



Notification Number: 2012/164/F

Order establishing the list of substances which tattooing products must not contain

Date received : 14/03/2012

End of Standstill : 15/06/2012

Issue of comments by : Commission

Message

Message 002

Communication from the Commission - SG(2012) D/5713

Directive 98/34/EC

Translation of the message 001

Notification: 2012/0164/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 - 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: 201200713.EN)

1. Structured Information Line

MSG 002 IND 2012 0164 F EN 14-03-2012 F NOTIF

2. Member State

F

3. Department Responsible

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3. Originating Department

Ministère du Travail, de l'Emploi et de la Santé
Direction Générale de la Santé



Sous-direction de la politique des pratiques et des produits de santé (PP)
Bureau des dispositifs médicaux et autres produits de santé (PP3)
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4. Notification Number

2012/0164/F - C00P

5. Title

Order establishing the list of substances which tattooing products must not contain

6. Products Concerned

Tattooing products

7. Notification Under Another Act

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8. Main Content

The provisions of the Public Health Code arise from Decree no 2008-210 of 3 March 2008 laying down the rules for the manufacture, packaging and importation of tattooing products, establishing a national surveillance system and amending the Public Health Code (regulatory provisions). For regulation purposes, these provisions divide substances contained in tattooing products into substances to be prohibited and substances to be authorised under certain circumstances. These two lists of substances are established by orders of the Minister of Health, at the proposal of the director-general of the "Agence française de sécurité sanitaire des produits de santé" (French Health Products Safety Agency) issued after an opinion has been obtained from a group of experts as regards the risk assessment of tattooing products.

9. Brief Statement of Grounds

The purpose of this draft order is to establish the list of substances that tattooing products must not contain pursuant to 1° of article R. 513-10-4 of the Public Health Code.

This draft law is intended to prohibit the most dangerous substances, including:

1°) substances classified for carcinogenicity, mutagenicity, reproductive toxicity and sensitisation by Regulation (EC) No 1272/2008 of 16 December 2008 as amended. These substances are currently listed in Annexes II and III (parts 1 and 2) and IV (columns 2 to 4, parts 1 and 2) of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

2°) substances that are not classified but have a high-risk toxicological profile, including:

- substances for cosmetic use that are not authorised for use on mucous membranes;
- aromatic amines that may be present as impurities in colouring agents used for tattooing products or may be released through deterioration;
- sensitising substances that are restricted for textiles.

10. Reference Documents - Basic Texts



Reference texts: French Public Health Code (Article R. 513-10-4).

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.

Catherine Day
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Commission européenne

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