



Notification Number: 2008/34/F

Draft Decree on the disposal of waste from care activities presenting the risk of infection that is produced by self-care patients and amending the Public Health Code (regulatory provisions)

Date received : 25/01/2008

End of Standstill : 28/04/2008

Issue of comments by : United Kingdom, United Kingdom

Message

Message 002

Communication from the Commission - SG(2008) D/50167

Directive 98/34/EC

Translation of the message 001

Notification: 2008/0034/F

No abre el plazo - Nezaahajuje 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: 200800167.EN)

1. Structured Information Line

MSG 002 IND 2008 0034 F EN 28-04-2008 25-01-2008 F NOTIF 28-04-2008

2. Member State

F

3. Department Responsible

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3. Originating Department

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Sous-direction de la prévention des risques liés à l'environnement et à l'alimentation
Bureau environnement extérieur et produits chimiques
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4. Notification Number

2008/0034/F - S00S

5. Title

Draft Decree on the disposal of waste from care activities presenting the risk of infection that is produced by self-care patients and amending the Public Health Code (regulatory provisions)

6. Products Concerned

This draft Decree concerns sharp waste produced by self-care individuals and arising from injected medicines, medical devices and diagnostic devices.

7. Notification Under Another Act

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8. Main Content

This Decree is based on the principle of extended producer responsibility in the area of sharp waste from injected medicines, medical devices and diagnostic devices.

Under the new arrangements, manufacturers of products generating sharp waste after use by self-care individuals will be required to provide special collectors for picking up injection waste, to be issued via pharmacies.

Furthermore, the draft Decree introduces a mechanism for certifying the conformity of apparatus for the pre-treatment by means of disinfection of waste from care activities presenting a risk of infection (DASRI), instead of the approval procedure currently provided for in Article R. 1335-8 of the Public Health Code.

9. Brief Statement of Grounds

As a consequence of the development of home treatment administered by the patients themselves, more than 1 million people every year produce sharp waste presenting infectious and/or toxicological risks. Such waste is often thrown away into the household waste disposal system, exposing household waste collection staff to the risk of accidents, in particular accidents that expose them to blood. This Decree is aimed at strengthening health safety. The provision of collectors intended for the safe collection of such waste represents the first link in the chain of specific disposal associated with it, in accordance with the regulations on DASRI.

10. Reference Documents - Basic Texts

a) Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work
The Public Health Code, in particular Articles L. 1311-1, L. 1335-2, L. 4211-1, R. 1335-1 to R. 1335-8



The Environment Code and in particular Article L.541-10

11. Invocation of the Emergency Procedure

NO

12. Grounds for the Emergency

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13. Confidentiality

a) NO

14. Fiscal measures

b) NO

15. Impact assessment

Impact studies

b) (The impact assessment is enclosed).

16. TBT and SPS aspects

TBT aspect (Agreement on Technical Barriers to Trade)

a) NO

b) -

iii) The draft does not have a significant effect on international trade.

SPS aspect (Agreement on Sanitary and Phytosanitary Measures)

a) NO

b) -

iii) The draft does not have a significant effect on international trade.

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