



Notification Number: 2003/398/F

## Decree on the collection, recovery and disposal of household medicine waste

Date received : 23/10/2003

End of Standstill : 26/01/2004

Issue of comments by : Italy

### Message

Message 002

Communication from the Commission - SG(2003) D/52063

Directive 98/34/EC

Translation of the message 001

Notification: 2003/0398/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: 200302063.EN)

#### 1. Structured Information Line

MSG 002 IND 2003 0398 F EN 26-01-2004 23-10-2003 F NOTIF 26-01-2004

#### 2. Member State

France

#### 3. Department Responsible

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#### 3. Originating Department

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#### 4. Notification Number



2003/0398/F - C10P

## 5. Title

Decree on the collection, recovery and disposal of household medicine waste

## 6. Products Concerned

This Decree concerns household medicine waste, consisting of medicines and their packaging, with the exception of waste from treatments which carry a risk of infection, since this waste is already subject to specific legislation.

## 7. Notification Under Another Act

Notification in accordance with other Community legislation

- a) Framework Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs (OJ L 33/79).
- b) Council Directive 93/43/EEC on the hygiene of foodstuffs (OJ L 175/93).
- c) Council Regulation (EEC) No 315/93 on contaminants in food (OJ L 37/93).

## 8. Main Content

This Decree is based on the principle of broader responsibility of the manufacturer in the area of waste from household medicines, including packaging and unused medicines.

In the system in question, pharmacists are obliged to accept household medicine waste free of charge.

Manufacturers of medicines are obliged to collect and recover waste collected in this way. They are also obliged to contribute to the elimination of packaging waste, which still remains the responsibility of local authorities, not returned to the pharmacy. In practice, this system is based on the system established by the Cyclamed association 10 years ago.

In order to participate, manufacturers, individually or collectively, must have an approval, issued for a maximum of 6 years by interministerial order. The Decree specifies the conditions for allocating and renewing these approvals.

## 9. Brief Statement of Grounds

Specific collection and recovery of medicines waste has been organised for 10 years by the Cyclamed association. This system is currently only approved for packaging while its main objectives and public recognition concern medicines.

This legislation aims to provide a specific regulatory framework for the collection and recovery of household medicine waste, while ensuring coherence with legislation on household packaging waste.

## 10. Reference Documents - Basic Texts

- a) Public Health Code, Articles L. 1311-1, L. 1312-1, L. 1335-2, L. 4211-2, L. 5111-1, L. 5121-1, R. 1335-1 to R. 1335-14 and R. 5000
- b) Environment Code, Article L. 541-10
- c) Decree No 92-377 of 1 April 1992

## 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**

The impact assessment is enclosed.

**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

b) The draft does not have any notable impact on international trade.

SPS aspect (Agreement on sanitary and phytosanitary measures)

a) No

b) The draft does not have any notable impact on international trade.

David O'Sullivan  
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