Commission Implementing Regulation (EU) No 20/2014 of 10 January 2014 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance butafosfan (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 20/2014

of 10 January 2014

amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance butafosfan

(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,

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

Whereas:

(1) 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 are established in accordance with Regulation (EC) No 470/2009.

(2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010[(2)].

(3) Butafosfan is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance for bovine species, while establishing the absence of the need to establish an MRL.

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

(5) The Committee for Medicinal Products for Veterinary Use recommended that there is no need to establish an MRL for butafosfan for porcine species.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 20/2014. (See end of Document for details)*

(6) According to Article 5 of Regulation (EC) No 470/2009 the European Medicines 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 another species.

(7) The CVMP recommended the extrapolation of the evaluation results of butafosfan from bovine and porcine species to all mammalian food-producing species.

(8) The entry for butafosfan in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the substance butafosfan for all mammalian food-producing species, while establishing the absence of the need to establish an MRL.

(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, 10 January 2014.

For the Commission

The President

José Manuel BARROSO