Commission Regulation (EC) No 1443/2006 of 29 September 2006 concerning the permanent authorisations of certain additives in feedingstuffs and an authorisation for 10 years for a coccidiostat (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1443/2006

of 29 September 2006

concerning the permanent authorisations of certain additives in feedingstuffs and an authorisation for 10 years for a coccidiostat

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[(1)], and in particular Articles 3, 9 and 9d(1) thereof,

Having regard to 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)], and in particular Article 25 thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.

(2) Article 25 of Regulation (EC) No 1831/2003 lays down transitional measures for applications for the authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of Regulation (EC) No 1831/2003.

(3) The applications for the authorisation of the additives listed in the Annexes to this Regulation were submitted before the date of application of Regulation (EC) No 1831/2003.

(4) Initial comments on those applications, as provided for in Article 4(4) of Directive 70/524/EEC, were forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. Those applications are therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

(5) Data were submitted in support of an application for authorisation without a time limit of the enzyme preparation of 3-phytase produced by *Hansenula polymorpha* (DSM 15087) for chickens for fattening, turkeys for fattening, laying hens, piglets, pigs for fattening and sows. On 7 March 2006 the European Food Safety Authority (the Authority) delivered its opinion on the use of this preparation which concludes that it does not present a risk for the consumer, the user, the animal category targeted or the environment. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1443/2006. (See end of Document for details)*

enzyme preparation, as specified in Annex I to this Regulation, should be authorised without a time limit.

(6) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) was provisionally authorised for the first time for piglets by Commission Regulation (EC) No 1411/1999[3]. New data were submitted in support of an application for authorisation without a time limit of that enzyme preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex I to this Regulation, should be authorised without a time limit.

(7) The use of the coccidiostat preparation of semduramicin sodium (AVIAX 5 %) was provisionally authorised for the first time for chickens for fattening, by Commission Regulation (EC) No 1041/2002[4]. New data were submitted in support of an application for authorisation for 10 years of that coccidiostat. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that substance, as specified in the Annex II, should be authorised for 10 years.

(8) Data were submitted in support of an application for authorisation without a time limit of 25-hydroxycholecalciferol, belonging to the group 'Vitamins, provitamins and chemically well-defined substances having similar effect' for chickens for fattening, laying hens and turkeys. On 26 May 2005 the Authority has delivered an opinion on the use of this preparation which concludes that it does not present a risk for the consumer, the user, the animal category targeted or the environment. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that vitamin preparation, as specified in Annex III, should be authorised without time limit.

(9) The assessment of these applications shows that certain procedures should be required to protect workers from exposure to the additives set out in the Annexes. Such protection should be assured by the application of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[5].

(10) 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:

F1 Article 1

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Textual Amendments

F1 Deleted by Commission Implementing Regulation (EU) 2018/353 of 9 March 2018 correcting Implementing Regulation (EU) 2017/1145 on the withdrawal from the market of certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those feed additives (Text with EEA relevance).

Article 2

The preparation belonging to the group ‘Coccidiostat and other medicinal substances’, as specified in Annex II, is authorised for 10 years as additive in animal nutrition under the conditions laid down in that Annex.

[F2]Article 3

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Textual Amendments

F2 Deleted by Commission Regulation (EC) No 887/2009 of 25 September 2009 concerning the authorisation of a stabilised form of 25-hydroxycholecalciferol as a feed additive for chickens for fattening, turkeys for fattening, other poultry and pigs (Text with EEA relevance).

Article 4

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

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