MRLs for ketoprofen in animal products (ruminants, pigs, horses)

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EU proposes MRLs for ketoprofen in animal products (ruminants, pigs, horses)

Draft Commission Implementing Regulation amending Regulation (EU) No 37/2010 as regards the classification of the substance ketoprofen 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 intends to set maximum residue levels (MRLs) for ketoprofen in meat, fat, offals, and milk derived from all ruminants (including cows and sheep), pigs, and horses (G/SPS/N/EU/808). Comments can be submitted to the European Union's SPS Enquiry Point until **4 April 2025**.

Impacted products

Meat, fat, liver, kidney, and milk from cows, sheep, goats, pigs, and horses

What is changing?

Under Regulation 2023/2194, the EU set an MRL for ketoprofen in poultry tissues (see MRLs for ketoprofen in poultry).

The European Commission now proposes to set the following MRLs for ketoprofen that apply to the tissues of all ruminants (including cows, sheep, and goats), pigs, and horses:

- muscle, kidney: 50 µg/kg
- fat, liver, milk: 20 µg/kg.

For pigs, the MRL on fat relates to “skin and fat in natural proportions”.

Why?

Following a request from the Commission, the European Medicines Agency evaluated and recommended setting MRLs for ketoprofen use in species of cows and pigs. On the basis of this evaluation, the Commission proposes that these MRLs are extended to all ruminants and horses.

Timeline

The Commission intends to publish this Regulation in April 2025. The MRLs will apply 20 days after publication.

What are the major implications for exporting countries?

The use of veterinary medicines containing ketoprofen was already permitted in cows, pigs, and horses, but this will be extended to all ruminants under the new Regulation. Food produced from all these animals will have to comply with the MRLs.

Recommended Actions

Countries that are members of the WTO can submit comments or concerns about potential impacts, via the National SPS notification authority of the country concerned, to the EU SPS Enquiry Point until **4 April 2025**.

Background

The Annex to Regulation 37/2010 sets out pharmacologically active substances that may be used in veterinary medicines, and their MRLs in food of animal origin. Ketoprofen may currently be used in relation to cows, pigs, horses, and poultry. MRLs for ketoprofen are only currently set for poultry.

The Annex to Regulation 37/2010 will be amended accordingly.

Resources

Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in food

Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal originstuffs of animal origin

European Commission: Residues of veterinary medicinal products

Sources

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

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