EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 June 2013
EMA/CVMP/250946/2013
Committee for Medicinal Products for Veterinary Use

Opinion of the Committee for Medicinal Products for Veterinary Use on the establishment of maximum residue limits

Procedure no: EMEA/V/MRL/003610/EXTN/0003

Name of the substance: Butafosfan (INN)

Basis for the opinion

Pursuant to Article 3 of Regulation (EC) No 470/2009 of 6 May 2009, Bayer Animal Health GmbH submitted to the European Medicines Agency on 19 December 2012 an application for the extension of maximum residue limits for butafosfan to porcine species.

Recommendation

The Committee, having considered the application, concluded that the establishment of maximum residue limits for butafosfan in porcine species is not necessary for the protection of human health.

Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the conclusion to all mammalian food producing species, and therefore recommends by consensus the amendment of table 1 of the Annex to Regulation (EU) No 37/2010 with regard to butafosfan as follows:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Butafosfan	NOT APPLICABLE	All mammalian food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	Alimentary tract and metabolism / mineral supplements

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The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the Committee.

The scientific conclusions of the Committee are presented in the European public MRL assessment report (EPMAR), provided in Annex I of this opinion.

The present opinion is forwarded to the European Commission and to the applicant together with its appendix.

London, 13 June 2013

Signature on file

Dr. A. Holm
Chair, on behalf of the CVMP

Annex I

European public MRL assessment report (EPMAR)