COMMISSION IMPLEMENTING REGULATION (EU) 2019/717

of 8 May 2019

renewing the approval of the active substance isoxaflutole 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 2003/68/EC ([2]) included isoxaflutole 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 isoxaflutole as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 31 July 2019.

(4) An application for the renewal of the approval of isoxaflutole 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 28 January 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 18 February 2016, the Authority communicated to the Commission its conclusion ([6]) on whether isoxaflutole can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented an initial draft renewal report for isoxaflutole to the Standing Committee on Plants, Animals, Food and Feed on 12 July 2016.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Directive 2003/68/EC of 11 July 2003 amending Council Directive 91/414/EEC to include trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone and isoxaflutole as active substances (OJ L 177, 16.7.2003, p. 12).
([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 (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance isoxaflutole. *EFSA Journal* 2016;14(3):4416, 115 pp. doi:10.2903/j.efsa.2016.4416. Available online: www.efsa.europa.eu.

(9) As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ([7]), which became applicable on 10 November 2018, the conclusion of the Authority infers that while no specific studies were available for non-target organisms, it is highly unlikely that isoxaflutole is an endocrine disrupter based on the scientific evidence and that no additional studies are considered necessary. Thus, the Commission considers that isoxaflutole is not to be considered as having endocrine disrupting properties.

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

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

(12) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

(13) The Commission considers that isoxaflutole does not have endocrine disrupting properties based on the available scientific information summarised in the conclusion of the Authority. However, in order to increase the confidence in this conclusion, the applicant should provide an updated assessment, in accordance with point 2.2(b) of Annex II to Regulation (EC) No 1107/2009, of the criteria laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 and in accordance with the guidance for the identification of endocrine disruptors ([8]).

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

(15) This Regulation should apply from the day after the date of expiry of the approval of the active substance isoxaflutole.

(16) 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 active substance

The approval of the active substance isoxaflutole, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

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 August 2019.

([7]) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

([8]) Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5311

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

Done at Brussels, 8 May 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Isoxaflutole CAS No 141112-29-0 CIPAC No 575	(5-cyclopropyl-1,2-oxazol-4-yl)(α,α,α-trifluoro-2-mesyl-p-tolyl)methanone	≥ 972 g/kg	1 August 2019	31 July 2034	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 isoxaflutole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment, Member States shall pay particular attention to: — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions, — the protection of aquatic organisms, wild mammals and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit this information within 2 years from the date of publication, by the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. The applicant shall also provide an updated assessment to confirm that isoxaflutole is not an endocrine disruptor within the meaning of points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 and in accordance with the guidance for the identification of endocrine disruptors (2) by 10 May 2021.

(1) Further details on the identity and the specification of the active substance are provided in the renewal report.
(2) Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 https://efsa.onlinelibrarv.wilev.eom/doi/epdt710.2903/i.efsa.2018.5311

ANNEX II

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

(1) in Part A, entry 63 on isoxaflutole is deleted;

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

'134	Isoxaflutole CAS No 141112-29-0 CIPAC No 575	(5-cyclopropyl-1,2-oxazol-4-yl)(α,α,α-trifluoro-2-mesyl-p-tolyl)methanone	≥ 972 g/kg	1 August 2019	31 July 2034	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 isoxaflutole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment, Member States shall pay particular attention to: — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions, — the protection of aquatic organisms, wild mammals and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit this information within 2 years from the date of publication, by the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. The applicant shall also provide an updated assessment to confirm that isoxaflutole is not an endocrine disruptor within the meaning of points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 and in accordance with the guidance for identification of endocrine disruptors (*) by 10 May 2021.

(*) Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 https://efsa.onlinelibrarv.wilev.eom/doi/epdt710.2903/i.efsa.2018.5311'.