Commission Implementing Regulation (EU) 2018/1076 of 30 July 2018 amending Regulation (EU) No 37/2010 to classify the substance isoflurane as regards its maximum residue limit (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1076

of 30 July 2018

amending Regulation (EU) No 37/2010 to classify the substance isoflurane 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 opinion of the European Medicines Agency formulated 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) Isoflurane is already included in that table as an allowed substance for equidae, for anaesthetic use only. The existing entry has a 'no MRL required' classification.

(4) An application for the extension of the existing entry for isoflurane to porcine species has been submitted to the European Medicines Agency ('EMA').

(5) EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended the establishment of an MRL for isoflurane in porcine species.

(6) According to Article 5 of Regulation (EC) No 470/2009, EMA 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) EMA has considered that the extrapolation of the entry for isoflurane to other age groups and species cannot be reliably assessed at this time due to insufficient data.

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

(9) It is appropriate to grant the stakeholders concerned a reasonable period of time to take measures that may be required to comply with the new MRL.

(10) 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*.

It shall apply from 29 September 2018.

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

Done at Brussels, 30 July 2018.

For the Commission

The President

Jean-Claude JUNCKER