



Notification Number: 2008/493/F

Decree on microorganisms and toxins

Date received : 12/11/2008

End of Standstill : 13/02/2009

Issue of comments by : Commission

Message

Message 002

Communication from the Commission - SG(2008) D/52164

Directive 98/34/EC

Translation of the message 001

Notification: 2008/0493/F

No abre el plazo - Nezahajuje 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 - Atidējimai 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 - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 200802164.EN)

1. Structured Information Line

MSG 002 IND 2008 0493 F EN 13-02-2009 12-11-2008 F NOTIF 13-02-2009

2. Member State

F

3. Department Responsible

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3. Originating Department

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4. Notification Number

2008/493/F - S00S

5. Title

Decree on microorganisms and toxins

6. Products Concerned

All operations involving the microorganisms and toxins included in a list (attached) and the products containing them

7. Notification Under Another Act

-

8. Main Content

The purpose of this draft Decree is principally to establish the conditions under which authorisation issued by the French Agency for the Safety of Health Products is obtained, which is required for all operations involving microorganisms or toxins, and products containing them, included in a list, which will be equivalent to that of the Order of 30 July 2004 classifying the lists of poisonous substances. Such authorisation, issued for one or for a series of operations performed at an identified site, is issued for a maximum period of 5 years, to a natural person named as the holder of the authorisation. Certain operations, which guarantee an adequate level of safety described in the authorisation dossiers of the products concerned (veterinary medicinal products, for example), are exempt from authorisation. The draft also lays down the rules on packaging, labelling and transporting products containing microorganisms and toxins. Finally, it establishes a regulatory framework for the prescription and the issue to the public of medicinal products for human and veterinary use containing microorganisms or toxins.

9. Brief Statement of Grounds

The draft text is intended to guarantee the control and traceability of microorganisms and toxins which may constitute a threat to public health (particularly a bioterrorist threat).

10. Reference Documents - Basic Texts

a) Article L.5139-2 of the Public Health Code; Order of 30 July 2004 classifying the lists of poisonous substances

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

a) NO

b) The draft has no significant impact on international trade.

SPS aspect

a) NO

b) The draft is not a sanitary or phytosanitary measure, pursuant to Annex A to the SPS Agreement.

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GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

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