MRL for fluralaner in fin fish

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EU to establish MRL for Salmonidae and other fin fish

Draft Commission Implementing Regulation (EU) 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

Draft Annex

Update

The European Commission has informed the World Trade Organization Sanitary and Phytosanitary Measures (WTO SPS) Committee that it will set a maximum residue limit (MRL) for the substance fluralaner (used in veterinary medicines) in Salmonidae and other fin fish (G/SPS/N/EU/847).

Impacted products

Fin fish

What is changing?

MRLs are currently in place for the substance fluralaner in poultry.

The EU proposes to set an MRL of 65 µg/kg for fin fish (Salmonidae and other fin fish), applicable to muscle and skin in natural proportions.

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 is expected to apply from August 2025.

Recommended Actions

The WTO consultation closed on 28 June 2025.

Background

Pharmacologically active substances and their MRLs in foods of animal origin are given in Regulation 37/2010 (Annex), which already allows the use of fluralaner in veterinary medicines for poultry.

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

Draft Commission Implementing Regulation as regards the classification of the substance fluralaner with respect to its maximum residue limit in foodstuffs of animal origin

Draft Annex

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