



Notification Number: 2006/109/F

Draft Decree on cosmetic vigilance, amending the Public Health Code (regulatory provisions)

Date received : 22/02/2006
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Issue of detailed opinion by : Commission

Message

Message 002

Communication from the Commission - SG(2006) D/50513
Directive 98/34/EC
Translation of the message 001
Notification: 2006/0109/F

No abre el plazo - Nezhahajuje 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: 200600513.EN)

1. Structured Information Line

MSG 002 IND 2006 0109 F EN 23-05-2006 22-02-2006 F NOTIF 23-05-2006

2. Member State

France

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3. Originating Department

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4. Notification Number

2006/0109/F – C20P

5. Title

Draft Decree on cosmetic vigilance, amending the Public Health Code (regulatory provisions)

6. Products Concerned

Cosmetic products – C20P

7. Notification Under Another Act

This notification is made in application of Article 8 of the amended Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, laying down a procedure for the provision of information in the field of technical standards and regulations.

8. Main Content

This draft Decree aims to define the methods of implementation of Articles L. 5131-9 and L. 5131-10 of the Public Health Code on cosmetic vigilance. It implements points 6 and 7 of Article L. 5131-11 of the Public Health Code.

In the chapter on cosmetic products, Article 1 includes a section 5 relating to cosmetic vigilance, which is divided into three sub-sections.

Sub-section 1 (Articles R. 5131-15 to R. 5131-18) includes general provisions on cosmetic vigilance. Article R. 5131-15 defines cosmetic vigilance as the surveillance of undesirable effects resulting from the use of cosmetic products. It applies to all these products after they have been placed on the market and includes (Article R. 5131-16): a statement of the undesirable effects and the gathered information relating thereto; the registration, evaluation and use of this information with the aim of prevention; all studies and all work concerning the safety of using cosmetic products; the creation and monitoring of agreed corrective actions.

Article R. 5131-17 defines undesirable effects and misuse.

Article R. 5131-18 lays down that a decision by the Director-General of the AFSSAPS (French Agency for the Safety of Health Products) lays down the model for statements on undesirable effects to be made by health professionals.

Sub-section 2 (Articles R. 5131-19 to R. 5131-21) includes the organisation of cosmetic vigilance. The AFSSAPS ensures the implementation of a national system of cosmetic vigilance (Article R. 5131-20). Health professionals are subject to good practices of cosmetic vigilance, the principles of which are defined by the decision by the Director-General of the AFSSAPS (Article R. 5131-21).

Sub-section 3 (Articles R. 5131-22 and R. 5131-23) specifies the obligations for the transmission of information on the composition of cosmetic products.

On receipt of the application by the Director-General of the AFSSAPS, if there are serious doubts about a substance, the manufacturer or the person on behalf of whom the cosmetic product is manufactured or the importer shall send the following information to the Director-General of the AFSSAPS: the list of cosmetic products containing that substance as well as its exact concentration, specifying the trade name and the category of product, the storage address on the information file, the presentation and the contents of the various packaging (Article R. 5131-22).

This information is the subject of secure storage and archiving. Article R. 5131-21 specifies that personnel with access to information provided in application of Article R. 5131-22 are subject to professional secrecy.



9. Brief Statement of Grounds

This draft Decree aims to establish, as already exists for medicines and medical devices, a vigilance system for cosmetic products, called “cosmetic vigilance”, which currently operates experimentally and relies solely on volunteers, and which therefore can not provide exhaustive information.

Furthermore, it is necessary for the AFSSAPS, the competent French Agency for the Health Safety of cosmetic products, to obtain information on the composition of cosmetic products in order to prevent any potential risks linked to an ingredient and to be able to identify easily the products that contain it, which will allow the AFSSAPS to exercise its powers with regard to the health policy by having a greater knowledge of the products placed on the market. The provision introduced aims to guarantee the AFSSAP the availability of the necessary information for completing its mission of health safety of cosmetic products. In fact, at present, the AFSSAPS can only access the qualitative and quantitative formula of a product in areas designated by the manufacturer. In cases of doubt about the innocuousness of a substance in the composition of cosmetic products, it can not, therefore, obtain an inventory of the products concerned.

10. Reference Documents - Basic Texts

a) Public Health Code (Articles L. 5131-1 to L. 5131-11)

Consumer Code (Article L 221-1-3)

Penal Code (Article 223-13)

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 (Agreement on technical barriers to trade)

a) No

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

SPS Aspect (Agreement on sanitary and phytosanitary measures)

a) No

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



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