



Notification Number: 2001/17/F

## **Draft Order establishing the content of the certificate laid down in Article L. 5138-3 of the Public Health Code.**

Date received : 17/01/2001

End of Standstill : Closed

Postponement : Yes

### Message

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Représentation Permanente de l'Irlande  
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Représentation Permanente du Royaume-Uni  
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Message 002



Communication from the Commission - SG(2001) D/50124  
Directive 98/34/EC  
Translation of the message 001  
Notification: 2001/17/F

(MSG: 200100124.EN)

**1. Structured Information Line**

MSG 001 IND 2001 0017 F FR 18-04-2001 17-01-2001 F NOTIF 18-04-2001

**2. Member State**

FRANCE

**3. Department Responsible**

Secrétariat général du Comité interministériel  
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**3. Originating Department**

Service responsable de l'élaboration du texte :  
Ministère de l'Emploi et de la Solidarité  
Direction générale de la santé  
Sous-direction de la politique des produits de santé  
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**4. Notification Number**

2001/17/F - COOP

**5. Title**

Draft Order establishing the content of the certificate laid down in Article L. 5138-3 of the Public Health Code.

**6. Products Concerned**

Starting materials for medicinal products

**7. Notification Under Another Act**

This notification is made pursuant to Article 8 of 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 Order has been drafted to implement Article L. 5138-3 of the Public Health Code with a view to establishing the content of the certificate of conformity with good practices.

The certificate of conformity shall thus provide details concerning the date of issue and the date of inspection referred to in Article R. 5266-24 of the Public Health Code laid down by the draft Decree, the name or corporate name and address of the applicant establishment or the company the establishment belongs to, the process laid down in Article R. 5266-22 of the abovementioned Code, the address of the site/s where the process is put into practice, and the starting material/s which are manufactured, imported or transported in accordance with this process.

### **9. Brief Statement of Grounds**

The certificate of conformity is issued following application by the manufacturer, importer or distributor of starting materials for medicinal products with a view to facilitating the export of their products. It enables certification that the establishment involved in the import, manufacture or transport of starting materials for medicinal products, declared regularly to the French Agency for the Safety of Health Products, conforms to the good practices referred to in Article L. 5138-2 of the Public Health Code which apply to their activity.

### **10. Reference Documents - Basic Texts**

- Proposal for a Directive of the European Parliament and of the Council on good manufacturing practice for starting materials of medicinal products and inspection of manufacturers;
- Public Health Code, particularly Articles L.5138-1, L.5138-2, L.5138-3, L. 5311-1, R. 5115-4 and R. 5171;
- Penal Code, particularly Articles 121-2, 131-38, 132-11 and R. 610-1.

### **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  
Secretary-General  
European Commission