Draft Regulation (certain “other substances” than 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 European notification of technical rules (EEA Hearing Act) and Annex II, Chapter XIX, no. 1 of the EEA Agreement (Directive 98/34/EC amended by 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 paragraph is inserted at the bottom of the EEA references**

*Chapters III and IV and Annexes 3-5 in 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 European notification of technical rules (EEA Hearing Act) and Annex II, Chapter XIX, no. 1 of the EEA Agreement (Directive 98/34/EC amended by Directive 98/48/EC).*

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

**Chapter III. Supplementary national provisions regarding the addition of certain “other substances” to foods, including food supplements**

**Section 6.** Scope of the Chapter

This Chapter contains supplementary national provisions relating to the addition of certain “other substances” to foods, including food supplements. The provisions apply in addition to and supplement the provisions relating to this in Section 1, cf. Regulation (EC) No 1925/2006.

Sections 7 – 10 only apply to the addition of “other substances” to foods, including food supplements, that:

1. have a purity of at least 50% or are concentrated 40 times or more and
2. are not normally consumed as a food in themselves and not normally used as an ingredient in foods.

Sections 7 to 10 do not apply for the addition of the following “other substances” to foods, including food supplements:

1. plants or parts of plants in fresh, dried, chopped, cut or powdered form,
2. extracts of plants or parts of plants exclusively made through basic aqueous extraction, possibly followed by dehydration,
3. microorganisms or
4. "other substances" listed in Parts A and B of Annex III to Regulation (EC) No 1925/2006.

For “other substances” which, pursuant to Section 6, paragraph two and three (a), (b) and (c), are not covered by Sections 7 to 10, the Norwegian Food Safety Authority can issue Regulations for amendments to Annex 5 that prohibit or set restrictions for the addition of the substances to foods, including food supplements.

**Section 7.** Conditions for adding certain “other substances” to foods, including food supplements.

It is only permitted to add “other substances” that are listed in Annex 3 to food, including food supplements. Such addition to foods must be in accordance with the conditions stipulated in Annex 3.

The restrictions that are set for the addition of “other substances” listed in Annex 3 must not be exceeded. This applies irrespective of the source and purpose of the addition of the substance.

**Section 8.** Requirements for the identity and purity of "other substances" listed in Annex 3.

For "other substances" listed in Annex 3, the requirements for identity and purity stipulated at any time in other relevant EEA legislation shall apply. If there are no requirements stipulated in other EEA legislation for the identity and purity of a substance listed in Annex 3, the generally accepted requirements for identity and purity that are recommended at any time by international bodies shall apply. The Norwegian Food Safety Authority can set special requirements for the identity and purity of certain “other substances” in Annex 3.

**Section 9.** Notification requirement when adding “other substances” listed in Annex 3, but which do not satisfy the conditions in the Annex

If a food business operator wishes to add an “other substance” that is listed in Annex 3, and the addition is not in compliance with the conditions in the Annex, the food business operator must notify the addition to the Norwegian Food Safety Authority. The notification must include all the information required in Annex 4. The notification only applies for the addition of the relevant “other substance” to the specific food, including food supplements. 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 4 has been received.

The food business operator may use 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 can 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 addition 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 “other substances” to foods, including food supplements, that originate within the EEA and are legally placed on the market in another EEA state, the Norwegian Food Safety Authority finds that it must lay down an individual decision prohibiting or placing other restrictions on the addition to those stipulated in the notification, the provisions in 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, shall apply.

**Section 10.** Application for authorisation to add “other substances” that are not listed in Annex 3.

The addition of “other substances” not listed in Annex 3 to foods, including food supplements, is only permitted if the Norwegian Food Safety Authority has authorised this. The application for authorisation must include all the information required in Annex 4. The application only applies to the addition of the relevant “other substance” to the specific food, including food supplements. The application 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 4 has been received.

The Norwegian Food Safety Authority shall decide on an application for authorisation within six months after the application is deemed to have been submitted pursuant to paragraph one. If the application 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 Safety Authority shall decide on the application within three months after it is deemed to have been submitted pursuant to paragraph one. If required, the Norwegian Food Safety Authority can extend this period from three to six months, and must notify the food business operator of this.

The Norwegian Food Safety Authority may lay down an individual decision prohibiting the addition or placing other restrictions on the addition to those stipulated in the application, including time limit or restriction on use in certain food categories.

If, when processing applications for authorisation to add “other substances” pursuant to paragraph one, to foods, including food supplements, ,that originate within the EEA and are legally placed on the market in another EEA state, the Norwegian Food Safety Authority finds that all or part of the application cannot be approved or that more restrictive conditions for use of the “other substance” to those stipulated in the application must be set, 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 11.** *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, including food supplements, to which “other substances” covered by Sections 7 to 10 have been added, cf. Annex 3, must submit 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 before the food can be placed on the Norwegian market. For food supplements, the food business operator must submit information regarding the declaration of content amounts pursuant to Section 8 of Regulation No 755 of 20 May 2004 relating to food supplements, instead of information pertaining to the nutrition declaration. When concerning food supplements, the food business operator must, in addition to information regarding the list of ingredients, also submit information about the name of the categories of nutrients or other substances with nutritional or physiological effect, that characterise the product or a statement of what type these are, cf. Section 7, paragraph three no. 1 of Regulation No 755 of 20 May 2004 relating to food supplements.

The food business operator that is responsible for the initial placing on the Norwegian market of a food, including food supplements, to which “other substances” covered Sections 7 to 10 are added, cf. Annex 3, and which was legally placed on the Norwegian market prior to XX XXXXX 20XX (the date on which 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 amendments to the information that is submitted to the Norwegian Food Safety Authority pursuant to paragraphs one and two and notice of permanent cessation of the placing of the food, including food supplements, on the Norwegian market, shall also be sent to the Norwegian Food Safety Authority.

**Section 12.** Transitional provision

Foods, including food supplements, to which “other substances” that are covered by Sections 7 to 10 have been added, cf. Annex 3, and which were legally placed on the Norwegian market prior to XX XXXXX 20XX (the date when these new provisions enter into force), but which do not satisfy the requirements in Sections 7 to 10, cf. Annex 3, can be placed on the Norwegian market until XX XXXXX 20XX (6 months from the date these new provisions enter into force).

Foods, including food supplements, that are covered by paragraph one, may then be sold until stocks are exhausted.

**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 and applications regarding authorisation to add “other substances” to foods, including food supplements, pursuant to Sections 9 and 10.

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

**Section 16.** The Norwegian Food Safety Authority’s issuing of Regulations for amendments in Annex 3 - 5

Immediately after having completed the processing of notifications or applications for authorisation to add “other substances” to foods, including food supplements, pursuant to Sections 9 and 10, the Norwegian Food Safety Authority shall propose and issue Regulations that make the necessary amendments to Annex 3 and, when required, can also stipulate separate requirements for identity and purity.

If required, the Norwegian Food Safety Authority may, at its own initiative, at any time propose and issue Regulations that amend Annexes 3 - 5.

**The new Annex 3 shall have the following wording:**

**Annex 3. Certain “other substances” that can be added to foods, including food supplements, cf. Chapter III.**

|  |  |  |
| --- | --- | --- |
| **Food category** |  | |
| **Food supplements intended for adults over the age of 18 (highest permitted content per recommended daily dose)** | **Name of the substance** | **Conditions of use** |
|  | Beta-alanine | 2 g per recommended daily dose, divided into maximum doses of 350 mg during the course of the day. The doses must be taken at intervals of at least 2 hours. |
|  | Docosahexaenoic acid (DHA) | 1,3 g per recommended daily dose. |
|  | D-Ribose | 6,2g per recommended daily dose. |
|  | Eicosapentaenoic acid (EPA) | 1,8 g per recommended daily dose. |
|  | Eicosapentaenoic acid (EPA) + Docosahexaenoic acid (DHA) | 5 g per recommended daily dose. |
|  | Inulin | 3 g per recommended daily dose. |
|  | Coenzyme Q10 | 100 mg per recommended daily dose. |
|  | Caffeine | 300 mg per recommended daily dose, divided among a minimum of 3 doses.  Must be labelled with "A daily intake of 400 mg of caffeine from all sources should not be exceeded". |
|  | Conjugated linoleic acids (CLA) | 3,5 g per recommended daily dose.  Must be labelled with “Should not be used for a continuous period of more than six months without consulting a doctor”. |
|  | Creatine | 3 g per recommended daily dose.  Must be labelled with “Should not be used for a continuous period of more than six months without consulting a doctor”. |
|  | Curcumin | 210 mg per recommended daily dose. |
|  | L-Alanine | 4,5 g per recommended daily dose. |
|  | L-Arginine | 6 g per recommended daily dose. |
|  | L-Citrulline | 2 mg per recommended daily dose. |
|  | L-Cysteine | 10 mg per recommended daily dose. |
|  | L-Cystine | 750 mg per recommended daily dose. |
|  | L-Phenylalanine | 1 g per recommended daily dose. |
|  | L-Glutamine | 20 g per recommended daily dose. |
|  | L-Glutamic acid | 5,5 g per recommended daily dose. |
|  | L-Glycine | 3,1 g per recommended daily dose. |
|  | L-Histidine | 4 g per recommended daily dose. |
|  | L-Isoleucine | 1,5 g per recommended daily dose. |
|  | L-Carnitine | 1,5 g per recommended daily dose.  Must be labelled: “Should not be used by people with congenital metabolic diseases and kidney disease without consulting a doctor.” |
|  | L-Carnitine-L-Tartrate | 2,25 g per recommended daily dose.  Must be labelled with “Should not be used by people with congenital metabolic diseases and kidney disease without consulting a doctor.” |
|  | L-Leucine | 1,3 g per recommended daily dose. |
|  | L-Lysine | 3 g per recommended daily dose. |
|  | L-Methionine | 210 mg per recommended daily dose. |
|  | L-Proline | 1,8 g per recommended daily dose. |
|  | L-Serine | 1,75 g per recommended daily dose. |
|  | L-Threonine | 2,4 g per recommended daily dose. |
|  | L-Tryptophan | 220 mg per recommended daily dose.  Must be labelled with “Should not be used by people who take anti-depressants”. |
|  | L-Tyrosine | 420 mg per recommended daily dose. |
|  | L-Valine | 1,5 g per recommended daily dose. |
|  | Lycopene | 10 mg per recommended daily dose. |
|  | Piperine from black pepper seeds | 1,5 mg per recommended daily dose. |
|  | Taurine | 1 g per recommended daily dose. |
| **Foods** |  | |
| Energy drinks and other water-based, non-alcoholic, carbonated and non-carbonated beverages with an amount of added caffeine that exceeds 15 mg/100 ml1 |  |  |
|  | Glucuronolactone | 24 mg/100 ml |
|  | Inositol | 10 mg/100 ml |
|  | Caffeine | 32 mg/100 ml from all sources.    Must be labelled with "A daily intake of 400 mg of caffeine from all sources should not be exceeded". |
|  | L-Isoleucine | 350 mg per 100 ml can be added if the product also contains the substances L-leucine and L-valine, such that the ratio for L-leucine:L-isoleucine:L-valine is 2:1:1 or 4:1:1. |
|  | L-Leucine | 1010 mg per 100 ml can be added if the product also contains the substances L-isoleucine and L-valine, such that the ratio for L-leucine:L-isoleucine:L-valine is 2:1:1 or 4:1:1. |
|  | L-Valine | 350 mg per 100 ml can be added if the product also contains the substances L-leucine and L-isoleucine, such that the ratio for L-leucine:L-isoleucine:L-valine is 2:1:1 or 4:1:1. |
|  | Taurine | 400 mg/100 ml. |
| Shots/drinking ampoules2 (water-based, non-alcoholic, carbonated and non-carbonated beverages) portioned into smaller units. |  |  |
|  | L-Isoleucine | 585 mg per 100 ml can be added if the product also contains the substances L-leucine and L-valine, such that the ratio between L-leucine:L-valine:L-isoleucine is 2:1:1. |
|  | L-Leucine | 1170 mg per 100 ml can be added if the product also contains the substances L-isoleucine and L-valine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
|  | L-Valine | 585 mg per 100 ml can be added if the product also contains the substances L-leucine and L-isoleucine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
| Sports drinks (Category I)1,2,3 (carbohydrate-electrolyte drinks) | Beta-alanine | 800 mg/100 ml can be added if maximum doses of 350mg are divided up over the course of the day. The doses must be taken at intervals of at least 2 hours. |
|  | Caffeine | 10 mg/100 ml can be added from all sources.  Must be labelled with "A daily intake of 400 mg of caffeine from all sources should not be exceeded". |
|  | L-Arginine | 56 mg/100 ml |
|  | L-Citrulline | 800 mg/100 ml |
|  | L-Glutamine | 1400 mg/100 ml |
|  | L-Isoleucine | 235 mg per 100 ml can be added if the product also contains the substances L-leucine and L-valine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
|  | L-Carnitine | 200 mg/100 ml  Must be labelled with “Should not be used by people with congenital metabolic diseases and kidney disease without consulting a doctor.” |
|  | L-Leucine | 470 mg per 100 ml can be added if the product also contains the substances L-isoleucine and L-valine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
|  | L-Valine | 235 mg per 100 ml can be added if the product also contains the substances L-isoleucine and L-leucine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
| Sports Drinks (Category II)1,2,4 (carbohydrate-electrolyte drinks which also contain protein/fat, for 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)). | Caffeine | 10 mg/100 ml from all sources.  Must be labelled with "A daily intake of 400 mg of caffeine from all sources should not be exceeded". |
|  | L-Arginine | 390 mg/100 ml |
|  | L-Glutamine | 1400 mg/100 ml |
|  | L-Isoleucine | 472 mg per 100 ml can be added if the product also contains the substances L-leucine and L-valine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
|  | L-Carnitine | 200 mg/100 ml  Must be labelled with “Should not be used by people with congenital metabolic diseases and kidney disease without consulting a doctor.” |
|  | L-Leucine | 900 mg/100 ml or  943 mg per 100 ml can be added if the product also contains the substances L-isoleucine and L-valine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
|  | L-Valine | 472 mg per 100 ml can be added if the product also contains the substances L-isoleucine and L-leucine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
| Sports gels2 marketed in single-serve units. |  |  |
|  | Caffeine | 200 mg/100 ml from all sources.  Must be labelled with "A daily intake of 400 mg of caffeine from all sources should not be exceeded". |
|  | L-Isoleucine | 180 mg per 100 ml can be added to sports gels2 if the product also contains the substances L-leucine and L-valine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
|  | L-Leucine | 380 mg per 100 g can be added if the product also contains the substances L-valine and L-isoleucine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
|  | L-Valine | 180 mg per 100 g can be added if the product also contains the substances L-isoleucine and L-valine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
|  | Taurine | 500 mg/100 g |
| Bars, etc. |  |  |
|  | Caffeine | 100 mg/100 g from all sources.  Must be labelled with "A daily intake of 400 mg of caffeine from all sources should not be exceeded". |
|  | L-Isoleucine | 555 mg per 100 g can be added if the product also contains the substances L-leucine and L-valine, such that the ratio between L-leucine:L-valine:L-isoleucine is 2:1:1. |
|  | L-Leucine | 1110 mg per 100 g can be added if the product also contains the substances  L-valine and L-isoleucine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |
|  | L-Valine | 555 mg per 100 g can be added if the product also contains the substances L-isoleucine and L-leucine, such that the ratio between L-leucine:L-isoleucine:L-valine is 2:1:1. |

1 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).

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

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

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

**The new Annex 4 shall be worded as follows:**

**Annex 4: Information to be submitted to the Norwegian Food Safety Authority**

The information that shall be submitted to the Norwegian Food Safety Authority together with notifications pursuant to Section 9 and applications for authorisation pursuant to Section 10, for the addition of certain “other substances” to foods, including food substances, that are not in compliance with the conditions in Annex 3.

For both categories it must be documented that the substance(s) sought for inclusion in Annex 3 is not novel food(s), i.e. has been on the market prior to 15 May 1997, cf. Regulation No 1215 of 25 July 2017 relating to novel foods.

**Food supplements**

1. *Name of the notifier or applicant (EEA producer, EEA importer or others responsible for initial placing on the Norwegian market), address, organisation number, telephone number and possible email address.*
2. *Name of the product.*
3. *Product form (for example, capsules, tablets, etc.) and description of product.*
4. *Name of the substance(s) notified or applied for.*
5. *Added quantity of the substance(s).*
6. *Total content of the substance(s) (total added quantity and any natural content of the same substances) per daily dose.*
7. Recommended daily dose.
8. *List of ingredients as specified in Regulation No 1497 of 28 November 2014 relating to food information for consumers.*
9. *If the notifier or applicant 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.
10. *Chemical name, chemical structure, chemical form (solid or liquid), CAS number of the substance(s), L-isomer form of the amino acid(s), oxidation number of the substance(s) (for example, Fe2+ or Fe3+) and the molecular weight of the substance(s).*
11. *Specification and method of analysis for the substance(s).*
12. *Description of the substance’s method of production using a production diagram that includes information of all raw materials used in production.*
13. *Relevant toxicological studies of the substance(s) and the notifier or applicant’s summary and assessment of these.*

**Foods other than food supplements**

1. *Name of the notifier or applicant (EEA producer, EEA importer or 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. *Name of the substance(s) notified or applied for .*
5. *Added quantity of the substance(s).*
6. *Total content of the substance(s) (total added quantity and any natural content of the same substances) per 100 g or 100 ml.*
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 or applicant 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.
10. *Chemical name, chemical structure, chemical form (solid or liquid), CAS number of the substance(s), L-isomer form of the amino acid(s), oxidation number of the substance(s) (for example, Fe2+ or Fe3+) and the molecular weight of the substance(s).*
11. *Specification and method of analysis for the substance(s).*
12. *Description of the substance’s method of production using a production diagram that includes information of all raw materials used in production.*
13. *Relevant toxicological studies of the substance(s) and the notifier or applicant’s summary and assessment of these.*

**The new Annex 5 shall have the following wording:**

**Annex 5 "Other substances" which, pursuant to Section 6, paragraphs two and three, are not covered by Sections 7 to 10, and which the Norwegian Food Safety Authority has prohibited or set restrictions for pursuant to Section 6, final paragraph**

**Part A Prohibition**

**Part B Restrictions**

**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 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 following new rows shall be added to the table between the row entitled “Approval of fortification - equivalent products not previously approved” and the row “Approval of new food - simplified application:**

|  |  |  |
| --- | --- | --- |
| Processing of notifications and applications for authorisation to add certain “other substances” to foods, including food supplements | 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.