MRL for fluralaner in fin fish

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EU establishes MRL for fluralaner in fin fish

Commission Implementing Regulation (EU) 2025/1908 of 24 September 2025 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

Update

The European Union (EU) has set a maximum residue limit (MRL) for the substance fluralaner, used in veterinary medicines in fin fish.

Impacted products

Fin fish

What is changing?

The EU has set an MRL for fluralaner of 65 µg/kg for Salmonidae and other fin fish, applicable to muscle and skin in natural proportions. MRLs were already in place for poultry.

Why?

In April 2024, Farmacologia En Aquacultura Veterinaria submitted an application to the European Medicines Agency (EMA) regarding MRLs for fluralaner in fin fish. Following this application, and based on the opinion of the Committee for Veterinary Medicinal Products, the EMA has recommended the establishment of MRLs for fluralaner used in Salmonidae (CVMP 2025).

Timeline

The new MRL applies from **15 October 2025**.

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Background

Regulation 470/2009 requires that MRLs for pharmacologically active substances intended for use in veterinary medicinal products administered to food-producing animals in the EU are subject to the opinion of the EMA.

Active substances and their MRLs in foods of animal origin are set out in Regulation 37/2010. The use of fluralaner in veterinary medicines for poultry was already permitted.

Resources

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

European Commission (2023) Control plans for residues of veterinary medicines, pesticides and contaminants.

European Commission: Residues of veterinary medicinal products

Sources

Commission Implementing Regulation (EU) 2025/1908 as regards the classification of the substance fluralaner with respect to its maximum residue limit in foodstuffs of animal origin

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