Notification Number: 2003/229/F

Draft Decree on autogenous vaccines for veterinary use, amending the Public Health Code (second part: Council of State Decrees).

Date received	:	30/06/2003
End of Standstill	:	02/10/2003 **(31/12/2003)**
Issue of detailed opinion by	:	Commission

Message

Message 002

Communication from the Commission - SG(2003) D/51270
Directive 98/34/EC
Translation of the message 001
Notification: 2003/0229/F

Fristerne indledes ikke - Kein Fristbeginn - Καμμία έναρξη προθεσμίας - Does not open the delays - No abre el plazo - N'ouvre pas de délais - Non fa decorrere la mora - Geen termijnbegin - Nao inicia o prazo - Määräaika ei ala tästä - Inleder ingen frist.

(MSG: 200301270.EN)

1. Structured Information Line
MSG 002 IND 2003 0229 F EN 02-10-2003 30-06-2003 F NOTIF 02-10-2003

2. Member State
FRANCE

3. Department Responsible
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4. Notification Number
2003/0229/F - CI0P

5. Title
Draft Decree on autogenous vaccines for veterinary use, amending the Public Health Code (second part: Council of State Decrees).

6. Products Concerned
Veterinary medicinal products

7. Notification Under Another Act
-

8. Main Content
This text concerns the conditions of authorisation for the preparation and use of autogenous vaccines for veterinary use. Article L 5141-2 of the Public Health Code defines an autogenous vaccine for veterinary use as any immunological veterinary medicine manufactured in order to bring about active immunity from pathogenic organisms originating from an animal or animals of the same breed, inactivated and used in the treatment of this animal or animals of the same breed. Article L. 5141-12 stipulates that the preparation of autogenous vaccines for veterinary use must be carried out by a qualified person having obtained, to this effect, authorisation issued by the French Food Safety Agency. Finally, Article L. 5141-16(10) lays down that the conditions with which authorisations to manufacture these autogenous vaccines for veterinary use must comply shall be determined by Decree.

The draft lays down the conditions regarding the qualification and range of responsibilities of the qualified person responsible for the preparation of autogenous vaccines for veterinary use. It lays down the methods according to which requests for authorisation for the preparation of these autogenous vaccines must be based, and the conditions for their processing by the French Food Safety Agency.

This draft text also lays down the rules regarding the labelling, tracking and use of autogenous vaccines for veterinary use.

It finally lays down all the obligations linked to drug control imposed on the holders of authorisations for the manufacture of autogenous vaccines, and creates two criminal offences of misdemeanour against the holder of the manufacturing authorisation for autogenous vaccines, one for non-compliance with the tracking obligation, and the other for non-compliance with drug control obligations.

9. Brief Statement of Grounds
This draft Decree has been drafted in application of Articles L. 5141-12,
L. 5142-16 (1 and 10) and L 5144-3 of the Public Health Code.

It aims to lay down the conditions under which autogenous vaccines for veterinary use must be prepared and used.

Following a complaint from an economic operator, the import of autogenous vaccines for veterinary use prepared by another Member State has been subject to a letter of notice, No 2001/4586 of 23 October 2001, to which the French authorities responded on 21 January 2002, indicating, in particular, that the import of autogenous vaccines for veterinary use was subject to the standard procedure for the import of veterinary medicines, and which is therefore subject to authorisation issued by the Director-General of the French Food Safety Agency. A Decree, currently being drafted, must define the rules applicable to these imports. The French authorities are also committed to prepare a draft Decree on autogenous vaccines for veterinary use. It is this draft which is the subject of this notification.

10. Reference Documents - Basic Texts
Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

Public Health Code, in particular Articles L. 5141-2, L 5141-12, L 5141-16 (1 and 10),
L 5143-4 and l 5144-3 thereof;

Rural Code, in particular Article L.2621-2 thereof;

Penal Code, in particular Article R 610-1 thereof;

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
-

David O'Sullivan

Secretary-General
European Commission

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