COMMISSION IMPLEMENTING REGULATION (EU) 2015/152

of 30 January 2015

amending the Annex to Regulation (EU) No 37/2010, as regards the substance 'tulathromycin'

(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 by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) 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 to be established in accordance with Regulation (EC) No 470/2009.

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

(3) Tulathromycin is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine and porcine species, applicable to muscle, fat (skin and fat for porcine species), liver and kidney, excluding animals producing milk for human consumption. The provisional MRL for that substance set out for bovine and porcine species expires on 1 January 2015.

(4) An application for the extension of the existing entry to ovine species applicable to muscle, fat, liver and kidney has been submitted to the European Medicines Agency.

(5) In accordance with Article 5 of Regulation (EC) No 470/2009 the European Medicines 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. The Committee for Medicinal Products for Veterinary Use recommended the extension of the MRL to ovine species and the extrapolation of the MRLs from ovine species to caprine species.

(6) The entry for tulathromycin in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the MRL for ovine and caprine species.

(7) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take measures that may be required to comply with the newly set MRL.

(8) 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.

([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).

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 1 April 2015.

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

Done at Brussels, 30 January 2015.

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 'tulathromycin' 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
'Tulathromycin	(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-ethyl-3,4,10,13-tetra-hydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethy-lamino)-ß-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopent-decan-15-one expressed as tulathromycin equivalents	Ovine, caprine	450 µg/kg 250 µg/kg 5 400 µg/kg 1 800 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	Anti-infectious agents/Antibiotics'
		Bovine	300 µg/kg 200 µg/kg 4 500 µg/kg 3 000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption Provisional MRLs expire on 1 January 2015	
		Porcine	800 µg/kg 300 µg/kg 4 000 µg/kg 8 000 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney	Provisional MRLs expire on 1 January 2015	