EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

In-Numru tan-Notifika : 2018/9010/N (Norway)

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

Data tal-wasla : 28/06/2018
Tmiem tal-Waqfien : 01/10/2018 (closed)

Message

Message 901

Communication from the Commission - TRIS/(2018) 01718
Procedure for the provision of information EC - EFTA

Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notification - Notifica - Pieteikums - Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie - Notificação - Hlásenie-Obvestilo - Ilmoitus - Anmälan - Нотификация : 2018/9010/N - Notificare.

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma’ jiftaħx il-perijodi ta’ dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201801718.EN)
1. MSG 901 IND 2018 9010 N EN 28-06-2018 N NOTIF

2. N

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4. 2018/9010/N - C50A

5. Draft Regulation (certain "other substances" than vitamins and minerals) amending the Norwegian Regulation on the addition of vitamins, minerals and certain other substances to foods.

6. C80A - Additives, vitamins, minerals and flavourings

7. - Regulation (EC) nº 1925/2006 concerning the addition of vitamins and minerals and certain other substances to foods
- Directive 2000/13/EC on the labelling and presentation and advertising of foodstuffs

8. Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods, is incorporated in No 54zzzu of Chapter XII of Annex II to the EEA-agreement, and implemented in national law in Section 1 of the Norwegian Regulation No 247 of 26 February 2010 on the addition of vitamins, minerals and certain other substances to foods.

The draft Regulation amends and replaces the supplementary national provisions relating to the addition of certain “other substances” than vitamins and minerals to foods, including food supplements, in Chapter III of the Norwegian Regulation No 247 of 26 February 2010 on the addition of vitamins, minerals and certain other substances to foods.

Section 6. Scope of the Chapter

The national provisions of Chapter III of the draft Regulation apply in addition to and supplement the provisions on the addition of certain “other substances” than vitamins and minerals to foods, including food supplements in Section 1, ref. Regulation (EC) No. 1925/2006. This means, inter alia, that the national provisions on certain “other substances” of Chapter III of the draft Regulation:
- apply to food supplements covered by Directive 2002/46/EC (ref. article 1 (2) of Regulation (EC) No 1925/2006),
- apply without prejudice to specific provisions laid down in certain Community legislation (ref. article 1 (3) of Regulation (EC) No 1925/2006),
- apply according to the definition of “other substance” (ref. article 2 (2) of Regulation (EC) No 1925/2006)
- apply in addition to and supplement the provisions on the addition of certain other substances of article 8 of Chapter III, ref. Annex III, of Regulation (EC) No 1925/2006.

Sections 7 – 10 of the draft Regulation only apply to the addition of “other substances” to foods, including food supplements, that:
a) have a purity of at least 50% or are concentrated 40 times or more and
b) are not normally consumed as a food in themselves and not normally used as an ingredient in foods.

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

a) plants or parts of plants in fresh, dried, chopped, cut or powdered form,

b) extracts of plants or parts of plants exclusively made through basic aqueous extraction, possibly followed by dehydration,

c) microorganisms or

d) "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 “other substances” to foods, including food supplements.

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

According to Section 7 of the draft Regulation, it is only permitted to add “other substances” that are listed in the “positive list” in Annex 3 to foods, including food supplements. Such addition to foods must be in accordance with the

conditions stipulated in the “positive list” in Annex 3.

The “maximum” values and 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. The "maximum" values specified in the “positive list” in Annex 3, are deemed safe by the Norwegian Food Safety Authority on the basis of safety assessments performed by the Norwegian Scientific Committee for Food and Environment and by the Norwegian Institute of Public Health.

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

For "other substances" listed in the “positive list” in Annex 3, the requirements for identity and purity stipulated at any time in other relevant EEA legislation shall, according to Section 8 of the draft regulation, 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, according to Section 9 of the draft Regulation, notify the addition to the Norwegian Food Safety Authority.

The notification must include all the information required in Annex 4.

The food business operator may commence using the addition six months after the notification is deemed to have been submitted. 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. 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 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 notification applies exclusively to the addition of the relevant “other substance” to the specific food, including food supplements. 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 prohibiting the addition or setting other restrictions on the addition to those stipulated in the notification.

Prior to the expiration of the deadlines 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. Given that the food, including food supplements, in question originate within the EEA, according to the rules of origin in Protocol 4 to the EEA Agreement, and is legally placed on the market in another EEA state, the provisions of the Norwegian 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, according to Section 10 of the draft Regulation, 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 Norwegian Food Safety Authority shall decide on an application for authorisation within six months after the application is deemed to have been submitted. 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. 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 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 application only applies to the addition of the relevant “other substance” to the specific food, including food supplements.

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. Given that the food, including food supplements, in question originate within the EEA, according to the rules of origin in Protocol 4 to the EEA Agreement, and is legally placed on the market in another EEA state, the provisions of the Norwegian 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

For the purposes of monitoring the market for foods, including food supplements, to which “other substances” covered by Sections 7 to 10 have been added, cf. the “positive list” in Annex 3, according to Section 11 of the draft Regulation, the food business operator that is responsible for the initial placing on the Norwegian market of such a food, including food supplements, 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 the Norwegian 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 the Norwegian Regulation No 755 of 20 May 2004 relating to food supplements.

Subsequent amendments to the information that is submitted to the Norwegian Food Safety Authority 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, according to Section 12 of the draft regulation, 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 the draft transitional provision, may then be sold until stocks are exhausted.

Section 15 Fees for specific services

According to Section 15 of the draft Regulation, the food business operators shall pay fees pursuant to the Norwegian 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.

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, according to Section 16 of the draft Regulation, 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.

Administrative appeals and court review

According to the general provisions of the Norwegian Act 10 February 1967 relating to the public administration, administrative appeals against individual decisions of the Norwegian Food Safety Authority, on prohibitions or restrictions on the addition of "other substances" to foods, including food supplements, pursuant to Sections 9 and 10, may be lodged with the Ministry of Health and Care Services.

Administrative decisions may also be reviewed by the general Norwegian courts.

Equivalence to other notifications

In its structure, this draft Regulation on the addition of certain "other substances" than vitamins and minerals to foods, is similar to the simultaneously notified Norwegian draft Regulation on the addition of vitamins and minerals to foods.

The two notified Norwegian draft Regulations, are also, in their structure, quite similar to the two former Danish notifications of draft Regulations on the addition of vitamins and minerals to foods (Notification No 2014/203/DK) and specific substances other than vitamins and minerals to foods (Notification No 2010/793/DK, which is a resubmission of Notification No 2010/400/DK), towards which the Commission has expressed favourable opinions.

9. The aim of the draft Regulation is to ensure the proper use of certain "other substances" than vitamins and minerals, added to foods, including food supplements. Neither Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods, nor other EU legislation contains special regulations on the use of "other substances" than vitamins and minerals in food, including in food supplements.

The Ministry of Health and Care Services finds that, in the interests of the protection of human health, there is a need for national regulation until common rules have been introduced in the EEA.

10. References of the Basic Texts: Norwegian Act No 124 of 19 December 2003 relating to food production and food safety etc. (Food Act).

Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.

11. No

12. -

13. No

14. No

15. Please see the Norwegian national public consultation:
https://www.mattilsynet.no/mat_og_vann/tilsatte_stoffer/tilsatte_vitaminer_mineraler_og_andre_stoffer/nasjonal_forskrifts bestemmelse_av_andre_stoffer_i_kosttilskuddnaeringsmidler.8357

16. TBT aspect

Yes

SPS aspect

No - The draft is not a sanitary or phytosanitary measure

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European Commission

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