COMMISSION IMPLEMENTING REGULATION (EU) 2018/113

of 24 January 2018

renewing the approval of the active substance acetamiprid 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 Commission 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) Commission Directive 2004/99/EC ([2]) included acetamiprid as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([4]).

(3) The approval of the active substance acetamiprid, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2018.

(4) An application for the renewal of the approval of acetamiprid was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(6) 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 ('the Authority') and the Commission on 27 November 2015.

(7) 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.

(8) On 19 October 2016 the Authority communicated to the Commission its conclusion ([6]) on whether acetamiprid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for acetamiprid to the Standing Committee on Plants, Animals, Food and Feed on 23 January 2017.

(9) The applicant was given the opportunity to submit comments on the draft renewal report.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Directive 2004/99/EC of 1 October 2004 amending Council Directive 91/414/EEC to include acetamiprid and thiacloprid as active substances (OJ L 309, 6.10.2004, p. 6).
([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 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).
([5]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).
([6]) EFSA Journal 2016;14(11):4610. Available online: www.efsa.europa.eu

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing acetamiprid that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of acetamiprid.

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

(12) The Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(13) Commission Implementing Regulation (EU) 2016/2016 [1] extended the approval period of acetamiprid to 30 April 2018 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply from 1 March 2018.

(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 the active substance

The approval of the active substance acetamiprid 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.

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 March 2018.

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

Done at Brussels, 24 January 2018.

For the Commission
The President
Jean-Claude JUNCKER

[1] Commission Implementing Regulation (EU) 2016/2016 of 17 November 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances acetamiprid, benzoic acid, flazasulfuron, mecoprop-P, mepanipyrim, mesosulfuron, propineb, propoxycarbazon, propyzamide, propiconazole, *Pseudomonas chlororaphis* Strain: MA 342, pyraclostrobin, quinoxyfen, thiacloprid, thiram, ziram, zoxamide (OJ L 312, 18.11.2016, p. 21).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Acetamiprid CAS No 135410-20-7 CIPAC No 649	(E)-N1-[(6-Chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine	≥ 990 g/kg	1 March 2018	28 February 2033	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on acetamiprid, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the risk to aquatic organisms, bees and other non-target arthropods, — the risk to birds and mammals, — the risk to consumers, — the risk to operators. Conditions of use shall include risk mitigation measures, where appropriate.

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

ANNEX II

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

(1) in Part A, entry 91 on acetamiprid is deleted;

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'119	Acetamiprid CAS No 135410-20-7 CIPAC No 649	(E)-N1-[(6-Chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine	≥ 990 g/kg	1 March 2018	28 February 2033	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on acetamiprid, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the risk to aquatic organisms, bees and other non-target arthropods, — the risk to birds and mammals, — the risk to consumers, — the risk to operators. Conditions of use shall include risk mitigation measures, where appropriate.'

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