COMMISSION IMPLEMENTING REGULATION (EU) 2015/1308

of 29 July 2015

amending Regulation (EU) No 37/2010 as regards the substance 'aluminium salicylate, basic'

(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) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit (hereinafter '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 established in a regulation.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Aluminium salicylate, basic, is already included in this table according to which aluminium salicylate, basic, is allowed for (i) the oral use for bovine species, excluding species producing milk for human consumption; and (ii) the topical use for all food producing species, excluding fin fish.

(4) An application for a modification of the existing entry for aluminium salicylate, basic, has been submitted to the European Medicines Agency (hereinafter 'EMA').

(5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended to maintain the 'No MRL required' classification for aluminium salicylate, basic, but only for the topical use of this substance and only for other food producing species than bovine species, caprine, *Equidae*, rabbit and fin fish. The existing entry for bovine species should be replaced by numerical MRLs as, given that the substance is now proposed for use in adult animals, the 'No MRL required' classification is no longer valid and the establishment of limits in bovine tissues and milk is required.

(6) According to Article 5 of Regulation (EC) No 470/2009, the EMA 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 EMA has considered that the extrapolation of the numerical MRLs for aluminium salicylate, basic, recommended for bovine species to goats, horses and rabbits is appropriate.

(8) Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.

(9) The analytical method for the monitoring of the proposed MRLs for aluminium salicylate, basic, in bovine tissues or in bovine milk is available, yet not sufficiently validated.

([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) According to Article 14(4) of Regulation (EC) No 470/2009, a provisional MRL may be established in cases where scientific data are incomplete, provided that there are no grounds for supposing that residues of that substance at the level proposed constitute a hazard to human health.

(11) The proposed numerical MRLs should therefore be provisional and expire on 31 December 2016.

(12) 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 28 September 2015.

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

Done at Brussels, 29 July 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 'aluminium salicylate, basic' 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
'aluminium salicylate, basic	Salicylic acid	Bovine, caprine, *Equidae*, rabbit	200 µg/kg	Muscle	Provisional MRLs expire on 31 December 2016.	Antidiarrhoeal and intestinal anti-inflammatory agents'
			500 µg/kg	Fat		
			1 500 µg/kg	Liver		
			1 500 µg/kg	Kidney		
		Bovine, caprine, *Equidae*	9 µg/kg	Milk		
	NOT APPLICABLE	All food producing species except bovine, caprine, *Equidae*, rabbit and fin fish	No MRL required	NOT APPLICABLE	For topical use only.	