



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

In-Numru tan-Notifika : 2016/9040/N (Norway)

Regulation relating to amendment of regulation on food supplements

Data tal-wasla : 11/11/2016

Tmien tal-Waqfien : 13/02/2017 (closed)

Message

Message 901

Communication from the Commission - TRIS/(2016) 03454

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 : 2016/9040/N - Notificare.

No abre el plazo - Nezahtuje 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: 201603454.EN)

1. MSG 901 IND 2016 9040 N EN 11-11-2016 N NOTIF

2. N

3A. ROYAL MINISTRY OF TRADE, INDUSTRY AND FISHERIES

Department for Trade Policy

P.O.BOX 8090 DEP

N-0032 OSLO

Norway

3B. The Norwegian Food Safety Authority

P.O. 383

N-2381 Brumunddal

4. 2016/9040/N - C80A

5. Regulation relating to amendment of regulation on food supplements

6. Food supplements

7. - Directive 2000/13/EC on the labelling and presentation and advertising of foodstuffs

8. National maximum limits for the amount of folic acid, magnesium, vitamin C, calcium and vitamin D in food supplements, cf. Article 5 of Directive 2002/46/EC. Separate maximum limits for young children from 1 and up to 3 years old, children from 3 and up to 11 years old, adolescents from 11 and up to 18 years old, and adults from 18 years old. Particular requirements for labelling of food supplements containing specific amounts of folic acid, calcium, vitamin C and



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vitamin D per daily portion of consumption as recommended by the manufacturer. The measures requiring additional mandatory food labelling has also been notified according to Article 39 and 45 of Regulation (EU) No 1169/2011 on the provision of food information to consumers.

9. Norway implemented Directive 2002/46/EC on food supplements in 2004, and existing national maximum limits for vitamins and minerals per daily dose were then continued. These national maximum limits are set to ensure that food supplements with vitamins and minerals are safe for the entire healthy population. However, since the existing maximum limits are old, they are now being revised. We have suggested establishing separate maximum limits for various age groups (young children, children, adolescents, adults), in order to make it possible to produce food supplements adapted to different consumer groups.

The existing maximum limits for magnesium and calcium of 600 mg and 1500 mg respectively, are proposed reduced in line with the tolerable upper intake levels (ULs) suggested by the Norwegian Scientific Committee for Food Safety (NSCFS) and updated intake data (see link below). The existing maximum limits for folic acid and vitamin D, are proposed to be decreased for the youngest age groups, while they are suggested increased for the older age groups, based on scientific opinions by the NSCFS. The maximum limit for vitamin C is proposed increased for all age groups, based on a scientific opinion by the NSCFS.

Differentiating the maximum limits for separate age groups means that a food supplement for some age groups (usually adults) may contain amounts of vitamins/minerals that involve a health risk for younger age groups, since ULs for these age groups will be exceeded. We have therefore deemed it essential requiring additional mandatory food labelling, in order to protect public health. Particular requirements for labelling of food supplements containing specific and high amounts of folic acid, calcium, vitamin C and vitamin D per daily portion, in one measured small unit quantity, shall ensure that the product reaches its right age group and that consumers are provided clear information that the consumption of certain amounts of vitamins or minerals might cause adverse health effects for specific age groups. The mandatory particulars are deemed essential in order to protect public health, in accordance with Article 39 of Regulation (EU) No 1169/2011.

Please see links to the relevant scientific opinions by the NSCFS for

- 1) magnesium; <http://www.vkm.no/dav/f9ef23feb7.pdf>,
- 2) calcium and vitamin C; <http://www.vkm.no/dav/289a369b0c.pdf>,
- 3) folic acid; <http://www.vkm.no/dav/86f93d4c96.pdf> and
- 4) vitamin D; <http://vkm.no/dav/422f24e6e0.pdf>

10. References of the Basic Texts: Regulation of 20 May 2004 No 755 on food supplements (implementing Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements in Norway). See this link:

<https://lovdata.no/dokument/SF/forskrift/2004-05-20-755?q=kosttilskudd>

Basic Texts have been forwarded within the framework of a previous notification: 2003/9008/N

11. No

12. -

13. No

14. No

15. See the Norwegian national public consultation:

http://www.mattilsynet.no/mat_og_vann/spesialmat_og_kosttilskudd/kosttilskudd/revisjon_av_nasjonale_maksimumsgrens_for_vitaminer_og_mineraler_i_kosttilskudd_separate_maksimumsgrenser.24618.



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16. TBT aspect

No - The draft has no significant impact on international trade

SPS aspect

No - The draft has no significant impact on international trade

European Commission

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