



Notification Number: 2006/393/F

Decree on the conformity check of reagents intended for analyses performed in the fields of veterinary public health and of the protection of plants and amending the Rural Code.

Date received : 25/07/2006

End of Standstill : 26/10/2006

Message

Message 002

Communication from the Commission - SG(2006) D/51787

Directive 98/34/EC

Translation of the message 001

Notification: 2006/0393/F

No abre el plazo - Nezaahajuje 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: 200601787.EN)

1. Structured Information Line

MSG 002 IND 2006 0393 F EN 26-10-2006 25-07-2006 F NOTIF 26-10-2006

2. Member State

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4. Notification Number

2006/0393/F - C10P

5. Title

Decree on the conformity check of reagents intended for analyses performed in the fields of veterinary public health and of the protection of plants and amending the Rural Code.

6. Products Concerned

Reagents intended for analyses performed in the fields of veterinary public health and of the protection of plants.

7. Notification Under Another Act

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8. Main Content

Article L. 203-1 of the Rural Code establishes the implementation of a conformity check of reagents intended for analyses performed in the fields of veterinary public health and of the protection of plants in the conditions laid down by a Council of State Decree.

The purpose of the draft Decree is to introduce the following provisions:

The list referred to in Article L.203-1 shall classify the reagents in three categories, A, B and C according to the level of conformity check required: quality-assured production for the three categories, initial conformity certificate delivered by the competent national reference laboratory for Category B and C reagents and conformity checks carried out by the same national reference laboratory for Category C reagents.

Changes to the characteristics or the effectiveness of a category B or C reagent must be notified by the competent national reference laboratory which may carry out the conformity check of the batches concerned.

Batches that do not conform cannot be placed on the market or must be recalled and the national reference laboratory may withdraw the initial certificate of conformity that it has issued in the event of repeated non-conformity.

KEY WORDS: REAGENTS – CONFORMITY CHECK – VETERINARY PUBLIC HEALTH – PROTECTION OF PLANTS

9. Brief Statement of Grounds

The draft contributes to enhancing the quality of the analyses carried out in the fields of veterinary public health and the protection of plants and complements the provisions of Article 12 of Regulation (EC) 882/2004 providing for the accreditation of official analysis laboratories.

10. Reference Documents - Basic Texts

a) Article L.203-1 of the Rural Code



11. Invocation of the Emergency Procedure

NO

12. Grounds for the Emergency

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13. Confidentiality

- a) NO
- b) Not applicable

14. Fiscal measures

NO

15. Impact assessment

NO

16. TBT and SPS aspects

TBT aspect (Agreement on Technical Barriers to Trade)

- a) No
- i) The draft is not a technical regulation or a conformity assessment procedure pursuant to Annex 1 to the TBT Agreement.

SPS Aspect (Agreement on Sanitary and Phytosanitary Measures)

- a) YES

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