Commission Implementing Regulation (EU) 2017/1455 of 10 August 2017 concerning the non-renewal of approval of the active substance picoxystrobin, 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1455

of 10 August 2017

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

Whereas:

(1) Commission Directive 2003/84/EC[(2)] included picoxystrobin as 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 picoxystrobin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2017.

(4) An application for the renewal of the approval of picoxystrobin 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 (hereinafter ‘the Authority’) and the Commission on 30 June 2015.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/1455. 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*

(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 1 June 2016 the Authority communicated to the Commission its conclusion[6] on whether picoxystrobin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The following concerns were identified: a clastogenic and aneugenic potential of metabolite IN-H8612 formed as a residue cannot be excluded and a high risk was identified for aquatic organisms and earthworms from exposure to picoxystrobin and for earthworm-eating mammals from exposure to metabolite IN-QDY63. Moreover, a number of areas of the assessment could not be finalised. Based on the data available in the dossier it was not considered possible to complete the assessment of genotoxicity for picoxystrobin and consequently health-based reference values for use in risk assessment could not be established and therefore consumer and non-dietary risk asessements could not be conducted. The compliance of the toxicity studies compared to the technical specification and the relevance of impurities could not be finalised given the incomplete assessment of the genotoxic potential of picoxystrobin. The absence of endocrine-mediated effects caused by picoxystrobin could also not be concluded. The dietary risk assessment from exposure to metabolites could not be finalised as further data are needed to define the toxicological profile of several metabolites; consequently, residue definitions for risk assessment purposes could not be derived. Furthermore, the genotoxic potential of several metabolites predicted to occur in groundwater could not be concluded based on the data available. Finally, the assessment of the risk from secondary poisoning via the aquatic food chain for birds and mammals could not be finalised.

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

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

(11) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 are satisfied. The approval of the active substance picoxystrobin should therefore not be renewed.

(12) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(13) Member States should be allowed sufficient time to withdraw authorisations for plant protection products containing picoxystrobin.

(14) For plant protection products containing picoxystrobin, 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 30 November 2018.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/1455. 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*

(15) Commission Implementing Regulation (EU) 2016/950[7] extended the expiry date of picoxystrobin to 31 October 2017 in order to allow the renewal process to be completed before the expiry of the approval of that substance. Given that a decision is taken ahead of this extended expiry date, this Regulation should apply as soon as possible.

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

(17) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

Article 1

Non-renewal of approval of active substance

The approval of the active substance picoxystrobin is not renewed.

Article 2

Transitional measures

Member States shall withdraw authorisations for plant protection products containing picoxystrobin as active substance by 30 November 2017 at the latest.

Article 3

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 30 November 2018 at the latest.

Article 4

Amendments to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 68, on picoxystrobin, is deleted.