



EUROPEAN COMMISSION

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

Notifikationsnummer : 2018/9009/N (Norway)

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

Modtagelsesdato : 28/06/2018

Afslutning af status quo-periode : 01/10/2018 (closed)

### **Message**

Message 901

Communication from the Commission - TRIS/(2018) 01712

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 : 2018/9009/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 késések - Ma' jiftaħ 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 - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201801712.EN)

1. MSG 901 IND 2018 9009 N EN 28-06-2018 N NOTIF

2. N

3A. Ministry of Trade, Industry and Fisheries

Department of Trade Policy

P.O. Box 8090, Dep

NO-0032 Oslo

Norway

Email: [technicalregulations@bis.gsi.gov.uk](mailto:technicalregulations@bis.gsi.gov.uk)

3B. Ministry of Health and Care Services

Department of Public Health

P.O. Box 8011 Dep,

NO-0030 Oslo

Norway

4. 2018/9009/N - C50A

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



## EUROPEAN COMMISSION

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

6. C80A - Additives, vitamins, minerals and flavourings

7. - Regulation (EC) n° 1925/2006 concerning the addition of vitamins and minerals and certain other substances to foods

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 vitamins and minerals to foods in Chapter II of the Norwegian Regulation No 247 of 26 February 2010 on the addition of vitamins, minerals and certain other substances to foods.

### Section 2. Scope of the Chapter

The national provisions of Chapter II of the draft Regulation apply in addition to and supplement the provisions on vitamins and minerals in Section 1, ref. Regulation (EC) No. 1925/2006. This means, inter alia, that the national provisions on vitamins and minerals of Chapter II of the draft Regulation:

- do not 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 in addition to and supplement the provisions on the addition of vitamins and minerals of articles 3 to 7 of Chapter II of Regulation (EC) No 1925/2006.

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

According to Section 3 of the draft Regulation, it is only permitted to add vitamins and minerals to foods in accordance with the conditions stipulated in the "positive list" in Annex 1. The "maximum" values specified in the "positive list" in Annex 1, 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 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, according to Section 4 of the draft Regulation, give notice of the addition to the Norwegian Food Safety Authority.

The notification must contain all the information required in Annex 2.

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 may 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 2 has been received.

The notification applies exclusively to the addition of the relevant vitamins and minerals to the specific food. 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.



## EUROPEAN COMMISSION

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

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 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 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.

For the purposes of monitoring the market for foodstuffs to which vitamins or minerals are added, according to Section 5 of the draft Regulation, 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, before the food can be placed on the Norwegian market, send information to the Norwegian Food Safety Authority about:

- the name and address of the food business operator,
- the name of the product,
- list of ingredients and
- nutrition declaration.

Subsequent changes to the information that is sent to the Norwegian Food Safety Authority 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 to submit such information.

### 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 pursuant to Section 4, regarding the addition of vitamins or minerals to foods.

### 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, according to Section 16 of the draft Regulation, 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.

### 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 vitamins and minerals to foods, 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



EUROPEAN COMMISSION

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

In its structure, this draft Regulation on the addition of vitamins and minerals to foods is similar to the simultaneously notified Norwegian draft Regulation on the addition of certain other substances than 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 vitamins and minerals added to foods. No common maximum quantities for the addition of vitamins and minerals to foodstuffs have been laid down in accordance with Article 6 (1) of 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.

The Ministry of Health and Care Services finds that, in the interests of protecting 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.

Regul

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\\_om\\_tilsetning\\_av\\_vitaminer\\_eller\\_mineraler\\_til\\_vanlige\\_naeringsmidler.29921](https://www.mattilsynet.no/mat_og_vann/tilsatte_stoffer/tilsatte_vitaminer_mineraler_og_andre_stoffer/nasjonal_forskrifts_bestemmelse_om_tilsetning_av_vitaminer_eller_mineraler_til_vanlige_naeringsmidler.29921)

16. TBT aspect

Yes

SPS aspect

No - The draft is not a sanitary or phytosanitary measure

\*\*\*\*\*

European Commission

Contact point Directive (EU) 2015/1535

Fax: +32 229 98043

email: [grow-dir2015-1535-central@ec.europa.eu](mailto:grow-dir2015-1535-central@ec.europa.eu)