Commission Implementing Regulation (EU) 2017/1526 of 6 September 2017 concerning the non-approval of the active substance beta-cypermethrin 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1526

of 6 September 2017

concerning the non-approval of the active substance beta-cypermethrin 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 beta-cypermethrin the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Implementing Decision 2011/266/EU[(3)].

(2) In accordance with Article 6(2) of Directive 91/414/EEC the United Kingdom received an application from Cerexagri SAS on 13 November 2009 for the inclusion of the active substance beta-cypermethrin in Annex I to Directive 91/414/EEC. Implementing Decision 2011/266/EU 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 assessment of the effects on human and animal health and the environment for the uses proposed by the applicant has been carried out in accordance with the procedure provided in Article 6(2) and (4) of Directive 91/414/EEC. The designated rapporteur Member State submitted a draft assessment report on 4 April 2013.

(4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (‘the Authority’). The Authority presented to the Commission its

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/1526. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

conclusion on the pesticide risk assessment of the active substance beta-cypermethrin[4] on 27 May 2014. The Authority concluded that for the uses of beta-cypermethrin assessed there is a high risk to aquatic organisms, bees and non-target arthropods. In addition, the risk assessment for soil and aquatic organisms and the exposure assessment for groundwater could not be finalised as insufficient information was provided in relation to the fate and behaviour of the cyclopropyl ring moiety of beta-cypermethrin. Furthermore, information on metabolism in livestock, which is necessary to confirm the residue definition for animal products, and information on the toxicity profile of metabolite PBA and its relevance for consumer risk assessment, were not provided.

(5) Consequently, it was not possible to conclude on the basis of the information available that beta-cypermethrin meets the criteria for inclusion in Annex I to Directive 91/414/EEC.

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

(7) Despite the arguments put forward by the applicant, the concerns referred to in recital 4 could not be eliminated. Consequently, it has not been demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing beta-cypermethrin satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(8) Beta-cypermethrin should therefore not be approved in accordance with Article 13(2) of Regulation (EC) No 1107/2009.

(9) This Regulation does not prevent the applicant from submitting a further application for beta-cypermethrin in accordance with Article 7 of Regulation (EC) No 1107/2009.

(10) 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 beta-cypermethrin 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*.