Commission Regulation (EU) No 759/2010 of 24 August 2010 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance tildipirosin (Text with EEA relevance)

COMMISSION REGULATION (EU) No 759/2010

of 24 August 2010

amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance tildipirosin

(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 for pharmacologically active substances intended for use in the European Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry should be established in accordance with Regulation (EC) No 470/2009.

(2) Pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin are set out in the Annex to 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[(2)].

(3) An application for the establishment of maximum residue limits (hereinafter ‘MRL’) for tildipirosin in bovine and porcine species has been submitted to the European Medicines Agency.

(4) The Committee for Medicinal Products for Veterinary Use (hereinafter ‘CVMP’) recommended establishing a provisional MRL for tildipirosin for bovine species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 759/2010. (See end of Document for details)*

consumption. The provisional MRL set out for muscle should not apply to the injection site, where residue levels should not exceed 11 500 μg/kg.

(5) According to 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 another species. The CVMP recommended to extrapolate the provisional MRLs for tildipirosin from bovine to caprine species.

(6) The CVMP recommended establishing provisional MRLs for tildipirosin for porcine species, applicable to muscle, skin, fat, liver and kidney. The provisional MRL set out for muscle should not apply to the injection site, where residue levels should not exceed 7 500 μg/kg.

(7) Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the substance tildipirosin for bovine, caprine and porcine species. The provisional MRLs set out in that table for tildipirosin for bovine, caprine and porcine species should expire on 1 January 2012.

(8) 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.

(9) 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 third day following its publication in the *Official Journal of the European Union*.

It shall apply from 24 October 2010.

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

Done at Brussels, 24 August 2010.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 759/2010. (See end of Document for details)*

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the following substance is inserted in alphabetical order:

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**
'Tildipirosin	Tildipirosin	Bovine, caprine	400 µg/kg	Muscle	Not for use in animals from which milk is produced for human consumption. The MRL for muscle shall not apply to the injection site, where residue levels shall not exceed 11 500 µg/kg. Provisional MRL shall expire on 1 January 2012.	Macrolide'
			200 µg/kg	Fat		
			2 000 µg/kg	Liver		
			3 000 µg/kg	Kidney		
		Porcine	1 200 µg/kg	Muscle	The MRL for muscle shall not apply to the injection site, where residue levels shall not exceed 7 500 µg/kg. Provisional MRL shall expire on 1 January 2012.	
			800 µg/kg	Skin and fat		
			5 000 µg/kg	Liver		
			10 000 µg/kg	Kidney		