5 October 2017
EMA/CVMP/616458/2017
Committee for Medicinal Products for Veterinary Use

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

Procedure no: EMEA/V/MRL/003471/EXTN/0002

Name of the substance: Fluazuron (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Farmacologia en Aquacultura Veterinaria FAV S.A. submitted to the European Medicines Agency on 20 April 2017 an application for the extension of maximum residue limits for fluazuron to fin fish.

Recommendation

The Committee, having considered the application, recommends by the majority of 26 out of 28 votes the extension of maximum residue limits for fluazuron to fin fish. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits established in bovine tissues to tissues of all ruminants except ovine species and to milk of bovine species in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Fluazuron	Fluazuron	All ruminants except bovine and ovine	200 µg/kg 7000 µg/kg 500 µg/kg 500 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	Antiparasitic agents / Agents (acting) against ectoparasites
		Bovine	200 µg/kg 7000 µg/kg 500 µg/kg 500 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	

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		Fin fish	200 µg/kg	Muscle and skin in natural proportions	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 divergent position is presented in Annex II 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)