports gels marketed in single-serve units.5  | NiacinVitamin B6 | 9,6 mg 2,3 mg  |
| Bars, etc. | Vitamin DVitamin EVitamin B6Folic acidNiacinVitamin CCalciumMagnesiumPhosphorusIronZincCopperManganeseSelenium ChromiumMolybdenumIodine | 3,6 µg 14 mg 2,8 mg 140 µg 11 mg 85 mg 350 mg 200 mg 230 mg7 mg6 mg0,6 mg0,6 mg30 µg40 µg50 µg60 µg |
| **Food category** | **Vitamin/Mineral**1 | **Maximum content per ready-to-eat portion/meal replacement bar** |
| Meal replacements for weight control (Products that are labelled and marketed as an alternative to 1-2 main meals).             | Vitamin AVitamin DVitamin EVitamin KVitamin CNiacinVitamin B6Folic acidCalciumPhosphorusMagnesiumIronZincCopperManganeseSeleniumIodineChromiumMolybdenum | 355 µg 2,5 µg 6,5 mg 34 mg 53 mg 11 mg 1,6 mg 145 µg 430 mg 484 mg 157 mg9 mg 5 mg 0,85 mg 1,5 mg 32 µg 86 µg 35 µg31 µg  |
| **Food category** | **Vitamin/Mineral**1 | **Maximum content per 100 g powder before preparation** |
| Young Child Formulae (1-3 years of age)               | Vitamin AVitamin DVitamin EVitamin KVitamin CNiacinVitamin B6Folic acidCalciumPhosphorusMagnesiumIronZincCopperManganeseFluorideSeleniumIodine | 500 µg 9,0 µg 11 mg 45 mg 86,4 mg 5,0 mg 0,53 145 µg 577 mg 366 mg 57 mg 8,4 mg 57 mg 0,38 mg 77 µg 54 µg 12 µg 120 mg  |
| **Food category** | **Vitamin/Mineral**1 | **Maximum content per 100 g or 100 ml (as specified in the nutrition declaration)** |
| **Miscellaneous** |  |  |
| Mayonnaise  | Vitamin D Vitamin E Chromium | 8 µg 4 mg 10 µg  |
| Household salt  | Iodine | 500 µg  |
| Salt used as an ingredient in various pastries | Iodine | 850 µg |
| Salt used as an ingredient in broths, soups, sauces etc.  | Iodine | 2000 µg |
| Fluoride tablets | Fluoride | 2,3 mg |
| Chewing gum  | Vitamin CCalciumFluoride | 450 mg 1200 mg 10 mg |

1 Thiamine, riboflavin, vitamin B12, biotin, pantothenic acid, potassium, chloride and sodium can be added to products in the various food categories in the table, provided that the amount is safe.

2 Vitamins and minerals that are added to flour due to compulsory requirements for this in the country of production and that are used as ingredients in baked goods are exempt from the notification requirement in Section 4.

3 Includes lactose-reduced and lactose-free products.

4 Can be powder or tablets that are dissolved in water. The maximum content specifies the content per 100 ml in the ready-to-drink product (irrespective of whether the nutrition declaration on the product applies for the product as sold or for the product as consumed (diluted)).

5 Only applies for products intended for people over the age of 18.

6 Applies for a maximum recommended intake of 500 ml per day.

7 Applies for a maximum recommended intake of 200 ml per day.

**The new Annex 2 shall be worded as follows:**

**Annex 2: *Information to be submitted to the Norwegian Food Safety Authority***

Information that has to be submitted to the Norwegian Food Safety Authority with notifications pursuant to Section 4 regarding the addition of vitamins or minerals to foods contrary to the conditions in Annex 1.

*1) Name of the notifier (EEA producer, EEA importer or other others responsible for initial placing on the Norwegian market), address, organisation number, telephone number and possible email address.*

*2) Name of the product.*

*3) Food category with description of the product.*

*4) Names of the vitamins or minerals notified.*

*5) Chemical names of the vitamins or minerals notified, cf. Section 1, cf. Annex II to Regulation (EC) No 1925/2006 and CAS number of the substance(s).*

*6) Amount added (excluding natural content) per 100 g or 100 ml of the vitamins or minerals notified.*

*7) List of ingredients as specified in Regulation No 1497 of 28 November 2014 relating to food information for consumers.*

*8) Nutrition declaration.*

*9) If the notifier is aware of other EEA countries where the same product (same product name and content) is already legally placed on the market, cf. Section 1 of Act No 13 of 12 April 2013 relating to the free movement of goods within the EEA (EEA Goods Act), cf. Regulation (EC) No 764/2008, any documentation of this must be submitted.*

**II**

The following amendments are made to Regulation No 406 of 13 February 2004 relating to the payment of fees for specific services provided by the Norwegian Food Safety Authority:

**In the table in Annex 1, Chapter I, the entire row entitled “Approval of fortification - equivalent products previously approved” is deleted.**

**In the table in Annex 1, Chapter II, the sub-heading is amended from “Processing of applications for approval of products” to “Processing of notifications and applications for authorisation and approval of products”.**

**Under the amended sub-heading “Processing of notifications and applications for authorisation and approval of products”, the row entitled “Approval of fortification - equivalent products not previously approved” is amended to:**

|  |  |  |
| --- | --- | --- |
| *Processing of notifications regarding the addition of vitamins and minerals to foods.* | 12.285 | e |

**III**

The amendments stipulated in I and II above will enter into force immediately, on a specific date or the different amendments may enter into force on different dates.