



EUROPEAN COMMISSION

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

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2017/0182/B (Belgium)

## **Ministerial decree amending the Ministerial Decree of 19 February 2009 regarding the manufacture and marketing of food supplements that contain substances other than nutrients and plants or plant preparations**

Date received : 10/05/2017

End of Standstill : 11/08/2017 (closed)

### **Message**

Message 002

Communication from the Commission - TRIS/(2017) 01172

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2017/0182/B

No abre el plazo - Nezaahajuje 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 - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201701172.EN)

1. MSG 002 IND 2017 0182 B EN 10-05-2017 B NOTIF

2. B

3A. SPF Economie, PME, Classes moyennes et Energie

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4. 2017/0182/B - C50A

5. Ministerial decree amending the Ministerial Decree of 19 February 2009 regarding the manufacture and marketing of food supplements that contain substances other than nutrients and plants or plant preparations



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### 6. Food supplements

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

- Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

- Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements.

8. The draft provides for an amendment to the Ministerial Decree of 19 February 2009 regarding the manufacture and marketing of food supplements that contain substances other than nutrients and plants or plant preparations

The draft defines the minimum and/or maximum values of four substances to be consumed per day in food supplements, namely:

- caffeine: maximum 80 mg/day

- lutein: between 2 and 10 mg/day

- lycopene: between 2.5 and 15 mg/day

- red yeast rice or any other source of monacolin K: maximum 10 mg/day of monacolin K

In order to ensure safety, a compulsory warning shall be introduced for caffeine and red yeast rice, which must appear on the product labelling:

- caffeine: 'Unsuitable for children or pregnant or lactating women.'

- red yeast rice: 'This product is unsuitable for pregnant or lactating women, children and adolescents, those over 70 years of age, those with liver, kidney or muscular problems, those taking medicinal products liable to interact (e.g.: cholesterol-lowering drugs) or those intolerant to statins.

If in doubt, please seek advice from your doctor or pharmacist.'

As a transitional measure, food supplements that do not meet the provisions of the draft decree but do meet the provisions of the existing decree may continue to be traded or labelled until [publication date + 10 days]; those which do not meet the provisions of the latter may continue to be marketed until stocks have been exhausted or until [signature date + 1 year], with the exception of products based on red yeast rice for which the decree shall be effective immediately, due to the increasing evidence of adverse effects.

9. There are currently no legal limits for caffeine, lutein, lycopene and red yeast rice in food supplements. The draft amends the existing decree on the basis of scientific opinion.

- caffeine: the proposed limits in the draft are based on Advisory report No 8689 on the use of caffeine in foodstuffs, issued by the Superior Health Council (SHC) on 11 January 2012

(<https://www.health.belgium.be/fr/avis-8689-utilisation-de-la-cafeine-dans-les-denrees-alimentaires>, available in French, English and Dutch). They are also based on the most recent data extracted from the 2014 food consumption survey concerning caffeine consumption, which confirms the estimates of the SHC.

- lutein and lycopene: the proposed limits in the draft are based on Advisory report No 8592; Revision of the recommendations concerning a supplementary intake of lycopene and lutein via food supplements, issued by the Superior Health Council (SHC) in December 2009

(<https://www.health.belgium.be/fr/avis-8592-revision-des-recommandations-concernant-un-apport-complementaire-en-lycopene-et-en-luteine>, available in French and Dutch).

- red yeast rice: the proposed limits in the draft are based on the Guidelines concerning products containing red yeast rice of 7 December 2016

([http://www.afmps.be/sites/default/files/downloads/richtsnoer\\_rode\\_rijst.pdf](http://www.afmps.be/sites/default/files/downloads/richtsnoer_rode_rijst.pdf), available in French and Dutch)

10. Restricting the sale or use of chemical substances, preparations or products

Reference(s) to basic text(s): Royal Decree of 12 February 2009 on the manufacture and commerce of food supplements that contain substances other than nutrients and plants or plant preparations

Ministerial Decree of 19 February 2009 on the manufacture and commerce of food supplements that contain substances other than nutrients and plants or plant preparations



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11. No

12. -

13. No

14. No

15. -

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.

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European Commission

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