# COMMISSION IMPLEMENTING REGULATION (EU) No 1359/2014

## of 18 December 2014

## 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 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 are 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 fat (skin and fat for porcine species), liver and kidney.

(4) An application for the modification of the existing entry for tulathromycin has been submitted to the European Medicines Agency.

(5) The CVMP recommended the modification of the current Acceptable Daily Intake for tulathromycin, as well as the establishment of a provisional MRL for bovine and porcine species as the analytical method for monitoring residues in bovine and porcine species is not sufficiently validated for the MRLs proposed. The incomplete scientific data on the validation of the analytical method does not constitute a hazard to human health.

(6) 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.

(7) The Committee for Medicinal Products for Veterinary Use concluded that the extrapolation to other food producing species cannot be supported for this substance.

(8) Regulation (EU) No 37/2010 should therefore be amended to include the provisional MRLs for tulathromycin in respect of bovine and porcine species, applicable to muscle, skin and fat, liver and kidney. The provisional MRLs set out in that Table for bovine and porcine species should expire on 1 January 2015.

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

([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).

(10) 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.

(11) 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 17 February 2015.

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

Done at Brussels, 18 December 2014

*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 tulathro-mycin equivalents | Bovine | 300 µg/kg<br>200 µg/kg<br>4 500 µg/kg<br>3 000 µg/kg | Muscle<br>Fat<br>Liver<br>Kidney | Not for use in animals from which milk is produced for human consump-tion<br>Provisional MRLs expire on 1 January 2015 | Anti-infectious agents/ Antibiotics' |
| | | Porcine | 800 µg/kg<br>300 µg/kg<br>4 000 µg/kg<br>8 000 µg/kg | Muscle<br>Skin and fat in natural proportions<br>Liver<br>Kidney | Provisional MRLs expire on 1 January 2015 | |