EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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 Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

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(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.

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1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2003/84/EC of 25 September 2003 amending Council Directive 91/414/EEC to include flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam as active substances (OJ L 247, 30.9.2003, p. 20).

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) 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.

(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: health-based reference values for use in risk assessment could not be established as it was not possible to conclude on the genotoxic potential of picoxystrobin based on the available data. Consequently, the consumer and non-dietary risk asessements could not be conducted. Furthermore, a clastogenic and aneugenic potential of metabolite IN-H8612 formed as a residue cannot be excluded. In addition, a high risk to aquatic organisms and earthworms from exposure to picoxystrobin and a high risk to earthworm-eating mammals from exposure to metabolize IN-QDY63 was identified.

(9) Moreover, a number of areas of the assessment could not be finalised. The compliance of the toxicity studies compared to the technical specification and the relevance of impurities could not be finalised given that the genotoxic potential of picoxystrobin remains inconclusive. An *in vitro* comparative metabolism study was not submitted and therefore the possible formation of unique human metabolites is unknown and the need for further tests and risk assessment cannot be concluded. 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, a residue definition 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.

(10) 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 (EC) 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.

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

(12) 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.

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[6] EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance picoxystrobin. EFSA Journal 2016;14(6):4515, 26 pp. doi:10.2903/j.efsa.2016.4515.

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

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

(15) 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 *[publications office insert date 15 months from the date of entry into force]*.

(16) 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.

(17) 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.

(18) 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 picoxystrobin is not renewed.

Article 2
Transitional measures

Member States shall withdraw authorisations for plant protection products containing picoxystrobin as active substance by [*Office of Publications please insert date 3 months from the date of entry into force*] 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 *[insert date 15 months from the date of entry into force]* at the latest.

[7] Commission Implementing Regulation (EU) 2016/950 of 15 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-DB, beta-cyfluthrin, carfentrazone ethyl, *Coniothyrium minitans* Strain CON/M/91-08 (DSM 9660), cyazofamid, deltamethrin, dimethenamid-P, ethofumesate, fenamidone, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mesotrione, oxasulfuron, pendimethalin, picoxystrobin, silthiofam and trifloxystrobin (OJ L 159, 16.6.2016, p. 3).

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.

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,

For the Commission
The President
Jean-Claude JUNCKER