EUROPEAN
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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Regulation (EU) No 37/2010 as regards the classification of the substance ketoprofen with respect to its maximum residue limit in foodstuffs of animal origin

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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amending Regulation (EU) No 37/2010 as regards the classification of the substance ketoprofen with respect to 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 of the Council[1], and in particular Article 14, in conjunction with Article 17, thereof,

Whereas:

(1) In accordance with Regulation (EC) No 470/2009, the Commission is to establish, by way of a regulation, maximum residue limits ('MRLs') 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.

(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 ketoprofen is already included in that table as an allowed substance for bovine, porcine and *equidae* species. The existing entry has a 'no MRL required' classification.

(4) In accordance with Article 3 of Regulation (EC) No 470/2009, on 14 December 2020, Huvepharma nv submitted an application to the European Medicines Agency ('Agency') for the extension of the existing entry for the substance ketoprofen to chicken.

(5) On 12 May 2022, the Agency, through the opinion of the Committee for Veterinary Medicinal Products, recommended the establishment of a 'no MRL required' classification for the substance ketoprofen in chicken.

(6) On 1 March 2023, the Commission requested the Agency to reconsider its opinion of 12 May 2022 to further examine possible safety concerns with regard to some metabolites and, where appropriate, to recommend numerical MRLs for ketoprofen in chicken tissues.

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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).

(7) On 16 May 2023, the Agency, based on the opinion of the Committee for Veterinary Medicinal Products, and having considered the application of Huvepharma nv and the request from the Commission, recommended the establishment of numerical MRLs for ketoprofen use in chicken, applicable to muscle, skin and fat in natural proportion, liver and kidney, but not for use in animals from which eggs are produced for human consumption.

(8) In accordance with 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. The Agency concluded that the extrapolation of the MRLs for ketoprofen from chicken tissues to the tissues of other poultry species is appropriate, but not to poultry eggs as no residue depletion data for the substance ketoprofen in eggs were provided.

(9) In view of the opinion of the Agency, the Commission considers it appropriate to establish the recommended MRL for ketoprofen in chicken tissues and to extrapolate it to other poultry species, but not to poultry eggs.

(10) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

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,

For the Commission
Ursula von der LEYEN
The President