COMMISSION IMPLEMENTING REGULATION (EU) 2023/454

of 2 March 2023

amending Regulation (EU) No 37/2010 as regards the classification of the substance toltrazuril 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) Toltrazuril is already included in that table as an allowed substance for all mammalian food-producing species in relation to muscle, fat (skin and fat in natural proportions for porcine species), liver and kidney, but excluding animals producing milk for human consumption. Furthermore, that substance is also included as an allowed substance for poultry in relation to muscle, skin and fat, liver and kidney. However, the substance is not allowed for use in animals from which eggs are produced for human consumption.

(4) In accordance with Article 9(1), point (b), of Regulation (EC) No 470/2009, on 29 June 2021, the Kingdom of the Netherlands submitted a request for the extension of the existing entry for toltrazuril in poultry to chicken eggs to the European Medicines Agency ('Agency').

(5) On 9 December 2021, the Agency, through the opinion of the Committee for Medicinal Products for Veterinary Use, recommended the establishment of an MRL for toltrazuril in chicken eggs.

(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 MRLs for toltrazuril from chicken eggs to the eggs of other poultry species is appropriate.

([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).

(8) In view of the opinion of the Agency, the Commission considers it appropriate to establish the recommended MRL for toltrazuril in poultry eggs.

(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,

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, 2 March 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 'toltrazuril' 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
'Toltrazuril	Toltrazuril sulfone	All mammalian food producing species	100 µg/kg 150 µg/kg 500 µg/kg 250 µg/kg	Muscle Fat Liver Kidney	For porcine species the fat MRL relates to "skin and fat in natural proportions". Not for use in animals from which milk is produced for human consumption.	Antiparasitic agents/A-gents acting against protozoa'
		Poultry	100 µg/kg 200 µg/kg 600 µg/kg 400 µg/kg 140 µg/kg	Muscle Skin and fat Liver Kidney Eggs	NO ENTRY	