

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2049

of 24 November 2021

renewing the approval of the active substance cypermethrin as a candidate for substitution 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) in conjunction with Article 24(1) thereof,

Whereas:

- (1) Commission Directive 2005/53/EC ⁽²⁾ included cypermethrin 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 cypermethrin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2022.
- (4) An application for the renewal of the approval of cypermethrin 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 applicants 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.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ L 241, 17.9.2005, p. 51).

⁽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 8 May 2017.
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft 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 8 August 2018, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether cypermethrin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. Following discussions with the Member States, the Authority was mandated by the Commission to examine additional risk mitigation measures that were not included in the Authority's conclusion. In its statement on risk mitigation measures on cypermethrin published on 4 October 2019 ⁽⁷⁾, the Authority presented the levels of the necessary drift reduction and the measures that would be needed to demonstrate low risk to the non-target organisms, in particular aquatic organisms and non-target arthropods, including bees. The Commission presented a draft renewal report for cypermethrin to the Standing Committee on Plants, Animals, Food and Feed on 24-25 January 2019.
- (9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ⁽⁸⁾, on the basis of the available scientific information summarised in the conclusion of the Authority, the Commission considers that cypermethrin is not to be considered as having endocrine disrupting properties.
- (10) The Commission invited the applicants to submit 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 applicants submitted comments, which have been carefully examined.
- (11) The representative uses are spray applications outdoors, for which the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied provided that appropriate mitigation measures are taken to ensure the required protection level for aquatic organisms and non-targeted arthropods including bees. Therefore, it has been established with respect to one or more representative uses of at least one plant protection product containing cypermethrin that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied where appropriate conditions and restrictions according to Article 6 of Regulation (EC) No 1107/2009 are set.
- (12) The risk assessment for the renewal of the approval of cypermethrin is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing cypermethrin may be authorised. It is therefore appropriate not to maintain the restriction to use as an insecticide.
- (13) The Commission, however, considers that cypermethrin is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Given that cypermethrin is a mixture of eight isomers, and it contains a significant proportion of non-active isomers, it fulfils the condition set out in the fourth indent of point 4 of Annex II to Regulation (EC) No 1107/2009.
- (14) It is therefore appropriate to renew the approval of cypermethrin as a candidate for substitution.

⁽⁶⁾ EFSA Journal 2018;16(8):5402. Conclusion on the peer review of the pesticide risk assessment of the active substance cypermethrin. Available online: www.efsa.europa.eu.

⁽⁷⁾ <https://www.efsa.europa.eu/en/efsajournal/pub/5822>.

⁽⁸⁾ 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).

- (15) 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 and restrictions. It is, in particular, appropriate to require further confirmatory information.
- (16) In order to increase the confidence in the conclusion that cypermethrin does not have endocrine disrupting properties, the applicants 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 ⁽⁹⁾.
- (17) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (18) Commission Implementing Regulation (EU) 2021/1449 ⁽¹⁰⁾ extended the approval period of cypermethrin to 31 October 2022 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 has been taken ahead of that extended expiry date, this Regulation shall apply as soon as possible.
- (19) 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 cypermethrin 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 twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 February 2022.

⁽⁹⁾ Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. <https://www.efsa.europa.eu/en/efsajournal/pub/5311>.

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2021/1449 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenoxy, chlormequat, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, etofenprox, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sulphur, tetraconazole, tri-allate, triflusalufuron and tritosulfuron (OJ L 313, 6.9.2021, p. 20).

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

Done at Brussels, 24 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (%)	Date of approval	Expiration of approval	Specific provisions
Cypermethrin CAS No 52315-07-8 CIPAC No 332	(RS)- α -cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (RS)- α -cyano-3-phenoxybenzyl-(1RS)-cis-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	920 g/kg cis:trans: 40/60 to 60/40 The following impurities are of toxicological concern and must not exceed the following levels in the technical material: hexane: 5g/kg	1 February 2022	31 January 2029	<p>Authorisations shall be limited to professional users.</p> <p>When authorising plant protection products containing cypermethrin for spray applications outdoors, in order to ensure the protection of non-target organisms, in particular aquatic organisms and non-target arthropods, including bees:</p> <ul style="list-style-type: none"> — risk mitigation measures achieving reduction of drift shall be required that lead to exposure $\leq 5,8$ mg a.s./ha in off-crop areas and, in addition, for spring applications to concentrations in water bodies $\leq 0,0038$ μg a.s./L, — only uses outside flowering of the crop and when no flowering weeds are present may be authorised. <p>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 cypermethrin, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic organisms, non-target arthropods, including bees; — the consumer risk assessment; — the technical specification of the active substance used in plant protection products.

				<p>Where considered appropriate, Member States shall set monitoring requirements when granting authorisations in accordance with Article 6(i) of the Regulation (EC) No 1107/2009, in order to complement the monitoring under Directives of the European Parliament and of the Council 2000/60/EC ⁽²⁾ and 2009/128/EC ⁽³⁾.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the toxicological profile of the metabolites bearing the 3-phenoxybenzoyl moiety; 2. the relative toxicity of individual cypermethrin isomers, in particular the enantiomer (1S cis αR); 3. 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. 4. Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605. <p>The applicant shall submit:</p> <ul style="list-style-type: none"> — the information referred to in point 1 by 15 December 2022; — the information referred to in point 2 by 15 December 2023; and — the information referred to in point 3 within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.
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					As regards Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of endocrine activity shall be submitted by 15 December 2023.
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⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

⁽²⁾ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

⁽³⁾ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

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

(1) in Part A, entry 103 on cypermethrin is deleted;

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

'14	Cypermethrin CAS No 52315-07-8 CIPAC No 332	(RS)- α -cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (RS)- α -cyano-3-phenoxybenzyl-(1RS)-cis-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	920 g/kg cis:trans: 40/60 to 60/40 The following impurities are of toxicological concern and must not exceed the following levels in the technical material: hexane: 5g/kg	1 February 2022	31 January 2029	<p>Authorisations shall be limited to professional users.</p> <p>When authorising plant protection products containing cypermethrin for spray applications outdoors, in order to ensure the protection of non-target organisms, in particular aquatic organisms and non-target arthropods, including bees:</p> <ul style="list-style-type: none"> — risk mitigation measures achieving reduction of drift shall be required that lead to exposure $\leq 5,8$ mg a.s./ha in off-crop areas and, in addition, for spring applications to concentrations in water bodies $\leq 0,0038$ μg a.s./L, — only uses outside flowering of the crop and when no flowering weeds are present may be authorised. <p>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 cypermethrin, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic organisms, non-target arthropods, including bees; — consumer risk assessment; — the technical specification of the active substance used in plant protection products.
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					<p>Where considered appropriate, Member States shall set monitoring requirements when granting authorisations in accordance with Article 6(i) of the Regulation (EC) No 1107/2009, in order to complement the monitoring under Directives of the European Parliament and of the Council 2000/60/EC (*) and 2009/128/EC (**).</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the toxicological profile of the metabolites bearing the 3-phenoxybenzoyl moiety; 2. the relative toxicity of individual cypermethrin isomers, in particular the enantiomer (1S cis αR); 3. 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. 4. Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 <p>The applicant shall submit:</p> <ul style="list-style-type: none"> — the information referred to in point 1 by 15 December 2022; — the information referred to in point 2 by 15 December 2023; and — the information referred to in point 3 within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.
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						As regards Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of endocrine activity shall be submitted by 15 December 2023.
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(*) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

(**) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of EN 5 EN pesticides (OJ L 309, 24.11.2009, p. 71).'