



Notification Number: 2006/436/F

Draft Order laying down good practice for manufacturing tattooing products

Date received : 14/08/2006

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Message

Message 002

Communication from the Commission - SG(2006) D/51966

Directive 98/34/EC

Translation of the message 001

Notification: 2006/0436/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.

(MSG: 200601966.EN)

1. Structured Information Line

MSG 002 IND 2006 0436 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

2006/0436/ F - S00S



5. Title

Draft Order laying down good practice for manufacturing 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

Good manufacturing practice is presented in the form of a series of recommendations on the conditions for preparing tattooing products, be they manufactured industrially, traditionally or for one person. This includes the following elements:

- a) General principles
- a) Documents
- b) Locations and Materials
- c) Personnel
- d) Raw materials and packaging articles
- e) Manufacture
- f) Subcontracting
- g) Complaints and product recall

9. Brief Statement of Grounds

The purpose of good practice in the manufacture of tattooing products is to monitor the quality of tattooing products when they are manufactured either in batches or extemporaneously. This forms part of an overall quality assurance system.

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* fungi), 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) 10. Article L. 513-10-3 of the Public Health Code.

11. Invocation of the Emergency Procedure

YES.



12. Grounds for the Emergency

The aforementioned studies demonstrate that there is a significant public health problem irrespective of the type of ink used, as regards the rules for manufacturing tattooing products.

13. Confidentiality

NO

14. Fiscal measures

a) 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 a significant effect 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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