

COMMISSION IMPLEMENTING REGULATION (EU) 2021/621**of 15 April 2021****amending Regulation (EU) No 37/2010 to classify the substance imidacloprid as regards its maximum residue limit in foodstuffs of animal origin****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council ⁽¹⁾, and in particular Article 14, in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated on 9 September 2020 by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit ('MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is established in a Regulation.
- (2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ⁽²⁾ sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.
- (3) The substance imidacloprid is not included in that table.
- (4) An application for the establishment of an MRL for imidacloprid in *Salmonidae* has been submitted to the European Medicines Agency (the 'Agency').
- (5) The Agency, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended the establishment of an MRL for imidacloprid in *Salmonidae*, applicable to muscle and skin in natural proportions.
- (6) According to Article 5 of Regulation (EC) No 470/2009, the Agency is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.
- (7) The Agency has considered that the extrapolation of the MRL for imidacloprid from *Salmonidae* to all fin fish is appropriate.
- (8) In view of the opinion of the Agency, it is appropriate to establish the recommended MRL for fin fish.
- (9) Regulation (EU) No 37/2010 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

⁽¹⁾ OJ L 152, 16.6.2009, p. 11.

⁽²⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the following entry is inserted in alphabetical order:

| Pharmacologically active Substance | Marker residue | Animal Species | MRL | Target Tissues | Other Provisions (<i>according to Article 14(7) of Regulation (EC) No 470/2009</i>) | Therapeutic Classification |
|------------------------------------|----------------|----------------|-----------|--|---|--|
| Imidacloprid | Imidacloprid | Fin Fish | 600 µg/kg | Muscle and skin in natural proportions | NO ENTRY | Antiparasitic agents/Agents against ectoparasites' |