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COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

Whereas:

(1) Commission Directive 2006/10/EC[2] included indoxacarb 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 indoxacarb, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2021.

(4) An application for the renewal of the approval of indoxacarb 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 2006/10/EC of 27 January 2006 amending Council Directive 91/414/EEC to include forchlorfenuron and indoxacarb as active substances (OJ L 25, 28.1.2006, p. 24).

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 draft 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 28 November 2016.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

(8) On 15 December 2017, the Authority communicated to the Commission its conclusion[6] on whether indoxacarb can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The ecotoxicology section of this conclusion was amended in 2018 to clarify the risk assessment for bees according to the relevant European Commission Guidance (SANCO/10329/2002-rev.2). On 15 May 2019, the Commission requested the Authority for an updated peer review concerning the risk to mammals and bees of indoxacarb. On 28 October 2019, the Authority adopted a statement on the updated peer review concerning the risk to mammals and bees posed by the active substance indoxacarb[7] which was reflected in a second update of the Authority's conclusion on whether indoxacarb can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) A critical area of concern was identified by the Authority in relation to the high long-term risk to wild mammals, in particular the long-term risk to small herbivorous mammals.

(10) Additionally, a high risk to consumers and workers was identified for the representative use in lettuce and a high risk to bees was identified for the representative use in maize, sweet corn and lettuce for seed production.

(11) Furthermore, several areas of the risk assessment could not be finalised due to insufficient data in the dossier. In particular, the consumer risk assessment could not be finalised due to lack of data on rotational crop metabolism, data regarding the metabolism in poultry, the magnitude of residues in primary and rotational crops and data on the effect of water treatment processes on the nature of residues in drinking water. In addition, the assessment concerning groundwater exposure for soil metabolite IN-U8E24 could not be finalised due to lack of data on soil degradation and adsorption. Similarly, the ecotoxicological risk assessment for several metabolites could not be finalised.

(12) On 14 November 2018, the applicant informed the Commission of its decision to withdraw from the renewal application the representative use in lettuce.

(13) The Commission invited the applicant to submit its comments on the conclusion of the Authority, the revised conclusion and the statement. Furthermore, in accordance with the third subparagraph 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.

(14) However, despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.

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6 EFSA Journal 2018;16(1):5140, 36 pp. doi:10.2903/j.efsa.2018.5140. Available online: www.efsa.europa.eu.

7 EFSA (European Food Safety Authority), 2019. Statement on the updated peer review concerning the risk to mammals and bees for the active substance indoxacarb. EFSA Journal 2019;17(10):5866, 10 pp.

(15) 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 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance indoxacarb in accordance with Article 20(1)(b) of that Regulation.

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

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

(18) For plant protection products containing indoxacarb, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should be as short as possible]

(19) Commission Implementing Regulation (EU) 2020/1511[8] extended the expiry date of indoxacarb to 31 October 2021 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 as soon as possible.

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

(21) 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 indoxacarb 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 119, on indoxacarb, is deleted.

Article 3

Transitional measures

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

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[8] Commission Implementing Regulation (EU) 2020/1511 of 16 October 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, picloram, prosulfocarb, sulphur, triflusulfuron and tritosulfuron (OJ L 344, 19.10.2020).

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by *[Office of Publications please insert date 6 months from the date of entry into force]*.

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
Ursula VON DER LEYEN