



Notification Number: 2019/151/F

## Order amending the order of 24 November 2003 on the packaging of clinical waste with infection risks and similar waste and anatomical parts of human origin

Date received : 02/04/2019

End of Standstill : 03/07/2019

### Message

Message 002

Communication from the Commission - TRIS/(2019) 00954

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2019/0151/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 - 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: 201900954.EN)

#### 1. Structured Information Line

MSG 002 IND 2019 0151 F EN 02-04-2019 F NOTIF

#### 2. Member State

F

#### 3. Department Responsible

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#### 3. Originating Department

Ministère des Solidarités et de la Santé

Direction générale de la santé

Sous-direction Sous-direction de la prévention des risques liés à l'environnement et à l'alimentation (EA)



Bureau de l'environnement extérieur et des produits chimiques (EA1)  
14, Avenue Duquesne  
75007 PARIS

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

2019/0151/F - S00S

#### **5. Title**

Order amending the order of 24 November 2003 on the packaging of clinical waste with infection risks and similar waste and anatomical parts of human origin

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

Cardboard boxes with plastic bags (combined packaging) for clinical waste with infection risks (DASRI [déchets d'activités de soins à risques infectieux]) that is solid or soft

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

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

In accordance with Article article R.1335-6 of the French Public Health Code, the Order of 24 November 2003 defines the standards with which packaging of clinical waste with infection risks comply. These standards are aimed at ensuring the safety of packaging and thus contribute to the prevention of accidental exposure to blood by healthcare professionals and those in charge of waste collection. They have been applied by manufacturers marketing this packaging on national territory since 2003.

The objective of this draft amending Order is to update the reference to standard NF X 30-507 on cardboard boxes with plastic bags (combined packaging) for DASRI that is solid or soft referred to in Article 4 of the Order of 24 November 2003, the new version of which was published in July 2018. Moreover, in accordance with Decree No 2009-697 of 16 June 2009 on standardisation, which provides that adherence to the standards is voluntary, the draft Order defines the design and marking requirements the cardboard boxes with inner plastic bags must meet (Annex 1 of the draft Order) and establishes a presumption of conformity with standard NF X 30-507: 2018. It also provides productions methods for tests designed to verify compliance with these requirements.

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

The Order of 24 November 2003 on the packaging of infectious clinical waste and similar waste (DASRI) and anatomical parts of human origin provides that DASRI packaging must be compliant with standards. This measure has shown to be effective in terms of health security. In fact, the annual report of 2015 on accidental exposure to blood (Surveillance of occupational blood and body fluids exposures in French healthcare facilities in 2015 - AES-Raisin Results 2015. French Institute for Health Surveillance [Institut de veille sanitaire]) highlights the very low rate of accidental exposure to blood through cuts connected to potentially faulty packaging (0.8 % of these accidents through percutaneous injury are associated with p DARSİ packaging).

The draft Order updates the reference to standard NF X 30 507, allowing the presumption of conformity to be given to the requirements which must be met by the cardboard boxes with inner plastic bags in order to guarantee an improved resistance of the combined packaging handles by establishing resistance tests of the



gripping means.

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

Reference(s) to basic text(s): - Article R. 1335-6 of the Public Health Code

Order of 24 November 2003 on the packaging of clinical waste with infection risks and similar waste and anatomical parts of human origin

The basic texts were forwarded with an earlier notification: 2002/468/F

#### **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 is neither a sanitary nor phytosanitary measure.

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European Commission

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