Commission Regulation (EC) No 1800/2004 of 15 October 2004 concerning the authorisation for 10 years of the additive Cycostat 66G in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1800/2004

of 15 October 2004

concerning the authorisation for 10 years of the additive Cycostat 66G in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances

(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 Article 9g(5)(b) thereof,

Whereas:

(1) In accordance with Directive 70/524/EEC, coccidiostats included in Annex I to that Directive before 1 January 1988 were provisionally authorised as from 1 April 1998 and transferred to Chapter I of Annex B with a view to their re-evaluation as additives linked to a person responsible for putting them into circulation. The robenidine product, Cycostat 66G, is an additive belonging to the group 'Coccidiostats and other medicinal substances' listed in Chapter I of Annex B of Directive 70/524/EEC.

(2) The person responsible for putting into circulation Cycostat 66G submitted an application for authorisation and a dossier, according to Article 9g(2) and (4) of that Directive.

(3) Article 9g(6) of Directive 70/524/EEC allows the automatic extension of the period of authorisation of the additives concerned until the Commission takes a decision in case of, for reasons beyond the control of the authorisation holder, no decision may be taken on the application before the expiry date of the authorisation. This provision is applicable to the authorisation of Cycostat 66G. The Commission requested the Scientific Committee for Animal Nutrition on 26 April 2001 a full risk evaluation and this request was consequently transferred to the European Food Safety Authority. Several requests for additional information were made during the re-evaluation process making it impossible to complete the re-evaluation within the time limits required by Article 9g.

(4) The Scientific Panel on Additives and Products or Substances used in Animal Feed attached to the European Food Safety Authority has delivered a favourable opinion with regard to the safety and to the efficacy of Cycostat 66G for chickens for fattening, rabbits for fattening and for turkeys.

(5) The re-evaluation of Cycostat 66G carried out by the Commission showed that the relevant conditions laid down in Directive 70/524/EEC are satisfied. Cycostat 66G should therefore be authorised for ten years as an additive linked to the person responsible for putting it into circulation and included in Chapter I of the list referred to Article 9t(b) of that Directive.

(6) As the authorisation for the additive is now linked to a person responsible for putting it into circulation, and replaces the previous authorisation which was not linked to any specific person, it is appropriate to delete the latter authorisation.

(7) Since there are no safety reasons for withdrawing the product robenidine from the market immediately, it is appropriate to allow a transitional period of six months for the disposal of existing stocks of the additive.

(8) 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

In chapter I of Annex B to Directive 70/524/EEC the additive robenidine, belonging to the group ‘Coccidiostats and other medical substances’, shall be deleted.

[F1]Article 2

. . . . . .

Textual Amendments

F1 Deleted by Commission Implementing Regulation (EU) 2020/148 of 3 February 2020 concerning the authorisation of robenidine hydrochloride (Robenz 66G) as a feed additive for chickens for fattening and amending Regulation (EC) No 1800/2004 (holder of authorisation Zoetis SA) (Text with EEA relevance).

Article 3

A period of six months from the date of entry into force of this Regulation is permitted to use up the existing stocks of robenidine.

Article 4

This Regulation shall enter into force on the third day following that of 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.