



Notification Number: 2001/419/F

Draft Decree on allergens specially prepared for individuals, amending the Public Health Code (second part: Council of State Decrees).

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Message

Department of Trade and Industry - Standards and Technical Regulations - Dir 2
Mrs Brenda O'Grady

EFTA Surveillance Authority
Ms Solveig Georgsdottir

ELOT
Mr E. Melagrakis

European Free Trade Association
Ms Kathleen Byrne

Kauppa-ja teollisuusministeriö
Mr Petri Kuurma

Kommerskollegium
Fru Kerstin Carlsson

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

Ministerie van Financien Belastingdienst - Douane / CDIU
De Heer IJ.G. van der Heiden

NSAI
Mr Tony Losty

Représentation Permanente de l'Irlande
Denis Colfer

Représentation Permanente du Royaume-Uni

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Message 002



Communication from the Commission - SG(2001) D/52226
Directive 98/34/EC
Translation of the message 001
Notification: 2001/419/F

(MSG: 200102226.EN)

1. Structured Information Line

MSG 002 IND 2001 0419 F EN 14-01-2002 12-10-2001 F NOTIF 14-01-2002

2. Member State

FRANCE

3. Department Responsible

Secrétariat général du Comité interministériel pour les questions de coopération économique européenne - 2, Bd Diderot 75012 Paris

Délégué interministériel aux Normes - 64 - 70, Allée de Bercy - Télédéc 811
75574 PARIS CEDEX 12

3. Originating Department

Ministère de l'emploi et de la Solidarité
Direction générale de la santé
Sous-direction de la politique des produits de santé
Madame Hélène Sainte-Marie
8, avenue de Ségur
75350 Paris 07 SP

4. Notification Number

2001/419/F - COOP

5. Title

Draft Decree on allergens specially prepared for individuals, amending the Public Health Code (second part: Council of State Decrees).

6. Products Concerned

Allergens.

7. Notification Under Another Act

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8. Main Content

Article L. 4211-6 of the Public Health Code lays down that any individual having obtained authorisation from the



French Agency for the Safety of Health Products (Agence française de sécurité sanitaire des produits de santé), and following the opinion of the National Academy of Medicine (Académie nationale de médecine), is permitted to prepare and supply allergens where they are specially prepared for an individual.

This draft lays down the application procedure for authorisations (information to be supplied in support of an initial application or a renewal of the authorisation, the time period for the Agency's reply), the reasons why the Director-General of the French Agency for the Safety of Health Products may amend, suspend or refuse authorisation, as well as the obligations to provide details that come within the scope of drug control.

In accordance with Article L. 4211-6 of the Public Health Code, authorisation is granted for renewable five-year periods.

9. Brief Statement of Grounds

This draft Decree is pursuant to Article L. 4211-6 (formerly L. 513) of the Public Health Code.

Article L. 513 of the Public Health Code formerly laid down the possibility for the Medicinal Products Agency (Agence du médicament) to grant authorisations, following the opinion of the National Academy of Medicine, for the preparation and supply of vaccines, serums and allergens provided that these medicines or products are specially prepared for individuals, and that they are therefore not the subject of a marketing authorisation procedure. Decree No 60-548 of 7 June 1960 laid down the conditions under which these authorisations were to be granted.

Act No 98-535 of 1 July 1998, on more stringent health monitoring and safety checks on health products intended for human consumption, amended Article L. 513 of the Public Health Code, which became Article L. 4211-6. Whereas authorisations for vaccines and serums were withdrawn, authorisations for allergens remained. The preservation of authorisation for allergens specially prepared for individuals (French abbreviation: APSI) was thought to be necessary insofar as there are still no marketing authorisations for allergens or allergen mixtures, as cited in Article L. 5121-8 of the Public Health Code, that are suitable for treating or diagnosing certain allergies in certain individuals.

This draft Decree aims to lay down the procedures according to which these authorisations, granted for renewable five year periods, may be granted, amended, renewed, suspended and withdrawn by the French Agency for the Safety of Health Products.

The applicant shall provide proof of training or professional experience in the field of allergens. In order to guarantee the quality of the APSIs prepared, information on their starter preparations and methods used in their preparation and supply are required.

As this system derogates from the common law on marketing authorisation, any decision in favour of the applicant (initial authorisation, amendment of initial authorisation or renewal of this authorisation for a five year period) must be subject to an explicit authorisation from the Director-General of the French Agency for the Safety of Health Products.

However, the holders of authorisations for the preparation and supply of allergens, granted pursuant to the aforementioned Decree of 7 June 1960, shall have six months from the publication date of this draft to submit an application for authorisation under the conditions laid down by the new provisions.

Article 2 of the draft makes APSIs subject to the rules on drug control.

Decree No 60-548 of 7 June 1960 is hereby repealed.



10. Reference Documents - Basic Texts

Articles L. 4211-6, R. 5144-3, R 5144-20 and R 5144-21 of the Public Health Code; Decree No 60-548 of 7 June 1960.

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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13. Confidentiality

No

14. Fiscal measures

No

David O'Sullivan
General Secretary
European Commission