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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2594

of 21 November 2023

concerning the denial of the renewal of the authorisation of a preparation of robenidine hydrochloride (Cycostat 66G) as a feed additive for rabbits for breeding and rabbits for fattening (holder of authorisation: Zoetis Belgium S.A.) and repealing Implementing Regulation (EU) No 532/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting or denying such authorisation.

(2) The preparation of robenidine hydrochloride (Cycostat 66G) was authorised for 10 years by Commission Implementing Regulation (EU) No 532/2011 ([2]) as a feed additive belonging to the additive category 'coccidiostats and histomonostats' for use for rabbits for breeding and rabbits for fattening.

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of robenidine hydrochloride (Cycostat 66G) as a feed additive for rabbits for breeding and rabbits for fattening, requesting the additive to be classified in the additive category 'coccidiostats and histomonostats'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) In order to prepare its opinion, the European Food Safety Authority ('the Authority') undertook an assessment of the preparation of robenidine hydrochloride (Cycostat 66G) to determine whether it still complies with the conditions for authorisation laid down in Article 5 of Regulation (EC) No 1831/2003, in accordance with Commission Regulation (EC) No 429/2008 ([3]) and the relevant Authority's guidance ([4]). In particular, the Authority reviewed the outcome of a literature search and re-considered the available data set in the light of the most recent Authority's guidance on the safety of feed additives. Pursuant to Article 8(2) of Regulation (EC) No 1831/2003, supplementary information was requested by the Authority to the applicant in the course of the assessment of the additive on 4 February 2022 concerning the characterisation, the safety for the consumer and the safety for the environment of the additive, and on 15 July 2022 concerning the safety evaluation strategy and corresponding testing strategy. The Authority received supplementary information from the applicant on 18 July 2022 and on 3 August 2022.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Implementing Regulation (EU) No 532/2011 of 31 May 2011 concerning the authorisation of robenidine hydrochloride as a feed additive for rabbits for breeding and rabbits for fattening (holder of authorisation Zoetis Belgium SA) and amending Regulations (EC) No 2430/1999 and (EC) No 1800/2004 (OJ L 146, 1.6.2011, p. 7).

([3]) Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

([4]) In particular, guidance on the renewal of the authorisation of feed additives, adopted on 8 October 2013 (EFSA Journal 2013;11(10):3431).

(5) However, in a letter dated 14 July 2022 addressed to the Commission, the applicant indicated that it was not willing to generate new data as requested by the Authority. In reply to that letter, the Commission clarified in a letter dated 8 November 2022 that a renewal of the authorisation of the preparation of robenidine hydrochloride (Cycostat 66G) could not be granted, should the Authority's opinion raise safety concerns due to a lack of required information and data. The applicant did not modify its position afterwards.

(6) The Authority stated in its opinion of 31 January 2023 ([5]) that, based on the available *in vitro* chromosomal aberration test and the results of the *in vivo* micronucleus test, the potential aneugenic activity of robenidine hydrochloride could not be excluded, and that no information on the potential aneugenicity of robenidine hydrochloride was made available in the application. In the absence of such data, the Authority indicated that it could not conclude on the safety of the preparation of robenidine hydrochloride (Cycostat 66G) for the target species and the consumer. The Authority added that, in the absence of adequate data on the ecotoxicological effects of robenidine hydrochloride on soil, water and sediment, it could also not conclude on the safety of the preparation of robenidine hydrochloride (Cycostat 66G) for the environment. And finally, owing to the lack of sufficient data, the Authority could not conclude that the preparation of robenidine hydrochloride (Cycostat 66G) is still efficacious against recent *Eimeria* spp. strains in rabbits. It results from the Authority's opinion of 31 January 2023 that it has not been established that the preparation of robenidine hydrochloride (Cycostat 66G) does not have an adverse effect on animal health, human health or the environment, and that it has not been established that it has a coccidiostatic effect, when used as a feed additive for rabbits for breeding and rabbits for fattening in the additive category 'coccidiostats and histomonostats'.

(7) As provided for by Article 5(1) of Regulation (EC) No 1831/2003, it belongs to the applicant for authorisation of a feed additive to adequately and sufficiently demonstrate, in accordance with the implementing rules referred to in Article 7 of that Regulation, that the conditions for authorisation set out in Article 5(2) and (3) of that Regulation are satisfied. As regards applications for renewal of authorisation, Regulation (EC) No 429/2008 requires in particular the applicant to present evidence establishing that, in the light of the current scientific knowledge, the additive remains safe under the approved conditions for target species, consumers, workers and the environment.

(8) In view of the above, it cannot be considered that, as regards the preparation of robenidine hydrochloride (Cycostat 66G), the conditions for the renewal of the authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the renewal of the authorisation of that preparation as a feed additive belonging to the category 'coccidiostats and histomonostats' for use for rabbits for breeding and rabbits for fattening should be denied.

(9) Therefore, the preparation of robenidine hydrochloride (Cycostat 66G) and feed containing it should be withdrawn from the market as soon as possible as far as the use for rabbits for breeding and rabbits for fattening is concerned. However, a limited period should be allowed for the withdrawal from the market of existing stocks of those products, in order to enable operators to comply properly with the withdrawal obligation.

(10) As a consequence of the non-renewal of the authorisation of the preparation of robenidine hydrochloride (Cycostat 66G) for rabbits for breeding and rabbits for fattening, Implementing Regulation (EU) No 532/2011 should be repealed.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([5]) EFSA Journal 2023;21(3):7863.

HAS ADOPTED THIS REGULATION:

Article 1

Denial of renewal of the authorisation

The renewal of the authorisation of the preparation of robenidine hydrochloride (Cycostat 66G) (identification number 5 1 758) as an additive in animal nutrition belonging to the category 'coccidiostats and histomonostats', for use for rabbits for breeding and rabbits for fattening, is denied.

Article 2

Repeal of Implementing Regulation (EU) No 532/2011

Implementing Regulation (EU) No 532/2011 is repealed.

Article 3

Transitional provisions

1. Existing stocks of the additive referred to in Article 1, which are intended for rabbits for breeding and rabbits for fattening, and of premixtures containing it, shall be withdrawn from the market by 12 March 2024.

2. Feed materials and compound feed which have been produced with the additive or premixtures referred to in paragraph 1 before 12 March 2024 and which are intended for rabbits for breeding and rabbits for fattening, shall be withdrawn from the market by 12 June 2024.

Article 4

Entry into force

This Regulation shall enter into force on the twentieth 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.

Done at Brussels, 21 November 2023.

For the Commission
The President
Ursula VON DER LEYEN