Commission Implementing Regulation (EU) 2020/968 of 3 July 2020 renewing the approval of the active substance pyriproxyfen 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) 2020/968

of 3 July 2020

renewing the approval of the active substance pyriproxyfen 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 2008/69/EC[(2)] included pyriproxyfen 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 pyriproxyfen, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 December 2020.

(4) An application for the renewal of the approval of the active substance pyriproxyfen 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 14 December 2017.

Changes to legislation: *Commission Implementing Regulation (EU) 2020/968 is up to date with all changes known to be in force on or before 28 February 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicants 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 17 May 2019, the Authority communicated to the Commission its conclusion[(6)] on whether pyriproxyfen can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report on pyriproxyfen to the Standing Committee on Plants, Animals, Food and Feed on 21 October 2019.

(9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[(7)], the conclusion of the Authority indicates that pyriproxyfen is not an endocrine disrupter.

(10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph 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) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance pyriproxyfen that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(12) The risk assessment for the renewal of the approval of the active substance pyriproxyfen is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing pyriproxyfen may be authorised.

(13) It is therefore appropriate to renew the approval of pyriproxyfen.

(14) 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 provide for certain conditions. It is, in particular, appropriate to require further confirmatory information.

(15) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(16) Commission Implementing Regulation (EU) 2019/1589[(8)] extended the approval period of pyriproxyfen to 31 December 2020 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal of the approval is taken ahead of the expiry of that extended approval period, this Regulation should apply from 1 August 2020, except for the provision concerning toluene content specified in column ‘Purity’ of the table in Annex I, which should apply from 1 August 2021.

(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:

***Changes to legislation:** Commission Implementing Regulation (EU) 2020/968 is up to date with all changes known to be in force on or before 28 February 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Article 1

Renewal of the approval of the active substance

The approval of the active substance pyriproxyfen is renewed as set out in Annex I.

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 2020.

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

Done at Brussels, 3 July 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *Commission Implementing Regulation (EU) 2020/968 is up to date with all changes known to be in force on or before 28 February 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Pyriproxyfen. 2-((1-(4-Phenoxyphenoxy)propan-2-yl)oxy)pyridine CIPAC No: 715. CAS No: 95737-68-1. EC No (Einecs or ELINCS): 429-800-1	4-phenoxyphenyl (*RS*)-2-(2-pyridyloxy) propyl ether	≥ 970 g/kg From 1 August 2021 Max. impurity: Toluene 5 g/Kg	1 August 2020	31 July 2035	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 pyriproxyfen 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 dietary exposure of consumers to residues of pyriproxyfen, — the protection of sediment-dwelling organisms and aquatic organisms,

a Further details on the identity and the specification of the active substance are provided in the renewal report.

***Changes to legislation:** Commission Implementing Regulation (EU) 2020/968 is up to date with all changes known to be in force on or before 28 February 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

					— the protection of bees. As regards the protection of sediment-dwelling organisms and aquatic organisms, for outdoor use of the plant protection products containing pyriproxyfen Member States shall include in the specific conditions appropriate risk mitigation measures, e.g. no-spray buffer zones and/ or spray drift reduction, to achieve a low risk for sediment-dwelling organisms and aquatic organisms. As regards the protection of bees, for outdoor use of plant protection products containing pyriproxyfen Member States shall include in the specific

a Further details on the identity and the specification of the active substance are provided in the renewal report.