Notification Number: 2015/617/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 : 06/11/2015

End of Standstill : 08/02/2016

Message

Message 002

Communication from the Commission - TRIS/(2015) 03439
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2015/0617/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 késéseket - Ma' jiftaħx 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 - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201503439.EN)

1. Structured Information Line
MSG 002 IND 2015 0617 F EN 06-11-2015 F NOTIF

2. Member State
F

3. Department Responsible
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4. Notification Number
2015/0617/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
Packaging of clinical waste with infection risks

7. Notification Under Another Act
-

8. Main Content
In accordance with Article article R.1335-6 of the French Public Health Code, the Order of 23 November 2004 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 draft order aims to update the references of these standards, necessary to take account of technical developments and improve packaging safety. So:
1. It updates versions of certain standards:
- For plastic bags and lined paper bags: standard NF X 30-501, version 2006;
- For packaging of liquid clinical waste with infection risks, standard NF X 30-506, version 2015.
2. It replaces technical specifications (design requirements and testing) with compliance with a standard drawn up to this effect:
- For cardboard boxes with plastic bag, standard NF X 30-507, version 2009.
3. It takes account of the publication of new standards:
- For boxes and mini-containers for sharps waste, drums and canisters, standards NF EN ISO 23 907 version 2012 and NF X 30-511 version 2015.
A summary of these provisions is provided in Annex 1.
For each of these types of packaging, compliance with the abovementioned French standards is not imperative insofar as compliance can also be assessed with regard to “any other standard of a Member state of the European Union or another state party to the European Economic Area, provided the standard in question provides at least the level of safety equivalent to the French standard”.
Furthermore, the draft order removes the information that must be displayed on the packaging of clinical waste with infection risks insofar as this is provided by the abovementioned standards, which are now mandatory.
Lastly, implementation on 1 July 2016 is proposed to enable manufacturers to manage their stocks and, where appropriate, adapt their processes to these new provisions.

9. Brief Statement of Grounds
Clause 6 of Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU provides for the placement of “clearly marked and technically safe containers for handling disposable sharp items and injection equipment”.

The provisions of the abovementioned Order of 24 November 2003 already complied with this clause by requiring compliance with standards for packaging clinical waste with infection risks. These standards are aimed at ensuring the safety of packaging of clinical waste with infection risks and thus preventing accidental exposure to blood by healthcare professionals.

The draft order submitted with this notification aims to update the references to French standards and to take account of international standards (standard NF EN ISO 23 907 in particular).

Furthermore, this update is expected by manufacturers (who actively participated in drafting the standards referred to in the draft order).

Lastly, the effectiveness of the safety system provided for by the Order of 24 November 2003 is assessed through the monitoring of hospital-acquired infections, including accidental exposure to blood by healthcare professionals, piloted by the French Institute for Public Health Surveillance (Institut de veille sanitaire - InVS). Thus, the impact of standard NF X 30-500 on boxes and mini-containers on reducing accidental exposure to blood was noted in a report drawn up by the InVS: “The proportion of containers in equipment involved in accidental percutaneous exposure to blood was 3.3% this year [2008] compared to 5.2% in 2007 and 6.9% in 2006. Evidently, this rate of accidental exposure associated with the use of containers seems low in France compared to those reported by other countries. This may be linked to the enforcement of standard NF X 30-500, but this is not easy to demonstrate” (Rapport du raisin, 2008).

10. Reference Documents - Basic Texts
Reference(s) to basic text(s): Article R. 1335-6 of the French Public Health Code.

Order of 24 November 2003 on the packaging of infectious clinical waste and similar waste and anatomical parts of human origin notification reference no. 2002/0468/F

Order of 6 January 2006 amending the Order of 24 November 2003 on the packaging of infectious clinical waste and similar waste and anatomical parts of human origin notification reference no. 2005/0352/F

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
-

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.

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European Commission

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