Official Journal
of the European Union

EN
L series

2025/1152

12.6.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1152

of 11 June 2025

renewing the approval of the active substance quinolin-8-ol as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulations (EU) No 540/2011 and (EU) 2015/408

(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), in conjunction with Article 24(1) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 993/2011 ([2]) included 8-hydroxyquinoline (common name for quinolin-8-ol) as an active substance in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]).

(2) In the meantime, the Commission extended the approval period of quinolin-8-ol, originally expiring on 31 December 2021, four times in accordance with Article 17 of Regulation (EC) No 1107/2009.

(3) The approval of the active substance quinolin-8-ol, as set out in Part B of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 December 2025.

(4) An application for the renewal of the approval as a candidate for substitution of the active substance quinolin-8-ol was submitted by the applicant, to Spain, the rapporteur Member State, and the Netherlands, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([4]) and within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be admissible by the rapporteur Member State.

(6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 9 July 2021. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of quinolin-8-ol.

([1]) OJ L 309, 24.11.2009, p. 1. ELI: http://data.europa.eu/eli/reg/2009/1107/oj.

([2]) Commission Implementing Regulation (EU) No 993/2011 of 6 October 2011 approving the active substance 8-hydroxyquinoline, 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 (OJ L 263, 7.10.2011, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2011/993/oj).

([3]) 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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

([4]) 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, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj).

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft 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 28 February 2024, the Authority communicated to the Commission its conclusion ([5]) indicating that, taking into account the approval criteria laid down in Annex II to Regulation (EC) No 1107/2009, plant protection products containing quinolin-8-ol can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The conclusion of the Authority also indicated that quinolin-8-ol is not considered to meet the criteria for endocrine disrupting properties as laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009.

(9) Commission Regulation (EU) 2017/776 ([6]) amended Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([7]) to include quinolin-8-ol (as 8-hydoxyquinoline) with classification as toxic for reproduction category 1B.

(10) Active substances that are classified as toxic for reproduction category 1B can only be approved if it is demonstrated that exposure to humans is negligible. The representative uses of quinolin-8-ol, which include conditions and restrictions, showed that, under these conditions and restrictions, negligible exposure of humans can be demonstrated, through both dietary and non-dietary exposure routes.

(11) The Commission communicated a renewal report to the Member States and the applicant on 13 June 2024 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 10 July 2024.

(12) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.

(13) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance quinolin-8-ol that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(14) Although the risk assessment for the renewal of the approval of the active substance quinolin-8-ol is based on a limited number of representative uses, this does not restrict the uses for which plant protection products containing quinolin-8-ol may be authorised. It is therefore appropriate not to maintain the restriction to use this active substance as a fungicide and bactericide only.

(15) Given that quinolin-8-ol is classified as toxic for reproduction category 1B, it fulfils the condition set in the sixth indent of point 4 of Annex II to Regulation (EC) No 1107/2009 to be approved as a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009.

(16) It is therefore appropriate to renew the approval of quinolin-8-ol as a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009.

(17) 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 and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions and restrictions. In particular, only professional uses of plant protection products containing quinolin-8-ol in permanent greenhouses that allow controlled exchange of material and energy with the surroundings and prevent release of plant protection products into the environment, by drip-irrigation, should be

([5]) EFSA (European Food Safety Authority), 2024. Peer review of the pesticide risk assessment of the active substance quinolin-8-ol. *EFSA Journal* 2024; 22(3):e8670 https://doi.org/10.2903/j.efsa.2024.8670.

([6]) Commission Regulation (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 116, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/776/oj).

([7]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

authorised, in order to ensure a negligible exposure of operators, workers, bystanders and residents. For the same reason, uses of quinolin-8-ol should be authorised only where a closed transfer system for loading and mixing the plant protection product into the application equipment is available. Additionally, a pre-harvest interval should be set and the re-use of soil in which crops treated with plant protection products containing quinolin-8-ol, are grown in permanent greenhouses should be restricted, in order to address the risk to soil macro-organisms identified by EFSA.

(18) It is also necessary to require further confirmatory information from the applicant as regards the non-dietary exposure to the active substance, confined rotational crops metabolism data addressing the fate of the parent compound in succeeding crops, as well as studies or information to confirm a lack of clastogenic and aneugenic potential for quinolin-8-ol.

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

(20) Commission Implementing Regulation (EU) 2015/408 ([8]) included 8-hydroxyquinoline (quinolin-8-ol) in the list of candidates for substitution. In the light of the renewal of approval of quinolin-8-ol as a candidate for substitution and the corresponding inclusion of quinolin-8-ol to Part E of the Annex to Implementing Regulation (EU) No 540/2011, the entry for quinolin-8-ol should be deleted from the Annex to Implementing Regulation (EU) 2015/408.

(21) Commission Implementing Regulation (EU) 2024/2781 ([9]) extended the approval period of quinolin-8-ol to 31 December 2025 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 the renewal of the approval of that active substance has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.

(22) This Regulation does not prevent the applicant from submitting additional information to amend the conditions of approval, as provided in Articles 7 and 14 of Regulation (EC) No 1107/2009.

(23) 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 the active substance

The approval of the active substance quinolin-8-ol, as specified in Annex I to this Regulation, is renewed, subject to the conditions and restrictions laid down in that Annex.

([8]) Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution. (OJ L 67, 12.3.2015, p. 18, ELI: http://data.europa.eu/eli/reg_impl/2015/408/oj).

([9]) Commission Implementing Regulation (EU) 2024/2781 of 31 October 2024 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 8-hydroxyquinoline, aminopyralid, azoxystrobin, *Candida oleophila* strain O, chlorantraniliprole, fluroxypyr, imazalil, kresoxim-methyl, metobromuron, oxyfluorfen, *Paecilomyces fumosoroseus* strain FE 9901, tefluthrin and terbuthylazine (OJ L, 2024/2781, 4.11.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2781/oj).

Article 2

Amendment 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

Amendment to Implementing Regulation (EU) 2015/408

The entry for quinolin-8-ol is deleted from the Annex to Implementing Regulation (EU) 2015/408.

Article 4

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 July 2025.

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

Done at Brussels, 11 June 2025.

For the Commission
The President
Ursula VON DER LEYEN

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Quinolin-8-ol CAS No: 148-24-3 CIPAC No: 677	Quinolin-8-ol	≥ 990 g/kg	1 July 2025	30 June 2032	Only uses by drip-irrigation by professional users in permanent greenhouses that allow controlled exchange of material and energy with the surroundings and prevent release of plant protection products into the environment may be authorised. Authorisations shall only be granted for uses where a closed transfer system for loading and mixing the plant protection product into the application equipment is available. A pre-harvest interval of at least 22 days after the last application must be respected and the soil in which crops are grown in permanent greenhouses shall not be re-used outside the greenhouse within 1 year after the last application. 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 quinolin-8-ol, 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 necessary personal protective equipment for operators and workers. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the non-dietary exposure for workers and operators, in particular a study examining exposure to workers and operators under realistic conditions of use; (2) confined rotational crops metabolism data addressing the fate of the parent compound in succeeding crops; (3) studies or information to confirm a lack of clastogenic and aneugenic potential for quinolin-8-ol. The applicant shall submit the information under points 1 and 2 by 2 July 2027 and under point 3 by 2 July 2026.

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

ANNEX II

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

(1) in Part B, entry 18 on 8-hydroxyquinoline is deleted;

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

No	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
'16	Quinolin-8-ol CAS No: 148-24-3 CIPAC No: 677	Quinolin-8-ol	≥ 990 g/kg	1 July 2025	30 June 2032	Only uses by drip-irrigation by professional users in permanent greenhouses that allow controlled exchange of material and energy with the surroundings and prevent release of plant protection products into the environment may be authorised. Authorisations shall only be granted for uses where a closed transfer system for loading and mixing the plant protection product into the application equipment is available. A pre-harvest interval of at least 22 days after the last application must be respected and the soil in which crops are grown in permanent greenhouses shall not be re-used outside the greenhouse within 1 year after the last application. 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 quinolin-8-ol, 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 necessary personal protective equipment for operators and workers. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the non-dietary exposure for workers and operators, in particular a study examining exposure to workers and operators under realistic conditions of use; (2) confined rotational crops metabolism data addressing the fate of the parent compound in succeeding crops; (3) studies or information to confirm a lack of clastogenic and aneugenic potential for quinolin-8-ol. The applicant shall submit the information under points 1 and 2 by 2 July 2027 and under point 3 by 2 July 2026.

[1] Further details on the identity and specification of the active substance are provided in the renewal report.'