Commission Implementing Regulation (EU) No 1191/2012 of 12 December 2012 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 sodium salicylate (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1191/2012

of 12 December 2012

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 sodium salicylate

(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 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 should be 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 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin[(2)].

(3) Sodium salicylate is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance for bovine and porcine species, excluding animals producing milk for human consumption, for all food-producing species except fin fish species, for topical use only, and for turkey, applicable to muscle, skin and fat, liver and kidney, excluding animals producing eggs for human consumption. The provisional MRL for that substance set out for turkey expires on 1 July 2015.

(4) Additional data were provided and assessed leading the Committee for Medicinal Products for Veterinary Use to recommend that the provisional MRLs for sodium salicylate for turkey should be set as definitive.

(5) The entry for sodium salicylate in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.

(6) 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 that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 12 December 2012.

For the Commission

The President

José Manuel BARROSO

ANNEX

The entry corresponding to sodium salicylate in Table 1 of the Annex to Regulation (EU) No 37/2010 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**
'Sodium salicylate	NOT APPLICABLE	Bovine, Porcine	No MRL required	NOT APPLICABLE	For oral use. Not for use in animals from which milk is produced for human consumption.	NO ENTRY
		All food-producing species except fin fish	No MRL required	NOT APPLICABLE	For topical use only.	
	Salicylic acid	Turkey	400 µg/kg	Muscle	Not for use in animals producing eggs for human consumption.	Anti-inflammatory agents/ Non-steroidal anti-inflammatory agents'
			2 500 µg/kg	Skin and fat in natural proportions		
			200 µg/kg	Liver		
			150 µg/kg	Kidney		

(**1**) OJ L 152, 16.6.2009, p. 11.

(**2**) OJ L 15, 20.1.2010, p. 1.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1191/2012.