Commission Implementing Regulation (EU) 2016/312 of 4 March 2016 correcting Regulation (EU) No 37/2010 as regards the substance 'tylvalosin' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/312

of 4 March 2016

correcting Regulation (EU) No 37/2010 as regards the substance 'tylvalosin'

(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 Commission has been made aware of the fact that in the Annex to Commission Regulation (EU) No 37/2010[(2)], as amended by Commission Implementing Regulation (EU) 2015/1492[(3)], as regards the substance 'tylvalosin', the marker residue 'tylvalosin' was erroneously indicated as marker residue for porcine species.

(2) The Annex to Regulation (EU) No 37/2010 should be corrected to indicate that the marker residue for porcine species and for skin and fat and liver of poultry species is 'Sum of Tylvalosin and 3-O-acetyltylosin' and that the marker residue 'tylvalosin' applies only to eggs of poultry species.

(3) This Regulation should apply retroactively from the date of application of Implementing Regulation (EU) 2015/1492 because the marker residue for porcine species was indicated erroneously and should therefore be corrected. It should therefore enter into force as a matter of urgency.

(4) 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

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'tylvalosin' is replaced by the following:

Tylvalosin	Sum of tylvalosin and 3-O-acetyltylosin	Porcine	50 µg/kg	Muscle	NO ENTRY	Anti-infectious agents/ Antibiotics
			50 µg/kg	Skin and fat		
			50 µg/kg	Liver		
			50 µg/kg	Kidney		
		Poultry	50 µg/kg	Skin and fat		
			50 µg/kg	Liver		
	Tylvalosin	Poultry	200 µg/kg	Eggs		

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 3 November 2015.

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

Done at Brussels, 4 March 2016.

For the Commission

The President

Jean-Claude JUNCKER

(**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).

(**3**) Commission Implementing Regulation (EU) 2015/1492 of 3 September 2015 amending Regulation (EU) No 37/2010 as regards the substance ‘tylvalosin’ (OJ L 231, 4.9.2015, p. 10).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/312.