EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 April 2023
EMA/CVMP/152101/2023
Committee for Veterinary Medicinal Products

MRL summary opinion[1]

Rafoxanide

Bovine and ovine milk

On 20 April 2023, the Committee for Veterinary Medicinal Products adopted an opinion[2] recommending the extrapolation of maximum residue limits for rafoxanide to milk in bovine and ovine species. Furthermore, with reference to Article 5 of Regulation (EC) No 470/2009 and in line with the criteria laid down in Commission Regulation (EU) 2017/880, the Committee agreed to extrapolate the maximum residue limits in bovine tissues and milk to all ruminants except ovine, for which (higher) MRLs are already established. Therefore, the Committee recommends the amendment of the entry for rafoxanide in table 1 of the Annex to Commission Regulation (EU) No 37/2010 of 22 December 2009 in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Rafoxanide	Rafoxanide	All ruminants except ovine	30 µg/kg 30 µg/kg 10 µg/kg 40 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Antiparasitic agents/Agents (acting) against endoparasites
		Ovine	100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk		

[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