



Notification Number: 2016/11/F

## **DECREE amending Article R.1335-8 of the Public Health Code and relating to 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) 00073

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2016/0011/F

No abre el plazo - Nezhahajuje 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: 201600073.EN)

#### **1. Structured Information Line**

MSG 002 IND 2016 0011 F EN 08-01-2016 F NOTIF

#### **2. Member State**

F

#### **3. Department Responsible**

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#### **3. Originating Department**

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Sous direction Environnement et Alimentation –  
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#### **4. Notification Number**

2016/0011/F - S00S

#### **5. Title**

DECREE amending Article R.1335-8 of the Public Health Code and relating to 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 decree extends the definition of potentially infectious healthcare waste (DASRI) to include waste from non-clinical safety tests performed on cosmetic products and tattooing products (Article 1(1)).

Furthermore, it defines the characteristics of disinfection pretreatment appliances, especially in terms of reducing the microbiological contamination of DASRIA and modifying its appearance, and establishes the obligation to obtain a certificate of conformity, issued by a body approved by the Ministry for Health, before they are placed on the market (Article 1(3) of the draft decree).

It provides that the use of these appliances at a disinfection pretreatment facility is subject to prior declaration being made to the director-general of the regional health authority. It introduces organisational, operational and monitoring conditions for these facilities (Article 1(3)).

It establishes sanctions in the event of failure to fulfil some of the aforementioned provisions. Moreover, in the event of a serious public health risk being identified, the director-general of the regional health authority shall rule that use of the disinfection pretreatment appliance be suspended.

This draft decree provides that disinfection pretreatment appliances whose approval was issued prior to the publication date of this decree shall retain the benefits of this approval for five years following the entry into force of this draft decree. After this time, they will need to obtain a certificate of conformity.

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

In France, DASRI and comparable waste (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**

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**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.

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European Commission

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