Commission Implementing Regulation (EU) 2015/394 of 10 March 2015 amending the Annex to Regulation (EU) No 37/2010 as regards the substance 'tulathromycin' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/394

of 10 March 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, porcine, ovine and caprine species, applicable to muscle, fat (skin and fat for porcine species), liver and kidney, excluding animals producing milk for human consumption. The provisional MRLs for that substance set out for bovine and porcine species expire on 1 January 2015.

(4) Additional data was provided and assessed by the Committee for Medicinal Products for Veterinary Use who recommended that the provisional MRLs for tulathromycin in bovine and porcine species should be set as definitive.

(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 concluded that the extrapolation to other food producing species cannot be supported for this substance.

(6) The entry for tulathromycin in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.

(7) 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, 10 March 2015.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/394. (See end of Document for details)*

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	Caprine	150 µg/kg	Muscle	Not for use in animals from which milk is produced for human consumption	Anti-infectious agents/ Antibiotics’
			250 µg/kg	Fat		
			5 400 µg/kg	Liver		
			1 800 µg/kg	Kidney		
		Bovine	300 µg/kg	Muscle		
			200 µg/kg	Fat		
			4 500 µg/kg	Liver		
			3 000 µg/kg	Kidney		
		Porcine	800 µg/kg	Muscle		
			300 µg/kg	Skin and fat in natural proportions		
			4 000 µg/kg	Liver		
			8 000 µg/kg	Kidney		

(**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).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/394.