Commission Implementing Regulation (EU) 2018/1967 of 12 December 2018 amending Regulation (EU) No 37/2010 to classify the substance paromomycin as regards its maximum residue limit (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1967

of 12 December 2018

amending Regulation (EU) No 37/2010 to classify the substance paromomycin as regards its maximum residue limit

(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 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 by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit ('MRL') 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 is established in a Regulation.

(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) Paromomycin is already included in that table as an allowed substance for all food producing species, applicable to muscle, liver and kidney.

(4) An application for the extension of the existing entry for paromomycin to chicken eggs has been submitted to the European Medicines Agency ('EMA').

(5) EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended the establishment of an MRL for paromomycin in chicken eggs.

(6) According to Article 5 of Regulation (EC) No 470/2009, EMA 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) EMA has considered that the extrapolation of the entry for paromomycin to the eggs of all poultry species is appropriate.

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

(9) It is appropriate to grant the stakeholders concerned a reasonable period of time to take measures that may be required to comply with the new MRL.

(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*.

It shall apply from 11 February 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 December 2018.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance ‘paromomycin’ 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**
‘Paromomycin	Paromomycin	All food producing species	500 µg/kg	Muscle	For fin fish the muscle MRL relates to ‘muscle and skin in natural proportions’. MRLs for liver and kidney do not apply to fin fish. Not for use in animals from which milk is produced for human consumption.	Anti-infectious agents/ Antibiotics’
			1 500 µg/kg	Liver		
			1 500 µg/kg	Kidney		
			200 µg/kg	Eggs		

(**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).

Status:
Point in time view as at 12/12/2018.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1967.