EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 February 2025
EMA/29093/2025
Veterinary Medicines Division

MRL summary opinion[1]

Fluralaner

Salmonidae and other fin fish

On 12 February 2024 the Committee for Veterinary Medicinal Products adopted an opinion[2] recommending the extension of maximum residue limits for fluralaner to Salmonidae. Furthermore, with reference to Article 5 of Regulation (EC) No 470/2009, the Committee recommended the extrapolation of the maximum residue limit for Salmonidae to all fin fish. Therefore, the Committee recommended the amendment of the entry for fluralaner in table 1 of the Annex to Regulation (EU) No 37/2010 of 22 December 2009 as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Fluralaner	Fluralaner	Poultry	65 µg/kg 650 µg/kg 650 µg/kg 420 µg/kg 1300 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney Eggs	NO ENTRY	Antiparasitic agents/ Agents against ectoparasites
		Fin fish	65 µg/kg	Muscle and skin in natural proportions		

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may request re-examination of any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to request such re-examination within 15 days of receipt of the opinion.