EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 October 2016
EMA/CVMP/615777/2016
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/004380/FULL/0001

Name of the substance: Fluralaner (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Intervet International B.V. submitted to the European Medicines Agency on 21 December 2015 an application for the establishment of maximum residue limits for fluralaner in chicken.

On 19 May 2016 the Committee for Medicinal Products for Veterinary Use adopted a list of questions to be addressed by the applicant. The response to the list of questions was submitted on 8 July 2016.

Recommendation

The Committee, having considered the application and having evaluated the response to the list of questions, recommends by consensus the establishment of maximum residue limits for fluralaner in chicken tissues and eggs. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits recommended in chicken tissues and eggs to tissues and eggs of other poultry species. Therefore, the Committee recommends by consensus the establishment of maximum residue limits for fluralaner in accordance with the following table:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Fluralaner	Fluralaner	Poultry	65 µg/kg 650 µg/kg 650 µg/kg 420 µg/kg 1300 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney Eggs	NO ENTRY	Antiparasitic agents / Agents against ectoparasites

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

The Icelandic and Norwegian CVMP members agree 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.

London, 6 October 2016

Signature on file

Dr D. Murphy
Chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)