



Notification Number: 2010/808/F

## Draft decree on the management of perforating healthcare waste posing infection risks produced by self-care patients

Date received : 23/12/2010

End of Standstill : 24/03/2011

### Message

Message 002

Communication from the Commission - SG(2010) D/53208

Directive 98/34/EC

Translation of the message 001

Notification: 2010/0808/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 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 - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201003208.EN)

#### 1. Structured Information Line

MSG 002 IND 2010 0808 F EN 23-12-2010 F NOTIF

#### 2. Member State

F

#### 3. Department Responsible

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#### 3. Originating Department

Ministère de l'écologie, du développement durable, des transports et du logement

Direction générale de la prévention des risques

Service de la prévention des nuisances et de la qualité de l'environnement

Bureau de la qualité écologique des produits



Grande Arche- paroi nord – 92055 La Défense Cedex

#### **4. Notification Number**

2010/0808/F - S20E

#### **5. Title**

Draft decree on the management of perforating healthcare waste posing infection risks produced by self-care patients

#### **6. Products Concerned**

The decree concerns medicines, medical devices and in-vitro diagnostic devices which, after having been used by self-care patients, become perforating healthcare waste posing infection risks.

#### **7. Notification Under Another Act**

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#### **8. Main Content**

The decree establishes the principle of extended producer responsibility (EPR) for the management of perforating healthcare waste posing infection risks produced by self-care patients, which from now on must be undertaken by users of medicines and manufacturers of medical devices and in-vitro diagnostic devices, or their representatives.

This responsibility covers, upstream, the free-of-charge provision of collectors so that self-care patients can dispose selectively and completely safely of their perforating waste. Downstream, it covers the way in which the collection, removal and processing of selectively collected waste are organised.

#### **9. Brief Statement of Grounds**

Local initiatives based primarily on partnerships between patients' associations and local authorities enable certain self-care patients to benefit free of charge from a collection network and suitable processing of their perforating healthcare waste posing infection risks. However, many self-care patients do not have access to such arrangements and dispose of their waste along with residual household refuse. This situation poses health risks to workers who collect and process household waste.

At the end of 2007, commitment 249 of the Environment Round Table embodied the collective desire to create a network based on the principle of extended producer responsibility (EPR) for the management of perforating healthcare waste posing infection risks produced by self-care patients. This commitment culminated in the creation of Article L. 4211-2-1 of the Code de la santé publique. The purpose of this network is to eliminate the health risk associated with the handling of this waste mixed with household waste by workers who collect and process household waste, and to ensure that this waste is processed in an environmentally-friendly way.

#### **10. Reference Documents - Basic Texts**

References to reference texts: a) Article L. 541-10 of the Code de l'environnement

b) Article L. 4211-2-1 of the Code de la santé publique

c) Article R. 1335-1 of the Code de la santé publique

d) Decree no. 2010-1263 of 22 October 2010 on the elimination of healthcare waste posing infection risks produced by self-care patients



**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**

Yes

**16. TBT and SPS aspects**

TBT aspect

No – The draft is not a technical regulation or conformity assessment.

NO - The draft will have no significant effect on international trade.

SPS aspect

No – The draft is not a sanitary or phytosanitary measure.

NO – The draft will have no significant effect on international trade.

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