



Notification Number: 2016/12/F

ORDER relating to the disinfection pretreatment of potentially infectious and other comparable healthcare waste

Date received : 08/01/2016

End of Standstill : 11/04/2016

Message

Message 002

Communication from the Commission - TRIS/(2016) 00077

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2016/0012/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 - Não 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: 201600077.EN)

1. Structured Information Line

MSG 002 IND 2016 0012 F EN 08-01-2016 F NOTIF

2. Member State

F

3. Department Responsible

Direction générale des entreprises – SQUALPI – Bât. Sieyès -Teledoc 151 – 61, Bd Vincent Auriol - 75703

PARIS Cedex 13

d9834.france@finances.gouv.fr

tél : 01 44 97 24 55

3. Originating Department

Direction générale de la santé,

Sous direction Environnement et Alimentation –

Bureau EA 1 (Mme CAAMANO)

14, avenue Duquesne

75 350 PARIS 007 SP



tél : 01 40 56 71 86
mél : delphine.caamano@sante.gouv.fr

4. Notification Number

2016/0012/F - S00S

5. Title

ORDER relating to the disinfection pretreatment of potentially infectious and other comparable healthcare waste

6. Products Concerned

Appliances for the disinfection pretreatment of potentially infectious and other comparable healthcare waste (DASRIA).

7. Notification Under Another Act

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8. Main Content

This draft order specifies the standard (NF X 30-503: 2015 'Reduction of microbiological and mechanical risks from potentially infectious and other comparable healthcare waste by disinfection pretreatment appliances' – part 1) according to which the tests attesting to the conformity of the appliances with the aforementioned characteristics must be performed. It includes a mutual recognition clause for appliances originating in the EU and EEA (Article 1).

It defines the approval conditions for the bodies responsible for issuing certificates of conformity for these appliances (Article 2, Annexes 1 and 2).

It defines the conditions for the declaration (Article 3, Annex 1), organisation, operation (Article 4, Annex 4) and monitoring (Article 4, Annex 5) of a disinfection pretreatment facility.

It is proposed to implement this text on 1 July 2016 to enable manufacturers to adapt to these new provisions.

9. Brief Statement of Grounds

In France, DASRIA is incinerated or thoroughly pretreated by disinfection. In the absence of a harmonised European standard, France is regulating the placement on the market of DASRIA disinfection pretreatment appliances due to their potential health and environmental impacts.

1) Reasons relating to public health risk management

Disinfection pretreatment appliances reduce the microbiological contamination of DASRIA. They consequently help to limit the risk of accidental exposure to blood for health professionals and professionals responsible for collection, whose practices may require them to handle waste downstream of these appliances. Proper management of the disinfection process of these appliances contributes to the safety of healthcare professionals and waste disposal professionals.

2) Reasons relating to environmental risk management

Making these appliances safe helps to limit the environmental dispersion, via DASRIA, of germs from hospital flora, for example germs from known infectious illnesses, but also germs specifically associated with hospital flora (germs that are resistant to antibiotics or certain disinfectant biocides, and new strains of highly resistant bacteria). The appearance of new pathogens (e.g. Human Immunodeficiency Virus [HIV], non-conventional transmissible agents, Severe Acute Respiratory Syndrome [SARS] virus, Ebola, etc.) increases the spectrum of biological agents liable to be present in this DASRIA and in the environment, in the absence of suitable treatment.



10. Reference Documents - Basic Texts

Reference(s) to basic text(s): Article R.1335-8 of the Public Health Code.

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

-

16. TBT and SPS aspects

TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft has no significant impact on international trade.

European Commission

Contact point Directive (EU) 2015/1535

Fax: +32 229 98043

email: grow-dir83-189-central@ec.europa.eu