Commission Implementing Regulation (EU) 2020/1685 of 12 November 2020 amending Regulation (EU) No 37/2010 to classify the substance bupivacaine as regards its maximum residue limit (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1685

of 12 November 2020

amending Regulation (EU) No 37/2010 to classify the substance bupivacaine as regards its maximum residue limit

(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 opinions of the European Medicines Agency formulated on 20 February 2020 and 18 June 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 bupivacaine is not included in that table.

(4) An application for the establishment of MRLs for bupivacaine for cutaneous and epilesional use only in porcine, for piglets up to 7 days of age, and in bovine, for calves up to 2 months of age, has been submitted to the European Medicines Agency ('Agency').

(5) The Agency, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has concluded that the establishment of an MRL for bupivacaine in porcine and bovine, within those age limitations, is not necessary for the protection of human health and recommended a 'no MRL required' classification.

(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 'no MRL required' classification for bupivacaine in porcine and bovine to other food-producing species is not appropriate at this time due to insufficient data.

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

(9) 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, 12 November 2020.

For the Commission

The President

Ursula VON DER LEYEN