EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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amending Regulation (EU) No 37/2010 as regards the classification of the substance fluralaner 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) In accordance with Regulation (EC) No 470/2009, the Commission is to establish, by way of a Regulation, maximum residue limits ('MRLs') 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.

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

(3) The substance fluralaner is included in that Regulation as an allowed substance for poultry.

(4) On 24 April 2024, Farmacologia En Aquacultura Veterinaria FAV S.A. submitted an application to the European Medicines Agency ('the Agency') in accordance with Article 3 of Regulation (EC) No 470/2009 for the establishment of the maximum residue limits of the substance fluralaner in Salmonidae and other fin fish.

(5) In accordance with Article 5 of Regulation (EC) No 470/2009, the Agency 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.

(6) On 12 February 2025[3], the Agency, based on the opinion of the Committee for Veterinary Medicinal Products, recommended the establishment of MRLs for

[1] OJ L 152, 16.6.2009, p. 11, ELI: http://data.europa.eu/eli/reg/2009/470/oj.

[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, ELI: http://data.europa.eu/eli/reg/2010/37(1)/oj).

fluralaner use in Salmonidae, applicable to muscle and skin in natural proportions. The Agency concluded that the extension by extrapolation of the MRLs for fluralaner to all fin fish is appropriate.

(7) In view of the opinion of the Agency, the Commission considers it appropriate to establish the recommended MRLs for fluralaner in all fin fish.

(8) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(9) 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*.

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

Done at Brussels,

For the Commission
Ursula VON DER LEYEN
The President

[3] Opinion of the Committee for Veterinary Medicinal Products of 12 February 2025 on the establishment of maximum residue limits (EMA/CVMP/27344/2025).