Notification Number: 2012/728/F

Decree defining the list of plants, other than mushrooms, authorised in food supplements and conditions for their use

Date received : 27/12/2012 End of Standstill : 02/04/2013

Issue of comments by : Austria, Czech Republic

Message

Message 002

Communication from the Commission - SG(2012) D/53344

Directive 98/34/EC

Translation of the message 001

Notification: 2012/0728/F

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 - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Мääräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201203344.EN)

1. Structured Information Line

MSG 002 IND 2012 0728 F EN 27-12-2012 F NOTIF

2. Member State

F

3. Department Responsible

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3. Originating Department

Ministère de l'économie sociale et solidaire et de la consommation

Direction générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF)

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4. Notification Number

2012/0728/F - C00A

5. Title

Decree defining the list of plants, other than mushrooms, authorised in food supplements and conditions for their use

6. Products Concerned

Food Supplements (Directive 2002/46/EC)

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 approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

8. Main Content

The draft decree defines the list of plants authorised in food supplements, as well as the general and specific conditions for their use. The specific conditions are particular to each plant and consist of the maximum level of metabolites or of the warnings and precautions addressed to populations at risk. More generally, any operator wishing to commercialise a food supplement containing one of these plants must make a quality dossier available to the monitoring authorities that includes the essential information in order to prove the safety of the food supplement. Furthermore, the decree prohibits the use of herbal preparations in such a way that the food supplement could be qualified as a medicine (e.g. the dose of the active substance must be less than the therapeutic dose).

On the basis of Decree No. 2006-352 (which transposes Directive 2002/46), this decree lists the plants contained in the food supplements which have been authorised since 2006 in application of the principle of the free movement of goods. The restrictions are therefore, for the most part, the result of regulations from other Member States. They may, furthermore, be adjusted on the basis of the requests made by operators following the procedures of Decree 2006-352.

9. Brief Statement of Grounds

Compliance with this decree is obligatory under the authorisation procedures of Decree No. 2006-352. The latter specifies that each operator wishing to commercialise a plant-based food supplement in France must submit the request to the DGCCRF (the Directorate-General for competition, consumption and fraud prevention.) In the event that approval is obtained, this body must add the plants contained in the product to the positive list established by decree.

The objective of this text is to ensure the transparency of administrative decisions and to protect consumer health.

10. Reference Documents - Basic Texts

Reference(s) to basic text(s): Decree No. 2006-352, specifically articles 7, 16 and 17 notified 2003/306/F. Reference documents must be sent with the preceding notification: 2003/306/F

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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13. Confidentiality

No

14. Fiscal measures

No

15. Impact assessment

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16. TBT and SPS aspects

TBT Aspect

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

SPS Aspect

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

Catherine Day Secrétaire général Commission européenne

Point de contact Directive 98/34

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