



Notification Number: 2006/437/F

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 (regulatory provisions)

Date received : 14/08/2006
End of Standstill : 15/11/2006 (15/02/2007)
Issue of detailed opinion by : Commission

Message

Message 002

Communication from the Commission - SG(2006) D/51967
Directive 98/34/EC
Translation of the message 001
Notification: 2006/0437/F

No abre el plazo - Nezhajuje 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: 200601967.EN)

1. Structured Information Line

MSG 002 IND 2006 0437 F EN 14-08-2006 F NOTIF

2. Member State

France

3. Department Responsible

Délégué interministériel aux normes – SQUALPI –
DGE 6 – Bâtiment Le Bervil-
12, rue Villiot-75572 PARIS CEDEX 12
suzanne.piau@industrie.gouv.fr ou syrte@industrie.gouv.fr
tél : 01 53 44 97 04 – fax : 01 53 44 98 88

3. Originating Department



Ministère de la Santé et des solidarités, DGS/SD5C, 14, avenue Duquesne-75700 PARIS 07 SP

4. Notification Number

2006/0437/F - S00S

5. Title

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 (regulatory provisions)

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

-

8. Main Content

This draft Decree lays down rules concerning:

- the manufacturing, packaging and importation of tattooing products;
- the composition of tattooing products;
- the labelling of tattooing products;
- the national monitoring system for tattooing products;
- public information, and
- criminal provisions.

9. Brief Statement of Grounds

At present, tattooing products are not subject to any regulation and their being placed on the market is no guarantee of their safety in terms of public health.

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 hazardous: contamination by *Streptococcus equinus*, mould, *Bacillus* and *Moraxella*. The aim of the proposed legislation is to guarantee the use of conforming and non-hazardous products and materials and to lay down hygiene measures guaranteeing that consumers are not contaminated during the delivery of the service.

10. Reference Documents - Basic Texts

Public Health Code (Articles L. 513-10-1 to L. 513-10-4)

Consumer Code (Article L.221-1-3).

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 use of tattooing products.

13. Confidentiality

NO

13. Confidentiality

No

15. Impact assessment

-

16. TBT and SPS aspects

TBT aspect (Agreement on Technical Barriers to Trade)

a) No

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.

Catherine Day
General Secretary
European Commission

Contact point Directive 98/34
Fax: (32-2) 296 76 60
email: Dir83-189-central@cec.eu.int

sent to :

BELNotif Qualité et Sécurité
Mme Descamps

Bundesministerium für Wirtschaft und Technologie (Referat EA3)
Frau Christina Jäckel



Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1
Frau MARKL Iris

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1
Frau Brigitte WIKGOLM

Cyprus org. for the promotion of quality Ministry of Commerce, Industry & Tourism
M. Antonis Ioannou

Czech Office for Standards, Metrology and testing
Mrs Lucie Ruzickova

Department of Trade and Industry STRD2
Mr Philip Plumb

Délégation Interministérielle aux Normes
Mme Piau

EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

ELOT
M.Mourtzanos K

EU internal market coordination (Ministry of Economics)
Mrs Zanda Liekna

Erhvervs- og Boligstyrelsen
Lene Hald Nielsen

European Free Trade Association
.

Hungarian Notification Centre Ministry of economy & transport
Mr Zsolt Fazekas

Institut Belge de Normalisation
Mme F. Hombert

Instituto Português da Qualidade
Sra Cândida Pires

Kauppa-ja teollisuusministeri
Ms. Leila Orava

Kommerskollegium
Mme Jenni Altin

Lithuanian Standards Board
Daiva Lesickiene



Malta standards Authority
Dr Lorna Cachia

Min. of Economic Affairs & Communication
Mr. Karl Stern

Min. of Industry, Energy & Technology
Mr K. Polychronidis

Ministerie van Financiën Belastingdienst - Douane Noord / CDIU
De Heer IJ.G. van der Heide

Ministerio de Asuntos Exteriores Secretaría de Estado para la Unión Europ
Esther Perez Pelaez

Ministero dello sviluppo economico F1 - Ispettorato tecnico industria
Signor Vincenzo Correggia

Ministry of Economy Dept for Economic Regulations
Mrs Barbara H. Kozłowska

NSAI
Mr Tony Losty

National Agency for Enterprise & Housing Dahlerups Pakhus
Mrs. Pernille Hjort Engstroem

Office of standards, metrology & Testing Director of the department of European I
Mrs Kvetoslava STEINLOVA

Représentation Permanente de la Belgique auprès de l'Union européenne
.

Représentation Permanente de la France
.

Représentation Permanente du Luxembourg
.

SL
.

Service de l'Energie de l'Etat
Mr J.-P. Hoffmann

Slovenian Institute for Standardization SIST
Mrs Vesna Stazisar

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT



sent to :

Department of Trade and Industry STRD2
Mr Philip Plumb

EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

European Free Trade Association
.

Hungarian Notification Centre Ministry of economy & transport
Mr Zsolt Fazekas

Kauppa-ja teollisuusministeri
Ms. Leila Orava

NSAI
Mr Tony Losty

Représentation Permanente de l'Irlande
Denis Colfer

Représentation Permanente du Royaume-Uni
.

SL
.

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT