



2024/859

19.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/859

of 18 March 2024

amending Regulation (EU) No 37/2010 as regards the classification of the substance sodium salicylate with respect to its maximum residue limit in foodstuffs of animal origin

(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,

Whereas:

- (1) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ⁽²⁾ sets out the pharmacologically active substances and their classification regarding maximum residue limits ('MRLs') in foodstuffs of animal origin.
- (2) The substance sodium salicylate is included in that table as an allowed substance.
- (3) On 30 September 2022, pursuant to Article 3 of Regulation (EC) No 470/2009, Dopharma B.V. submitted an application to the European Medicines Agency ('Agency') for the extension of the existing entry for the substance sodium salicylate to chicken.
- (4) On 5 October 2023, the Agency, based on the opinion of the Committee for Veterinary Medicinal Products, set up pursuant to Article 139 of Regulation (EU) 2019/6 of the European Parliament and of the Council ⁽³⁾, and having considered the application of Dopharma B.V., recommended the extension of maximum residue limits for the substance sodium salicylate in chicken and the establishment of numerical MRLs.
- (5) The Agency also concluded that the extrapolation of the MRLs for sodium salicylate from chicken tissues to the tissues of other poultry species other than turkey is appropriate.
- (6) In view of the opinion of the Agency, the Commission considers it appropriate to establish the recommended MRL for sodium salicylate in chicken tissues and to extrapolate it to other poultry species other than turkey, but restricted to animals not producing eggs for human consumption as no residue data were provided for eggs.
- (7) Regulation (EU) No 37/2010 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

⁽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⁾ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

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*.

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

Done at Brussels, 18 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the pharmacologically active substance 'sodium salicylate' 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		For topical use only.	
	Salicylic acid	Turkey	400 µg/kg 2 500 µg/kg 200 µg/kg 150 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney	Not for use in animals producing eggs for human consumption.	Anti-inflammatory agents / Non-steroidal anti-inflammatory agents'.
		Poultry other than turkey	250 µg/kg 250 µg/kg 500 µg/kg 1 000 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney		