Notification Number: 2016/540/F

Order establishing the concentration levels of di-(2-ethylhexyl) phthalate above which the use of tubing containing said substance is prohibited under Article L5214-1 of the French Public Health Code

Date received	:	11/10/2016
End of Standstill	:	12/01/2017
Issue of comments by	:	Commission

Message

Message 002

Communication from the Commission - TRIS/(2016) 03133
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2016/0540/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 - Não 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 - Nu deschide perioadele de stagnare.

(MSG: 201603133.EN)

1. Structured Information Line
MSG 002 IND 2016 0540 F EN 11-10-2016 F NOTIF

2. Member State
F

3. Department Responsible
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3. Originating Department

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Direction générale de la santé.
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4. Notification Number
2016/0540/F - S10S

5. Title
Order establishing the concentration levels of di-(2-ethylhexyl) phthalate above which the use of tubing containing said substance is prohibited under Article L5214-1 of the French Public Health Code

6. Products Concerned
Product: Medical devices
Service: Hospital services

7. Notification Under Another Act
-

8. Main Content
Article L5214-1, as amended by Law No 2016-41, prohibits use of tubing containing di-(2-ethylhexyl) phthalate (DEHP) in paediatric, neonatal and maternity services. The aim of the draft order is to establish the levels of di-(2-ethylhexyl) phthalate (DEHP) above which the use of tubing containing said substance is prohibited.

The draft national regulation sets the maximum concentration of DEHP at 0.1 % weight by weight (w/w) of plasticised material, above which the use of said tubing is prohibited.

This limit is not necessarily applicable to all types of tubing used. It is thus laid down that, if alternatives for certain categories of medical devices designated on a restrictive basis are not currently available, the maximum permitted level of DEHP should be increased to 40 % w/w of plasticised material. This limit corresponds to that set out in monograph 3.1.1.2 of the European Pharmacopoeia (8th edition) (Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components).

The notified draft order references the provisions applicable to DEHP present in electrical and electronic equipment, set out in Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as amended by Commission Directive (EU) 2015/1787.

9. Brief Statement of Grounds
In February 2008, the European Scientific Committee on Emerging and Newly Identified Health Risks published a report on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk. It showed that there may be a risk to human health, especially concerning premature infants and during certain medical procedures. The Committee encourages the use of other alternatives not containing DEHP, if available. The update of the report in 2015 reaffirmed these conclusions.

Largely on the basis of this opinion, the French authorities' intention as regards the draft order is, as a precaution, to reduce the exposure to DEPH of vulnerable groups (newborn babies and infants) in hospitals, a substance which is classified as toxic to reproduction category 2 under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. The proposed measure is justified on health grounds. It remains proportionate and limited in terms of its effects on the free movement of goods. The regulation concerns a specific field of use of the products in question (paediatric, neonatal and maternity services), while setting a specific limit for certain categories of specifically listed medical devices. In light of the above, the draft order seems justified and necessary in view of helping to improving health security on national territory.

10. Reference Documents - Basic Texts
Reference(s) to basic text(s): - Opinion of the European Scientific Committee on Emerging and Newly Identified Health Risks of 2008 on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk, updated in 2015
- Article L5214-1 of the Public Health Code

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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