



Notification Number: 2004/342/UK

## The Food with Added Phytosterols or Phytostanols (Labelling)(Wales) Regulations 2004 –parallel regulations are being proposed for other parts of the United Kingdom

Date received : 18/08/2004  
End of Standstill : Closed  
Issue of comments by : Spain  
Issue of detailed opinion by : Commission

### Message

Message 001

Communication from the Commission - SG(2004) D/51690  
Directive 98/34/EC

Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notification - Notifica - Pieteikums - Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie - Notificação - Hlášenie-Obvestilo - Ilmoitus - Anmälan : 2004/0342/UK.

No abre el plazo - Nezhajuje odlady - 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.

(MSG: 200401690.EN)

#### 1. Structured Information Line

MSG 001 IND 2004 0342 UK EN 19-11-2004 18-08-2004 UK NOTIF 19-11-2004

#### 2. Member State

United Kingdom

#### 3. Department Responsible

Department of Trade and Industry: Standards and Technical Regulations Directorate

#### 3. Originating Department

Food Standards Agency Wales



#### 4. Notification Number

2004/0342/UK – C80A

#### 5. Title

The Food with Added Phytosterols or Phytostanols (Labelling)(Wales) Regulations 2004 –parallel regulations are being proposed for other parts of the United Kingdom

#### 6. Products Concerned

Food and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters (there are collectively referred to as “phytosterols” below).

#### 7. Notification Under Another Act

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

#### 8. Main Content

The draft Regulations put in place supporting measures for the domestic implementation of Commission Regulation (EC) No 608/2004. By virtue of Article 13(4) of Directive 2000/13/EC, small packages with a surface area of less than 10cm<sup>2</sup> and certain indelibly marked bottles are exempt from the requirements of Regulation 608/2004. However, the draft regulations require small packages and certain indelibly marked bottles to be labelled with the particulars specified in items 1 and 5 in the second paragraph of Article 2 of Regulation 608/2004. These particulars require labelling to indicate (a) the presence of added phytosterols and (b) that the product may not be nutritionally appropriate for pregnant and breastfeeding women, and children under the age of five years.

#### 9. Brief Statement of Grounds

These national measures are justifiable on the grounds of ‘protection of public health’ as allowed under Article 18(2) of Directive 2000/13/EC. In its September 2002 view on the long- term effects of the intake of elevated levels of phytosterols from multiple dietary sources, the Scientific Committee on Food (SCF) states that it is advisable to avoid phytosterol intakes above the range of 1-3 grams per day. The Committee also recommends that consumption of phytosterols should be avoided by pregnant and breastfeeding women, and children under the age of 5 years.

#### 10. Reference Documents - Basic Texts

Scientific Committee on Food (2002). General view of the Scientific Committee on Food on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on beta carotene.

#### 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**

Impact Assessment is attached.

**16. TBT and SPS aspects**

TBT Aspect

NO - The draft does not have a significant effect on international trade.

SPS Aspect

NO - The draft is not a sanitary or phytosanitary measure in the sense of Annex A of the SPS Agreement.

David O'Sullivan  
General Secretary  
European Commission

Contact point Directive 98/34  
Fax: (32-2) 296 76 60  
email: Dir83-189-central@cec.eu.int

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sent to :

BELNotif Qualité et Sécurité  
Mme Descamps

Bundesministerium für Wirtschaft Referat XA2  
Frau Christina Jäckel

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1  
Frau MARKL Iris

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1  
Frau Brigitte WIKGOLM

Cyprus org. for the promotion of quality Ministry of Commerce, Industry & Tourism  
M. Antonis Ioannou



Czech Office for Standards, Metrology and testing  
Mrs. Fofonkova Helena

Département of Trade and Industry STRD2  
Mr Philip Plumb

Délégation Interministérielle aux Normes  
Mme Piau

EFTA Surveillance Authority  
Mr. Gunnar Thor PETURSSON

ELOT  
Mr E. Melagrakis

EU internal market coordination (Ministry of Economics)  
Ms Kristine Rieksting

Erhvervs- og Boligstyrelsen  
Lene Hald Nielsen

European Free Trade Association  
.

Hungarian Notification Centre Ministry of economy & transport  
Mr Zsolt Fazekas

Institut Belge de Normalisation  
Mme F. Hombert

Instituto Português da Qualidade  
Sra Cândida Pires

Kauppa-ja teollisuusministeri  
M. Henri Backman

Kommerskollegium  
Mme Kerstin Carlsson

Lithuanian Standards Board  
Daiva Lesickiene

Malta standards Authority  
Dr Lorna Cachia

Min. de Asuntos Exteriores  
Esther Perez Pelaez

Min. of Economic Affairs & Communication  
Mr. Alver Marcus

Min. of Industry, Energy & Technology



Mr K. Polychronidis

Ministerie van Financien Belastingdienst - Douane / CDIU  
De Heer IJ.G. van der Heide

Ministero delle attivit produttive F1 - Ispettorato tecnico industria  
Signor Vincenzo Correggia

Ministry of Economy, Labour and Social  
Ms Joanna Tomaszewska

NSAI  
Mr Tony Losty

Office of standards, metrology & Testing Director of the department of European I  
Mrs Kvetoslava STEINLOVA

Représentation Permanente du Luxembourg  
.

Slovenian Institute for Standardization SIST  
Mrs Vesna Stazisar

Undersecretariat of Foreign Trade General Directorate of Standardisation  
Saadettin DOGAN