

**COMMISSION IMPLEMENTING REGULATION (EU) 2016/2074**  
**of 25 November 2016**  
**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 the Council <sup>(1)</sup>, 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 <sup>(2)</sup> sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.
- (3) Aluminium salicylate, basic is currently included in that table as an allowed substance for topical use in all food producing species, except bovine, caprine, equidae, rabbit and fin fish. Aluminium salicylate, basic is also allowed substance for bovine, caprine, equidae and rabbit species according to provisional MRL set for that substance which expire on 31 December 2016.
- (4) An application for the modification of the existing entry for aluminium salicylate, basic to remove the provisional status of the MRL in bovine, caprine, equidae and rabbit species 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 the removal of the provisional status of the MRL for aluminium salicylate, basic in bovine, caprine, equidae and rabbit species.
- (6) 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.

<sup>(1)</sup> OJ L 152, 16.6.2009, p. 11.

<sup>(2)</sup> 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).

*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 25 January 2017.

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

Done at Brussels, 25 November 2016.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## 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 500 µg/kg 1 500 µg/kg 1 500 µg/kg	Muscle Fat Liver Kidney	NO ENTRY	Antidiarrheal and intestinal anti-inflammatory agents'
		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	