9 December 2021
EMA/CVMP/683921/2021
Committee for Veterinary Medicinal Products (CVMP)

Opinion of the Committee for Veterinary Medicinal Products for the establishment of maximum residue limits

Procedure no: EMEA/V/MRL/003363/EXTN/0004

Name of the substance: Toltrazuril (INN)

Basis for the opinion

Pursuant to Article 9(1)(b) of Regulation (EC) No 470/2009 of 6 May 2009, the Netherlands submitted to the European Medicines Agency on 29 June 2021 a request for the extension of maximum residue limits for toltrazuril to chicken eggs.

Recommendation

The Committee, having considered the application, recommends by consensus the extension of maximum residue limits for toltrazuril to chicken eggs. 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 conclusions to poultry eggs. Therefore, the Committee recommends the extension of maximum residue limits for toltrazuril in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Toltrazuril	Toltrazuril sulfone	All mammalian food producing species	100 µg/kg 150 µg/kg 500 µg/kg 250 µg/kg	Muscle Fat Liver Kidney	For porcine species the fat MRL relates to 'skin and fat in natural proportions'. Not for use in animals from which milk is produced for human consumption.	Antiparasitic agents/ Agents acting against protozoa
		Poultry	100 µg/kg 200 µg/kg 600 µg/kg 400 µg/kg 140 µg/kg	Muscle Skin and fat Liver Kidney Eggs	NO ENTRY	

The Norwegian CVMP member agrees with the above-mentioned recommendation of the Committee.

The scientific conclusions of the Committee are presented in the European public MRL assessment report (EPMAR), provided in Annex I of this opinion.

The analytical method for monitoring of residues is appended to this opinion.

The present opinion is forwarded to the European Commission and to the applicant together with its appendices.

Annex I

European public MRL assessment report (EPMAR)