COMMISSION IMPLEMENTING REGULATION (EU) 2022/634

of 13 April 2022

amending Regulation (EU) No 37/2010 as regards the classification of the substance bambermycin 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,

Having regard to the opinion of the European Medicines Agency formulated on 15 July 2021 by the Committee for Medicinal Products for Veterinary Use,

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 maximum residue limits (MRLs) in foodstuffs of animal origin.

(3) Bambermycin is already included in that table as an allowed substance for rabbits, for oral use only. The existing entry has a 'no MRL required' classification.

(4) In accordance with Article 3 of Regulation (EC) No 470/2009, on 3 December 2019, Huvepharma N.V. submitted an application for the extension of the existing entry for bambermycin to chicken tissues to the European Medicines Agency ('Agency').

(5) On 18 March 2021, the Agency, through the opinion of the Committee for Medicinal Products for Veterinary Use ('the CVMP'), concluded that the establishment of an MRL for bambermycin in chicken tissues was not necessary and recommended a 'no MRL required' classification.

(6) On 5 May 2021, the Commission requested the Agency to reconsider its opinion of 18 March 2021 with a view to establishing MRLs in order to facilitate official controls and enforcement of legislative provisions by competent authorities.

(7) On 15 July 2021, the Agency, based on the opinion of the Committee, having considered the application and the request from the Commission, recommended the establishment of numerical MRLs for bambermycin for use in chicken, applicable to muscle, skin and fat in natural proportions, liver and kidney, however not for use in animals from which eggs are produced for human consumption.

([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) According to 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.

(9) The Agency concluded that the extrapolation of the MRLs for bambermycin from chicken tissues to the tissues of other poultry species is appropriate, but not to poultry eggs.

(10) In view of the Opinion of the Agency it is considered appropriate to establish the recommended MRL for bambermycin in chicken tissues and to extrapolate it to other poultry species, but not to poultry eggs.

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

(12) 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, 13 April 2022.

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 'bambermycin' 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
'Bambermycin	NOT APPLICABLE	Rabbit	No MRL required	NOT APPLICABLE	For oral use only	Anti-infectious agent/ Antibiotics'
	Flavophospholipol A	Poultry	100 µg/kg	Muscle	Not for use in animals from which eggs are produced for human consumption	
			100 µg/kg	Skin and fat in natural proportions		
			3 000 µg/kg	Liver		
			20 000 µg/kg	Kidney		