EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 September 2020
EMA/CVMP/446874/2020
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/004481/FULL/0002

Name of the substance: Imidacloprid (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Benchmark Animal Health Norway AS submitted to the European Medicines Agency on 23 April 2019 an application for the establishment of maximum residue limits for imidacloprid in *Salmonidae*.

On 12 September 2019 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 17 January 2020.

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 imidacloprid in accordance with the following table:

Pharmaco-logically active substance	**Marker residue**	**Animal species**	**MRLs**	**Target tissues**	**Other provisions**	**Therapeutic classification**
Imidacloprid	Imidacloprid	Fin fish	600 µg/kg	Muscle and skin in natural proportions	NO ENTRY	Antiparasitic agents / Agents against ectoparasites

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.

Annex I

European public MRL assessment report (EPMAR)