



Notification Number: 2013/676/E

Draft Royal Decree amending Royal Decree 1487/2009, of 26 September, on food supplements.

Date received : 13/12/2013

End of Standstill : 14/03/2014

Issue of comments by : Finland, France

Message

Message 002

Communication from the Commission - TRIS/(2013) 03323

Directive 98/34/EC

Translation of the message 001

Notification: 2013/0676/E

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 - Nao 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: 201303323.EN)

1. Structured Information Line

MSG 002 IND 2013 0676 E EN 13-12-2013 E NOTIF

2. Member State

E

3. Department Responsible

Subdirección General de Asuntos Industriales, Energéticos, de Transportes, Comunicaciones y Medio Ambiente.

Dirección General de Coordinación de Políticas Comunes y de Asuntos Generales de la Unión Europea. Secretaría de Estado para la Unión Europea.

Ministerio de Asuntos Exteriores y de Cooperación.

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3. Originating Department

Subdirección General de Gestión de Riesgos Alimentarios.
Agencia Española de Seguridad Alimentaria y Nutrición.
Ministerio de Sanidad, Servicios Sociales e Igualdad.

4. Notification Number

2013/0676/E - C00A

5. Title

Draft Royal Decree amending Royal Decree 1487/2009, of 26 September, on food supplements.

6. Products Concerned

Food supplements

7. Notification Under Another Act

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

8. Main Content

Royal Decree 1487/2009, of 26 September, on food supplements, incorporated 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 into our legal framework.

This provision basically sets out the harmonised list of vitamins and minerals, and the forms thereof which can be used as ingredients in the production of food supplements (reflected in annexes I and II).

The intention of the proposed amendment is to extend this list at national level to include other substances that can be used in the production of food supplements.

These other substances with nutritional or physiological effects, in addition to their forms, are included in annex III, and can be used in quantities that, in accordance with the recommended daily consumption dose of the product given by the manufacturer, do not exceed the maximum daily quantities established in this annex.

Specifically, for substances mentioned in annex III obtained from sources for which human consumption as a food was not significant in the European Union before 15 May 1997 and that are considered to be included within the scope of application of Regulation (EC) No 258/1997 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, compliance with the provisions set out in this Regulation is established as a requirement.

9. Brief Statement of Grounds

In the preamble of the provision to be amended, Royal Decree 1487/2009, of 26 September, it is indicated that whenever sufficient scientific data is available and they have not been regulated within the scope of the European Union, specific standards can be adopted related to other nutrients or other substances with



nutritional or physiological effects that are used as ingredients in food supplements.

In the same way, it is established that the substances that have been approved by the Scientific Committee on Food (currently the European Food Safety Authority) can be used in the production of food supplements for use in the production of foods intended for infants and young children, and other foods for specific nutritional uses.

For this reason, taking into account the conclusions of the report of 5 December 2008 from the Commission to the Council and to the European Parliament, on the use of substances other than vitamins and minerals in food supplements, and the fact that a wide range of nutrients and other substances exists that may be present in food supplements, it was considered appropriate to regulate this issue at national level with the aim of guaranteeing an increased level of consumer protection and increasing the competitiveness of Spanish companies within the framework of the single market.

In the amendment of this Royal Decree, the reports of the Scientific Committee on Food and other recognised scientific bodies have been taken into account, as have the reports of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) evaluating the safety of these new substances, except for those that have traditionally been considered as dietetics or that have traditionally been consumed in our country, and their established doses.

This information can be consulted at http://www.aesan.msc.es/AESAN/web/publicaciones_estudios/seccion/revista_del_comite_cientifico.shtml and further details can be found in the attached report: Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on conditions for the use of certain substances other than vitamins, minerals and plants to be used in food supplements - 2
Reference number: AESAN- 2013-004. Document approved by the Scientific Committee in its plenary session on 20 November 2013).

10. Reference Documents - Basic Texts

References to the basic texts: Royal Decree 1487/2009, of 26 September, on food supplements.
The basic texts were forwarded with an earlier notification: 2009/33/E

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

-

13. Confidentiality

No

14. Fiscal measures

No

15. Impact assessment

-



16. TBT and SPS aspects

TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft is not a sanitary or phytosanitary measure.

European Commission

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