Notification Number: 2007/74/F

Order amending the amended Order of 7 August 1997 relating to restrictions on the marketing and use of certain products containing dangerous substances.

Date received	:	12/02/2007
End of Standstill	:	14/05/2007
Issue of comments by	:	Commission

Message

Message 002

Communication from the Commission - SG(2007) D/50382
Directive 98/34/EC
Translation of the message 001
Notification: 2007/0074/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 - Määräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 200700382.EN)

1. Structured Information Line
MSG 002 IND 2007 0074 F EN 14-05-2007 12-02-2007 F NOTIF 14-05-2007

2. Member State
France

3. Department Responsible
Délégué interministériel aux normes – SQUALPI –
DARQSI-DGE- –bâtiment le Bervil-
12 rue Villiot-75572 PARIS CEDEX 12
suzanne.piau@industrie.gouv.fr ou syrte@industrie.gouv.fr
tél : 01 53 44 97 04 – fax : 01 53 44 98 88

3. Originating Department

Ministère de la Santé et des Solidarités
Direction générale de la Santé
Sous-direction de la gestion des risques des milieux
Bureau Air, Sol, Déchets
8, avenue de Ségur
75350 Paris 07 SP
tel : 01 40 56 60 00

4. Notification Number
2007/0074/F - C10C

5. Title
Order amending the amended Order of 7 August 1997 relating to restrictions on the marketing and use of certain products containing dangerous substances.

6. Products Concerned
Chemical industry producing the following glycol ether and products containing it: 1,2-diethoxyethane; ethylene glycol diethyl ether (EGDEE); CAS number: 629-14-1
This substance shall be added to Annex III of the Order of 7 August 1997 (substances toxic to reproduction: category 2). It is thus prohibited to sell this substance to consumers, as such or as an ingredient in preparations, in a concentration of over 0.5%.

7. Notification Under Another Act
-

8. Main Content
This draft Order will make it possible to anticipate European legislation by introducing a national ban on the use of a glycol ether, EGDEE, in a concentration of more than 0.5%, in consumer products for public use. This glycol ether is soon to be classified as toxic to reproduction in category 2 by European experts (Directive 67/548 relating to the classification, packaging and labelling of dangerous substances).
Article 1 stipulates that the glycol ether referred to in point 6 shall be added to Annex III of the Order of 7 August 1997, in the substances toxic to reproduction of category 2.
Key words: dangerous substances, restriction on marketing and use, glycol ether, toxic to reproduction

9. Brief Statement of Grounds
The draft Order is proposed within the framework of the Interministerial action plan on glycol ethers, drawn up following the opinion of the French Higher Public Health Council of 7 November 2002 (attached). On 28 October 2004, an Order had already been issued within this framework (cf. attached Order and notification) in order to anticipate European legislation and ban two glycol ethers classified as toxic to reproduction under category 2 in consumer products intended for use by the general public. In fact, once a substance has been classified as dangerous by European experts, there is a relatively long administration period for the harmonised classification to be published, and, furthermore, the subsequent restrictions on marketing are subject to a further delay of at least six months. The draft Order concerns EGDEE, the last glycol ether that will soon be classified under the same category by European experts (the 30th Adaptation to Technical Progress of Directive 67/548/EEC is due to be adopted in February 2007).

10. Reference Documents - Basic Texts

a) - Directive 76/769/CEE relating to restrictions on the marketing and use of dangerous substances and preparations,
- Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances, in particular the 28th Adaptation to Technical Progress,
– Directive 88/379/EEC relating to the classification, packaging and labelling of dangerous preparations,
– Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, and in particular Notification No 2003/0459/F,
– the Customs Code,
- the Employment Code, and in particular Articles L. 231-6, R.231-51 et seq.;
- the Public Health Code, and in particular Articles L. 5132-1, L. 5132-2 and R. 5161;
- the Consumer Code, in particular Article L. 221-1 thereof;
- the Environment Code, and in particular Article L.521-6 thereof;
– Order of 7 August 1997, as amended, relating to restrictions on the marketing and use of certain products containing dangerous substances, transposing Directive 76/769/EEC;
– Order of 9 November 2004 defining the classification criteria and the packaging and labelling conditions for dangerous preparations and transposing Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations,
- the amended Order of 20 April 1994 relating to the declaration, classification, packaging and labelling of substances, transposing Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances;
- amended Order of 7 August 1997 relating to restrictions on the marketing and use of certain products containing dangerous substances,
- Order of 13 October 1998 relating to restrictions on the marketing and use of certain products containing dangerous substances;
- the opinion of the French Higher Public Health Council of 7 November 2002.

b) No 2003/0459/F – C10C

The toxicological data on the substance in question (EGDEE), which led to the classification of EGDEE in category 2 of substances toxic to reproduction (with risk phrase R61: may cause harm to the unborn child) and which justify the issuing of the Order in question, are the result of the findings of studies conducted on mice and rabbits (oral administration of 0, 50, 150 or 500 mg/kg of EGDEE to CD1 mice, from the sixth to fifteenth day of pregnancy, produced deformities from 150 mg/kg, without discernable toxic effects in mothers / oral administration of 0, 25, 50 or 100 mg/kg of EGDEE to NZW mice, from the sixth to fifteenth day of pregnancy, produced various deformities from 50 mg/kg, without discernable toxic effects in mothers, these only occurring at 100 mg/kg).

Furthermore, the report of a group of experts from the French Higher Public Health Council (CSHPF), attached hereto, on glycol ethers in consumer and health products (2002) highlighted a consumer health risk posed by glycol ethers classified as toxic to reproduction. On the basis of this report, the CSHPF issued an opinion in November 2002, attached hereto, mentioning a number of recommendations, including banning category 2 glycol ethers toxic to reproduction in consumer products.

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
a) NO
b) iii) The draft will not have any notable impact on international trade.

SPS aspect (Agreement on Sanitary and Phytosanitary Measures)
a) NO
b) iii) The draft will not have any notable impact on international trade.

Catherine Day
Secretary-General
European Commission

Point de contact Directive 98/34
Fax: (32-2) 296 76 60
email: dir83-189-central@ec.europa.eu

---
sent to :

BELNotif Qualité et Sécurité
Mme Descamps

BundesMinisterium für Wirtschaft und Technologie (Referat EA3)
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

CU N Lovseth Hanne Leen
.

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

Czech Office for Standards, Metrology and testing
Mrs Lucie Ruzickova

Department of Trade and Industry Office of Science & Innovation
Mr Philip Plumb

Délégation Interministérielle aux Normes
Mme Piau

EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

ELOT
M.Mourtzanos K

EU internal market coordination (Ministry of Economics)
Mrs Zanda Liekna

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 Portugês da Qualidade
Sra Cândida Pires

Kauppa-ja teollisuusministeri
Ms. Leila Orava

Kommerskollegium
Ms Kerstin Carlsson

Lithuanian Standards Board
Daiva Lesickiene

Malta standards Authority
Francis E. Farrugia

Min. of Economic Affairs & Communication
Mr. Karl Stern

Min. of Industry, Energy & Technology

Mr K. Polychronidis

Ministerie van Financiën Belastingsdienst - Douane Noord / CDIU
De Heer IJ.G. van der Heide

Ministerio de Asuntos Exteriores Secretaría de Estado para la Unión Europ
Esther Perez Pelaez

Ministero dello sviluppo economico F1 - Ispettorato tecnico industria
Signor Vincenzo Correggia

Ministry of Economy Dept for Economic Regulations
Mrs Barbara H. Kozlowska

Ministry of Economy and Commerce Division for Internal Market
Razvan CUC

NSAI
Mr Tony Losty

National Agency for Enterprise & Housing Dahlerups Pakhus
Mrs. Pernille Hjort Engstroem

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

Représentation Permanente de la Belgique auprès de l'Union européenne
.

Représentation Permanente de la France
.

Représentation Permanente du Luxembourg
.

SL
.

Service de l'Energie de l'Etat
Mr J.-P. Hoffmann

Slovenian Institute for Standardization SIST
Mrs Vesna Stazisar

State Agency for Metrology and Technical Surveillance
Violetta Veleva

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT

---
sent to :

CU N Lovseth Hanne Leen
.

Department of Trade and Industry Office of Science & Innovation
Mr Philip Plumb

EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

European Free Trade Association
.

Hungarian Notification Centre Ministry of economy & transport
Mr Zsolt Fazekas

Kauppa-ja teollisuusministeri
Ms. Leila Orava

Ministry of Economy and Commerce Division for Internal Market
Razvan CUC

NSAI
Mr Tony Losty

Représentation Permanente de l'Irlande
Denis Colfer

Représentation Permanente du Royaume-Uni
.

SL
.

State Agency for Metrology and Technical Surveillance
Violetta Veleva

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT