MRL for rafoxanide in food of animal origin

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Introduction of MRL for rafoxanide in milk from cattle and sheep

Commission Implementing Regulation (EU) 2023/2203 of 20 October 2023 amending Regulation (EU) No 37/2010 as regards the classification of the substance rafoxanide with respect to its maximum residue limit in foodstuffs of animal origin

Update

The EU has introduced a maximum residue level (MRL) for rafoxanide in milk from cattle and sheep. In addition, the existing MRLs for rafonaxide in muscle, fat, liver, and kidney of cattle now apply to all ruminants except sheep.

Impacted products

muscle, fat, liver, and kidney of ruminants except sheep; milk from cattle and sheep

What is changing?

The European Commission is introducing an MRL for the antiparasitic agent rafoxanide in milk from cattle and sheep at 10 µg/kg.

In addition, the MRLs for rafoxanide in cattle – for muscle and fat (30 µg/kg), liver (10 µg/kg), and kidney (40 µg/kg) – now apply to all ruminants except sheep.

The Annex to Regulation 37/2010 on pharmacologically active substances and their MRLs in food of animal origin will be amended accordingly.

Why?

Based on a request from the Republic of Ireland, the European Medicines Agency recommended a definitive MRL for rafoxanide in milk from cattle and sheep.

The Agency also concluded that the existing MRLs for rafoxanide in muscle, fat, liver, and kidney from cattle can be extrapolated to all ruminants except sheep.

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Timeline

Date of application: 12 November 2023.

What are the major implications for exporting countries?

Rafoxanide is now allowed in milk from cattle and sheep within the maximum limit of 10 µg/kg. The limits set for muscle, fat, liver, and kidney from cattle are extended to all ruminants except sheep.

Recommended Actions

Countries that export muscle, fat, liver, kidney, or milk from cattle and sheep must ensure that the established residue limits of rafonaxide in those products destined for the EU are not exceeded.

Background

Rafoxanide is an antiparasitic agent that can be used against endoparasites in cattle and sheep. The provisional MRL for rafoxanide for milk from cattle and sheep at 10 µg/kg expired on 31 December 2017.

Resources

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

European Commission: Residues of veterinary medicinal products

European Medicines Agency: Maximum residue limits (MRL)

Sources

Regulation 2023/2203 as regards the classification of the substance rafoxanide with respect to its maximum residue limit in foodstuffs of animal origin

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Regulation 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin

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