COMMISSION IMPLEMENTING REGULATION (EU) 2017/840

of 17 May 2017

concerning the non-approval of the active substance orthosulfamuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 13(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ([2]) is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For orthosulfamuron the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2006/806/EC ([3]).

(2) In accordance with Article 6(2) of Directive 91/414/EEC Italy received on 4 July 2005 an application from Isagro S.p.A. for the inclusion of the active substance orthosulfamuron in Annex I to Directive 91/414/EEC. Decision 2006/806/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State submitted a draft assessment report on 27 July 2012. In accordance with Article 6(3) of Commission Regulation (EU) No 188/2011 ([4]) additional information was requested from the applicant. The evaluation by Italy of the additional information submitted by the applicant was submitted in the format of addenda to the draft assessment report and compiled by the European Food Safety Authority (hereinafter 'the Authority') in August 2013.

(4) The draft assessment report was reviewed by the Member States and the Authority. The Authority presented to the Commission its conclusion on the pesticide risk assessment of the active substance orthosulfamuron ([5]) on 3 September 2013. The Authority concluded that the information available on the nature of residues in primary and succeeding crops in combination with a lack of toxicological information and intake assessment on some plant metabolites does not allow finalising the assessment of the consumer risk. In addition, also the risk assessment to soil dwelling organisms and aquatic organisms could not be finalised. Moreover, the Authority identified concerns from some metabolites, and consequently the exposure assessment to groundwater could not be finalised.

(5) The Commission invited the applicant to submit its comments on the conclusion of the Authority, and, in accordance with Article 9(1) of Regulation (EU) No 188/2011 on the draft review report. The applicant submitted its comments, which have been carefully examined.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([3]) Commission Decision 2006/806/EC of 24 November 2006 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of orthosulfamuron in Annex I to Council Directive 91/414/EEC (OJ L 329, 25.11.2006, p. 74).

([4]) Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (OJ L 53, 26.2.2011, p. 51).

([5]) EFSA Journal 2013;11(9):3352. Available online: www.efsa.europa.eu.

(6) However, despite the arguments put forward by the applicant, the concerns identified/referred to in recital 4 could not be eliminated.

(7) Consequently it has not been demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing orthosulfamuron satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(8) Orthosulfamuron should therefore not be approved pursuant to Article 13(2) of Regulation (EC) No 1107/2009.

(9) In accordance with Article 8(1)(b) of Directive 91/414/EEC, Member States were given the possibility to grant provisional authorisations for plant protection products containing orthosulfamuron for an initial period of three years. Commission Implementing Decision 2013/205/EU [1] allowed Member States to extend provisional authorisations for orthosulfamuron for a period ending on 30 April 2015 at the latest.

(10) As all existing authorisations have expired, it is not necessary to provide an additional period to withdraw authorisations for plant protection products containing orthosulfamuron.

(11) This Regulation does not prejudice the submission of a further application for orthosulfamuron in accordance with Article 7 of Regulation (EC) No 1107/2009.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Non-approval of active substance

The active substance orthosulfamuron is not approved.

Article 2

Entry into force

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, 17 May 2017.

For the Commission
The President
Jean-Claude JUNCKER

[1] Commission Implementing Decision 2013/205/EU of 25 April 2013 allowing Member States to extend provisional authorisations granted for the new active substances acequinocyl, aminopyralid, ascorbic acid, flubendiamide, gamma-cyhalothrin, ipconazole, metaflumizone, orthosulfamuron, Pseudomonas sp. strain DSMZ 13134, pyridalil, pyroxsulam, spiromesifen, thiencarbazone and topramezone (OJ L 117, 27.4.2013, p. 20).