



Notification Number: 2003/305/F

Draft Order on nutrients and substances which may be used in the manufacture of food supplements.

Date received : 19/08/2003
End of Standstill : 20/11/2003 (20/02/2004)
Issue of detailed opinion by : Commission

Message

Message 002

Communication from the Commission - SG(2003) D/51593
Directive 98/34/EC
Translation of the message 001
Notification: 2003/0305/F

Fristerne indledes ikke - Kein Fristbeginn - Καμμία έναρξη προθεσμίας - Does not open the delays - No abre el plazo - N'ouvre pas de délais - Non fa decorrere la mora - Geen termijnbegin - Nao inicia o prazo - Määräaika ei ala tästä - Inleder ingen frist.

(MSG: 200301593.EN)

1. Structured Information Line

MSG 002 IND 2003 0305 F EN 20-11-2003 19-08-2003 F NOTIF 20-11-2003

2. Member State

France

3. Department Responsible

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3. Originating Department

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DGCCRF
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4. Notification Number

2003/0305/F - C50A

5. Title

Draft Order on nutrients and substances which may be used in the manufacture of food supplements.

6. Products Concerned

Vitamins and minerals which may be used in food supplements.

7. Notification Under Another Act

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

8. Main Content

The aim of this Order is to reproduce the list of vitamins, minerals and their additives laid down in Annexes I and II to Directive 2002/46/EC.

Furthermore, this draft Order lays down the permissible levels of vitamins and minerals that may be present in foodstuffs, pending the adoption of the measures laid down in Article 5(4) of the aforementioned Directive.

In order to conform with the opinion of the French Agency for Food Safety (AFSSA), zero levels have been laid down for both vitamin K and fluoride. In fact, the Agency considered that:

- there is no intake of vitamin K which can be considered insufficient, as it presents risks for persons on an anti-coagulant treatment containing anti-vitamin molecules, who must limit their dietary intake of this vitamin.
- due to an excessive intake of fluoride in drinking water and medical supplements, the appearance of mild fluoroses has been observed in 0.5% of French children. It should be noted that safe fluoride limits are close to the advised nutritional intake.

Article 4 of this Order authorises, provisionally until 31 December 2009, 10 substances not listed in Annex II to the Directive, in accordance with Article 4(6) of Directive 2002/46/EC.

9. Brief Statement of Grounds

Pending the establishment of Community-wide maximum levels, it has become necessary to lay down, in a national text, the maximum quantities of vitamins and minerals permissible in food supplements.

The quantities given are those permitted to date in France, except with regard to the one vitamin and minerals



not authorised in France.

With regard to these substances, the levels proposed by AFSSA, in its opinion of 28 April 2003, attached, have been retained.

10. Reference Documents - Basic Texts

a) Draft decree on food supplements, Notification No

b) Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

c) Opinion given by AFSSA, 28 April 2003.

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

Not provided

16. TBT and SPS aspects

TBT aspect (Agreement on technical barriers to trade)

a) Yes

SPS aspect (Agreement on sanitary and phytosanitary measures)

a) No

b) i) x

David O'Sullivan
Secretary-General
European Commission

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