COMMISSION IMPLEMENTING REGULATION (EU) 2023/981

of 17 May 2023

amending Regulation (EU) No 37/2010 as regards the classification of the substance praziquantel with respect to its maximum residue limit in foodstuffs of animal origin

(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 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]), and in particular Article 14, in conjunction with Article 17 thereof,

Whereas:

(1) In accordance with Regulation (EC) No 470/2009, the Commission is to establish, by way of a Regulation, maximum residue limits ('MRLs') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Praziquantel is already included in that table as an allowed substance for ovine and *equidae* species. The existing entry has a 'no MRL required' classification.

(4) In accordance with Article 3 of Regulation (EC) No 470/2009, on 27 July 2021, VETHELLAS AEBE submitted a request to the European Medicines Agency ('Agency') for the extension of the existing entry for praziquantel to fin fish.

(5) On 8 September 2022, the Agency, through the opinion of the Committee for Medicinal Products for Veterinary Use, concluded that the establishment of an MRL for praziquantel in fin fish, in relation to muscle and skin in natural proportions, was appropriate.

(6) In accordance with Article 5 of Regulation (EC) No 470/2009, the Agency is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.

(7) The Agency concluded that the extrapolation of the 'no MRL required' classification for praziquantel in ovine species to other ruminants, except cattle, is appropriate.

(8) In view of the opinion of the Agency, the Commission considers it appropriate to establish an MRL for praziquantel in fin fish, in relation to muscle and skin in natural proportions and to establish the recommended 'no MRL required' classification for praziquantel in all ruminants except bovine species.

(9) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

([1]) OJ L 152, 16.6.2009, p. 11.

([2]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

Article 2

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, 17 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'praziquantel' is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Praziquantel	NOT APPLICABLE	All ruminants except bovine, *Equidae*	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY
	Praziquantel (sum of isomers)	Fin fish	20 µg/kg	Muscle and skin in natural proportions	NO ENTRY	NO ENTRY'