



Notification Number: 2006/441/F

Draft Order laying down the list of substances that may not be used in tattooing products

Date received : 14/08/2006

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Message

Message 002

Communication from the Commission - SG(2006) D/51971

Directive 98/34/EC

Translation of the message 001

Notification: 2006/0441/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' 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.

(MSG: 200601971.EN)

1. Structured Information Line

MSG 002 IND 2006 0441 F EN 14-08-2006 F NOTIF

2. Member State

France

3. Department Responsible

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3. Originating Department

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4. Notification Number

2006/0441/F - S00S



5. Title

Draft Order laying down the list of substances that may not be used in tattooing products

6. Products Concerned

Products for tattooing involving piercing the skin, defined as any colouring substance or preparation designed to create, through the piercing of the skin, a mark on the surface of the human body, with the exception of products that are medical devices.

7. Notification Under Another Act

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8. Main Content

The draft Order prohibits the use of certain substances in tattooing products. The list of these substances is drawn up in the Annex to the Order. The substances concerned are those mentioned in the Annex to the Council of Europe Resolution of 19 June 2003 on tattooing products and contain aromatic amines, well known for their carcinogenic properties, and the substances listed in the Annex to the Order provided for in Article R. 5131-3(1) of the Public Health Code, that is to say substances which are prohibited in cosmetic products.

9. Brief Statement of Grounds

The Council of Europe's study ("Chemical composition of tattooing and permanent make-up products" by Wolfgang Bäuml, John Lundsgaard, Hans Jørgen Talberg and Rudolf Vasold) has shown the dangerous characteristics of the offending substances, mainly aromatic amines, the carcinogenic nature of which has, moreover, been clearly demonstrated in the scientific literature.

This list, drawn up in this study and appended as an Annex to the Council of Europe Resolution Res AP(2003)2 of 19 June 2003, has been reviewed and supplemented by the working group on tattooing products located at the French health authority, the French Agency for the Safety of Health Products (AFSSAPS).

In August 2004, following an alert by the RAPEX network, the services of the DGCCRF and of the AFSSAPS took and analysed samples of the ink exposed by this alert. The analyses tested positive for the fungus indicated (*Acremonium fungii*), for two bacteria of the *Pseudomonas* genus (*aeruginosa* and *putida*) and for one bacterium of the *Aeromonas* genus. Following this incident, the same authorities carried out a study among the distributors and importers of tattooing products in 12 French departments. Of 66 samples of various colours taken from 20 product brands, 7 products taken from 4 different brands were found not to conform and to be dangerous: contamination by *Streptococcus equinus*, mould, *Bacillus* and *Moraxella*. The aim of the proposed legislation is to guarantee that conforming and non-dangerous products and materials are used and to lay down hygiene measures guaranteeing that consumers are not contaminated during the delivery of the service.

10. Reference Documents - Basic Texts

- a) Article R.5233-4 of the Public Health Code (draft Decree laying down rules for the manufacture, packaging and import of, and the national monitoring system for, tattooing products, and amending the Public Health Code)
- b) Article R.5131-3 of the Public Health Code.
- c) Amended Order of 6 February 2001 laying down the list of substances that may not be used in cosmetic products



11. Invocation of the Emergency Procedure

YES.

12. Grounds for the Emergency

The aforementioned studies demonstrate that there is a significant and widespread public health problem as regards the composition of tattooing products.

13. Confidentiality

NO

14. Fiscal measures

b) NO

15. Impact assessment

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16. TBT and SPS aspects

TBT aspect (Agreement on Technical Barriers to Trade)

a) NO

b) iii) The draft does not have any notable impact on international trade.

SPS Aspect (Agreement on Sanitary and Phytosanitary Measures)

a) NO

b) i) The draft is not a sanitary or phytosanitary measure pursuant to Annex A to the SPS Agreement.

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