



Notification Number: 2003/459/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 : 10/12/2003

End of Standstill : 11/03/2004

Issue of comments by : Italy

### Message

#### Message 002

Communication from the Commission - SG(2003) D/52368

Directive 98/34/EC

Translation of the message 001

Notification: 2003/0459/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: 200302368.EN)

#### 1. Structured Information Line

MSG 002 IND 2003 0459 F EN 11-03-2004 10-12-2003 F NOTIF 11-03-2004

#### 2. Member State

France

#### 3. Department Responsible

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#### 4. Notification Number

2003/0459/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 ethers and products containing them:

- ethylene glycol dimethyl ether (CAS No 110-71-4)
- diethylene glycol dimethyl ether (CAS No 111-96-6)
- triethylene glycol dimethyl ether (CAS No 112-49-2)

These three substances shall be added to Annex III to the Order of 7 August 1997 (substances toxic to reproduction: category 2). It is thus prohibited to sell them to consumers, as such or as an ingredient in preparations, in a concentration of over 0.5%.

#### 7. Notification Under Another Act

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#### 8. Main Content

This draft Order will make it possible to anticipate, at national level, banning the use, in a concentration of more than 0.5%, of three glycol ethers, EGDME, DEGDME and TEGDME, which are classified as toxic to reproduction in category 2 by European experts (Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances).

Article 1 stipulates that the three glycol ethers referred to in point 6 shall be added to Annex III to the Order of 7 August 1997, in the substances toxic to reproduction in category 2.

Key words: dangerous substances, restrictions on marketing and use, glycol ethers, toxic to reproduction

#### 9. Brief Statement of Grounds

A group of French experts from the French Higher Public Health Council (CSHPF) performed a risk assessment on the glycol ethers present in consumer products, following which an opinion was issued (cf. report and opinion attached hereto). Following this opinion, the Minister for Health, the Family and Disabled Persons proposed the above-mentioned Order, in order for all glycol ethers, which have been established to be toxic to reproduction in category 2, to be banned at national level in concentrations above 0.5% in consumer products intended for the general public.

The three substances in question have been classified as being toxic to reproduction, as proven in animal experiments, by European experts (European Commission CMR group, Environment DG, ISPRA). This classification has been published in the case of one of the three glycol ethers, DEGDME (28th ATP of Directive 76/769/EEC) and is in progress for the other two, EGDME and TEGDME (they will be included in the 29th ATP, which will be voted on in January 2004).

A number of substances have been classified as dangerous in this way by European experts, but the



administrative delays in publishing these harmonised classifications in the framework of adaptations to technical progress of Directive 67/548/EEC, are fairly long. In addition, the marketing restrictions that follow on from them (category 1 and 2 CMRs), although almost automatic, necessitate an additional delay of at least 6 months. It was consequently inconceivable to defer the restrictions on marketing these three glycol ethers, for which the health risks to the public have been established by European experts and confirmed by the CSHPF.

## 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,
- 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;
- the Environment Code, and in particular Article L.521-6;
- the amended Order of 7 August 1997 concerning restrictions on the marketing and use of certain products containing dangerous substances, transposing Directive 76/769/EEC; ([www.legifrance.gouv.fr/Waspad/1AX9970817P2](http://www.legifrance.gouv.fr/Waspad/1AX9970817P2))
- 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; ([www.legifrance.gouv.fr/Waspad/1AX9940508P16](http://www.legifrance.gouv.fr/Waspad/1AX9940508P16))
- the amended Order of 21 February 1990 defining the classification criteria and the packaging and labelling conditions of dangerous preparations, transposing Directive 88/379/EEC relating to the classification, packaging and labelling of dangerous preparations; ([www.legifrance.gouv.fr/Waspad/39124](http://www.legifrance.gouv.fr/Waspad/39124))
- the Order of 13 October 1998 relating to restrictions on the marketing and use of certain products containing dangerous substances; ([www.legifrance.gouv.fr/Waspad/251398](http://www.legifrance.gouv.fr/Waspad/251398))
- the opinion of the French Higher Public Health Council of 7 November 2002.

f) The relevant data relating to the three targeted substances (EGDME, DEGDME and TEGDME), which justify issuing the Order referred to, come from the attached report from a group of French experts from the French Higher Public Health Council (CSHPF), on glycol ethers in consumer products and health. This report demonstrated a risk to consumer health from these glycol ethers. On the basis of this report, the CSHPF issued an opinion in November 2002, attached hereto, mentioning a number of recommendations, including banning glycol ethers toxic to reproduction in category 2 in consumer products, the use of which would cause significant exposure.

## 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 and SPS aspects (Agreements drawn up within the framework of the WTO)

TBT aspect (Agreement on technical barriers to trade)

a) No

SPS aspect (Agreement on sanitary and phytosanitary measures)

a) No

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