Notification Number: 2006/434/F

Draft decision relating to good manufacturing and wholesale distribution practice for medicated feedingstuffs

Date received	:	14/08/2006
End of Standstill	:	15/11/2006
Issue of detailed opinion by	:	Commission

Message

Message 002

Communication from the Commission - SG(2006) D/51959
Directive 98/34/EC
Translation of the message 001
Notification: 2006/0434/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 - Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma' jiftaħx 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: 200601959.EN)

1. Structured Information Line
MSG 002 IND 2006 0434 F EN 15-11-2006 14-08-2006 F NOTIF 15-11-2006

2. Member State
France

3. Department Responsible
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4. Notification Number
2006/0434/F - C30A

5. Title
Draft decision relating to good manufacturing and wholesale distribution practice for medicated feedingstuffs

6. Products Concerned
Medicated feedingstuffs

7. Notification Under Another Act
-

8. Main Content
This text relates to the conditions for the manufacture and wholesale distribution of medicated feedingstuffs by the veterinary pharmaceutical establishments referred to in Article L. 5142-1 of the Public Health Code and to the specific good practices imposed on them in application of Articles L. 5142-3, R. 5142-42 and R. 5142-54. These good practices are laid down by decision of the Director-General of the French Food Safety Agency.

It introduces detailed technical regulations regarding the conditions for the manufacture and wholesale distribution of medicated feedingstuffs, supplementing the general provisions regarding the operation of veterinary pharmaceutical establishments and the specific provisions relating to establishments responsible for medicated feedingstuffs arising from the transposition of Articles 3, 4, 5 and 6 of Directive 90/167/EEC.

The provisions regarding the approval conditions for users manufacturing medicated feedingstuffs for the animals on their holding and good practices applicable to these extemporaneous preparations of medicated feedingstuffs are governed by other statutory provisions and two implementing orders: the Order of 9 June 2004 on the approval of users for the extemporaneous preparation of medicated feedingstuffs and the Order of the same date on good practices in the extemporaneous preparation of veterinary medicinal products.

9. Brief Statement of Grounds
As regards the manufacture of medicated feedingstuffs, this draft decision has been drawn up in application of Articles L. 5142-3, R. 5142-42 and R. 5142-54 of the Public Health Code. It forms part of an approach of publishing technical references that can be enforced on the industries involved and that serve as a basis for accelerated inspections, with regard to safety, of the conditions of production of veterinary medicinal products. It is based on good manufacturing practices for veterinary medicinal products, taking account of the European guidelines, and on the Annexes to Regulation 183/2005.

With regard to wholesale distribution, France has chosen a specific framework for distributors of packaged medicated feedingstuffs and has therefore supplemented the statutory provisions of the Public Health Code with a chapter in this technical reference.

10. Reference Documents - Basic Texts

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products;

- Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community;

- the Public Health Code, and in particular Articles L. 5142-3, R. 5142-42 et R. 5142-54;

11. Invocation of the Emergency Procedure
NO

12. Grounds for the Emergency
-

13. Confidentiality
a) NO

14. Fiscal measures
b) NO

15. Impact assessment
In France, medicated feedingstuffs are veterinary medicinal products in their own right. France wanted to provide a framework for the manufacturing conditions for these veterinary medicinal products based on good manufacturing practices, as has been done for other veterinary medicinal products. It has therefore taken its inspiration from the existing guidelines for veterinary medicinal products. In addition, these medicated feedingstuffs are manufactured on sites for the manufacture of animal feed subject to Regulation 183/2005 and to Annex II thereof for this type of activity, which means that these good manufacturing practices also take account of the requirements laid down under Regulation 183/2005.

Health impact: The good practice guide makes it possible to provide a high level of health protection by improving the quality of medicated feedingstuffs and the safety of residues thereof in food of animal origin; improved safety of medicated feedingstuffs (production assessed and qualified taking into account the developments required in the marketing authorisations for the medicinal product on which the feedingstuff is based, traceability).

Economic impact: The drafting of the good practice guide underwent a consultation process involving professionals in the sector, which made it possible to gather information about and take account of the approach taken by businesses in the sector. The improvement of the manufacturing conditions of medicated feedingstuffs makes it possible to improve the management of a potential crisis, and constitutes a safety element for businesses.

Sociological impact: A reference that puts the emphasis on the better production and use of medicated feedingstuffs gives consumers and citizens greater confidence in farmers.

16. TBT and SPS aspects
TBT aspect (Agreement on Technical Barriers to Trade)

a) No
b) iii) The draft will not have any notable impact on international trade.

SPS Aspect (Agreement on Sanitary and Phytosanitary Measures)
a) No
b) iii) The draft will not have any notable impact on international trade.

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