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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2006) final

Draft

COMMISSION REGULATION

of

concerning a requirement for approval in accordance with Regulation (EC) No 183/2005 of the European Parliament and of the Council for feed business establishments manufacturing or placing on the market feed additives of the category "coccidiostats and histomonostats"

(Text with EEA relevance)

(Memorandum from Mr M. KYPRIANOU)

Draft

COMMISSION REGULATION

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene[1], and in particular Article 10(3) thereof,

Whereas:

(1) Regulation (EC) No 183/2005 provides for the approval of certain feed business establishments. The principal objective of the approval system set up by Regulation (EC) No 183/2005 is to subject establishments manufacturing and/or placing on the market products deemed sensitive to the relevant hygiene requirements laid down in that Regulation. That Regulation provides for a possibility to extend the scope of the approval requirement.

(2) "Coccidiostats and histomonostats" are one of the categories of feed additives referred to in Article 6(1)(e) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[2]. This category of feed additives is deemed to be equally sensitive as the categories for which an approval requirement is provided for in Regulation (EC) No 183/2005.

(3) Therefore, establishments manufacturing and/or placing on the market feed additives belonging to the category "coccidiostats and histomonostats" should equally be subject to the same approval requisites.

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1 OJ L 35, 8.2.2005, p. 1.

2 OJ L 268, 18.10.2003, p. 29, Regulation as amended by Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

(4) Transitional measures should be provided for as regards establishments manufacturing and/or placing on the market feed additives of the category "coccidiostats and histomonostats" which were not required to be approved under national legislation. Establishments approved under Directive 95/69/EC are already covered by Art. 18(1) of Regulation (EC) No 183/2005.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Feed business operators shall ensure that establishments under their control and covered by Regulation (EC) No 183/2005 are approved by the competent authority, where such establishments manufacture and/or place on the market feed additives of the category "coccidiostats and histomonostats". The approval shall be carried out in accordance with Regulation (EC) No 183/2005.

Article 2

Establishments manufacturing and/or placing on the market feed additives of the category "coccidiostats and histomonostats" and which on the date of entry into force of this Regulation were not required by national legislation to be approved for this category of feed additives, may continue their activities until a decision has been taken on their application for approval, on condition that they submit that application to the competent authority in whose area their establishment is located by [for OPOCE: please insert 3 months after date of entry into force] at the latest.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [for OPOCE: please insert 1 month after date of entry into force].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
Markos KYPRIANOU
Member of the Commission