COMMISSION IMPLEMENTING REGULATION (EU) 2016/146

of 4 February 2016

renewing the approval of the active substance lambda-cyhalothrin, as a candidate for substitution, 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, and amending the Annex to Implementing Regulation (EU) No 540/2011

(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 20(1) thereof,

Whereas:

(1) The approval of the active substance lambda-cyhalothrin, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]), expires on 30 June 2016.

(2) An application for the renewal of the inclusion of lambda-cyhalothrin in Annex I to Council Directive 91/414/EEC ([3]) was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010 ([4]) within the time period provided for in that Article.

(3) The applicants submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.

(4) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 28 February 2013.

(5) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(6) On 11 March 2015, the Authority communicated to the Commission the revised version of its conclusion of 23 April 2014 ([5]) on whether lambda-cyhalothrin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft review report for lambda-cyhalothrin to the Standing Committee on Plants, Animals, Food and Feed on 28 May 2015.

(7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that the approval criteria provided for in Article 4 are satisfied. Those approval criteria are therefore deemed to be satisfied.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).
([3]) 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).
([4]) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).
([5]) EFSA Journal 2014;12(5):3677. Available online: www.efsa.europa.eu

(8) The risk assessment for the renewal of the approval of lambda-cyhalothrin is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing lambda-cyhalothrin may be authorised. It is therefore appropriate not to maintain the restriction to uses as an insecticide.

(9) The Commission however considers that lambda-cyhalothrin is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. The Acceptable Operator Exposure Level (AOEL) is significantly lower than those of the majority of the approved active substances within the group of insecticides. Moreover, lambda-cyhalothrin is a bioaccumulative and toxic substance in accordance with points 3.7.2.2 and 3.7.2.3 respectively, of Annex II to Regulation (EC) No 1107/2009, given that the bioconcentration factor is greater than 2000 and the long-term no-observed effect concentration for freshwater organisms is less than 0,01 mg/L. Lambda-cyhalothrin therefore fulfils the conditions set in the first and second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.

(10) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, necessary to include certain conditions. It is, in particular, appropriate to require further confirmatory information.

(11) It is therefore appropriate to renew the approval of lambda-cyhalothrin as a candidate for substitution.

(12) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(13) Commission Implementing Regulation (EU) 2015/1885 [1] extended the expiry date of lambda-cyhalothrin to 30 June 2016 in order to allow the renewal process to be completed before the expiry of its approval. However, given that a decision on renewal has been taken ahead of the extended expiry date, this Regulation should apply from 1 April 2016.

(14) 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

Renewal of the approval of active substance as a candidate for substitution

The approval of the active substance lambda-cyhalothrin, as a candidate for substitution, is renewed as set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

[1] Commission Implementing Regulation (EU) 2015/1885 of 20 October 2015 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-D, acibenzolar-s-methyl, amitrole, bentazone, cyhalofop butyl, diquat, esfenvalerate, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), glyphosate, iprovalicarb, isoproturon, lambda-cyhalothrin, metalaxyl-M, metsulfuron methyl, picolinafen, prosulfuron, pymetrozine, pyraflufen-ethyl, thiabendazole, thifensulfuron-methyl and triasulfuron (OJ L 276, 21.10.2015, p. 48).

Article 3

Entry into force and date of application

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 1 April 2016.

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

Done at Brussels, 4 February 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Lambda-Cyhalothrin CAS No 91465-08-6 CIPAC No 463	A 1:1 mixture of: (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or of (R)-α-cyano-3-phenoxybenzyl (1S)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate	900 g/kg	1 April 2016	31 March 2023	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on lambda-cyhalothrin, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the: (a) protection of operators, workers and bystanders; (b) metabolites potentially formed in processed commodities; (c) risk to aquatic organisms, mammals and non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate. The applicants shall submit confirmatory information as regards: 1. a systematic review to assess the evidence available as regards potential sperm effects linked to exposure to lambda-cyhalothrin using guidance available (e.g. EFSA GD on Systematic Review methodology, 2010); 2. toxicological information to assess the toxicological profile of the metabolites V (PBA) and XXIII (PBA(OH)). The applicants shall submit those information to the Commission, the Member States and the Authority by 1 April 2018.

[1] Further details on identity and specification of active substance are provided in the review report.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 12 on lambda-cyhalothrin is deleted;

(2) in Part E, the following entry is added:

	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'5	Lambda-Cyhalothrin CAS No 91465-08-6 CIPAC No 463	A 1:1 mixture of: (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or of (R)-α-cyano-3-phenoxybenzyl (1S)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate	900 g/kg	1 April 2016	31 March 2023	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on lambda-cyhalothrin, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the: (a) protection of operators, workers and bystanders; (b) metabolites potentially formed in processed commodities; (c) risk to aquatic organisms, mammals and non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate. The applicants shall submit confirmatory information as regards: 1. a systematic review to assess the evidence available as regards potential sperm effects linked to exposure to lambda-cyhalothrin using guidance available (e.g. EFSA GD on Systematic Review methodology, 2010); 2. toxicological information to assess the toxicological profile of the metabolites V (PBA) and XXIII (PBA(OH)). The applicants shall submit those information to the Commission, the Member States and the Authority by 1 April 2018.'

(1) Further details on identity and specification of active substance are provided in the review report.