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

Notification Number : 2022/0395/S (Sweden)

Dietary supplements

Date received : 07/06/2022
End of Standstill : 08/09/2022 (closed)

Message

Message 002

Communication from the Commission - TRIS/(2022) 02012
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2022/0395/S

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: 202202012.EN)
1. MSG 002 IND 2022 0395 S EN 07-06-2022 S NOTIF

2. S

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4. 2022/0395/S - C80A

5. The Swedish Food Agency's regulations on food supplements

6. Food supplements

7. -

8. These draft regulations will supersede the Swedish Food Agency's current regulations (LIVSFS 2003:9) on food supplements, which transpose Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. The draft regulations contain updated references to other provisions and are linguistically closer to the wording of the Directive than those currently in force. The Swedish Food Agency is also using the possibility provided for in the Directive to introduce maximum levels for certain vitamins and minerals in food supplements. The draft regulations specify that the recommended daily dose of a

food supplement may not contain levels of vitamin D exceeding 80 micrograms or levels of iodine exceeding 200 micrograms. The maximum levels will apply to all food supplements that are intended to be placed on the market in Sweden. However, the draft regulations provide the option to apply for an exemption from the maximum levels for individual products, and for exemptions to be granted if the applicant is able to submit scientific evidence demonstrating that the level of vitamin D or iodine in the product in question proposed by the applicant does not present a risk to human health.

As regards national maximum levels for vitamin D and iodine: The Commission has the power, under the provisions of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, to lay down maximum levels for vitamins and minerals in food supplements. This has not been done and Sweden (the Swedish Food Agency) has therefore opted, on the basis of the Directive, to introduce national maximum levels for vitamin D and iodine, pending a possible decision by the Commission. The national maximum levels shall apply from 1 January 2024. Therefore, to protect the health of Swedish consumers, food supplements with excessive levels of vitamin D and/or iodine from other EU countries cannot be marketed in Sweden.

Sections 11-13 of the draft regulations constitute special Swedish provisions in relation to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

9. The draft regulations update and supersede, in their entirety, the current regulations on food supplements, LIVSFS 2003:9, which transpose Directive 2002/46/EC. The purpose of the draft regulations is also to protect human health in Sweden by introducing maximum levels for vitamin D and iodine in the recommended daily dose. The Swedish Food Agency considers there is strong scientific support for the risks of consuming amounts of these substances over time that exceed the proposed maximum levels. Food supplements containing levels of these substances exceeding the proposed maximum levels are present on the market.

Notification 2022/299/S ‘The Swedish Food Agency’s regulations on food supplements’ is being withdrawn with this notification.

10. No basic texts available

11. No

12. -

13. No

14. No

15. Yes

16. TBT aspect

NO - The project has no significant impact on international trade.

SPS aspect

NO - The project has no significant impact on international trade.

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European Commission

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