COMMISSION IMPLEMENTING REGULATION (EU) 2018/1914

of 6 December 2018

concerning the non-renewal of approval of the active substance quinoxyfen, 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 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) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2004/60/EC ([2]) included quinoxyfen 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 quinoxyfen, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2019.

(4) An application for the renewal of the approval of quinoxyfen 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 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 5 December 2016.

(7) In accordance with Article 11(4) of Implementing Regulation (EU) No 844/2012, that assessment was limited to a targeted assessment. The assessment did not go beyond the identity, methods of analysis, environmental fate and behavior and ecotoxicology information that related to the potential persistent bioaccumulative and toxic (PBT) properties, very persistent and very bioaccumulative (vPvB) properties and persistent organic pollutant (POP) properties of quinoxyfen, since the approval criteria set out in point 3.7.2 and 3.7.3 of Annex II to Regulation (EC) No 1107/2009 are not satisfied.

(8) 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.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Directive 2004/60/EC of 23 April 2004 amending Council Directive 91/414/EEC to include quinoxyfen as active substance (OJ L 120, 24.4.2004, p. 39).
([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).

(9) On 24 November 2017 the Authority communicated to the Commission its conclusion [1] on whether quinoxyfen can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The conclusion is limited to a hazard targeted assessment (focussed on the elements referred to in point 3.7 of Annex II to Regulation (EC) No 1107/2009) and does not cover all the approval criteria. The Authority concluded that quinoxyfen is a PBT substance as well as a vPvB substance.

(10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined.

(11) However, despite the arguments put forward by the applicant, the concerns related to the substance could not be eliminated.

(12) Based on the concerns identified, it has not been established with respect to one or more representative uses of at least one plant protection product containing quinoxyfen that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of quinoxyfen in accordance with Article 20(1)(b) of that Regulation.

(13) Member States should be provided with sufficient time to withdraw authorisations for plant protection products containing quinoxyfen.

(14) For plant protection products containing quinoxyfen, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 27 March 2020.

(15) Commission Implementing Regulation (EU) 2018/524 [2] extended the expiry date of quinoxyfen to 30 April 2019 in order to allow the renewal process to be completed before the expiry of the approval of that substance. Given that a decision has been taken ahead of this extended expiry date, this Regulation should apply as soon as possible.

(16) This Regulation does not prevent the submission of a further application for the approval of quinoxyfen pursuant to Article 7 of Regulation (EC) No 1107/2009.

(17) 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-renewal of approval of active substance

The approval of the active substance quinoxyfen is not renewed.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 82, on quinoxyfen, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing quinoxyfen as active substance by 27 June 2019 at the latest.

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[1] EFSA (European Food Safety Authority), 2018. Peer review of the targeted hazard assessment of the pesticide active substance quinoxyfen. EFSA Journal 2018;16(1):5085 [11 pp.]. DOI: 10.2903/j.efsa.2018.5085.

[2] Commission Implementing Regulation (EU) 2018/524 of 28 March 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances Bacillus subtilis (Cohn 1872) Strain QST 713, identical with strain AQ 713, clodinafop, clopyralid, cyprodinil, dichlorprop-P, fosetyl, mepanipyrim, metconazole, metrafenone, pirimicarb, Pseudomonas chlororaphis strain: MA 342, pyrimethanil, quinoxyfen, rimsulfuron, spinosad, thiacloprid, thiamethoxam, thiram, tolclofos-methyl, triclopyr, trinexapac, triticonazole and ziram (OJ L 88, 4.4.2018, p. 4).

Article 4

Grace Period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 27 March 2020 at the latest.

Article 5

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, 6 December 2018.

For the Commission
The President
Jean-Claude JUNCKER