COMMISSION IMPLEMENTING REGULATION (EU) 2019/1690

of 9 October 2019

renewing the approval of the active substance alpha-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 2004/58/EC ([2]) included alpha-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 alpha-cypermethrin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2020.

(4) An application for the renewal of the approval of alpha-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 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 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 7 May 2017.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Directive 2004/58/EC of 23 April 2004 amending Council Directive 91/414/EEC to include alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham as active substances (OJ L 120, 24.4.2004, p. 26).
([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).

(7) The Authority communicated the draft 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 7 August 2018, the Authority communicated to the Commission its conclusion ([6]) on whether alpha-cypermethrin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the renewal report for alpha-cypermethrin to the Standing Committee on Plants, Animals, Food and Feed on 24 and 25 January 2019.

(9) The applicant was given the opportunity to submit comments on the draft renewal report.

(10) As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ([7]), the conclusion of the Authority indicates that it is highly unlikely that alpha-cypermethrin is an endocrine disrupter via the estrogenic, steroidogenic and thyroid modalities. Furthermore, the available evidence indicates that alpha-cypermethrin is unlikely to be an endocrine disruptor via the androgenic modality. Thus, the Commission considers that alpha-cypermethrin is not to be considered as having endocrine disrupting properties.

(11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance 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 alpha-cypermethrin is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing alpha-cypermethrin may be authorised. It is therefore appropriate not to maintain the restriction to use as an insecticide only.

(13) The Commission, however, considers that alpha-cypermethrin is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Some of its toxicological reference values are significantly lower than those of the majority of the approved active substances within groups of substances. Alpha-cypermethrin, therefore fulfils the condition set in the first indent of point 4 of Annex II to Regulation (EC) No 1107/2009.

(14) It is therefore appropriate to renew the approval of alpha-cypermethrin as a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009.

(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. It is, in particular, appropriate to require further confirmatory information.

(16) The Commission considers that alpha-cypermethrin 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 for the androgenic modality, 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]).

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

([6]) *EFSA Journal* 2018;16(8):5403.
([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/10.2903/j.efsa.2018.5311

(18) Commission Implementing Regulation (EU) 2019/707 ([9]) extended the expiry date of alpha-cypermethrin to 31 July 2020 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 start to apply earlier than that date.

(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 as a candidate for substitution

The approval of the active substance alpha-cypermethrin, as a candidate for substitution, 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 November 2019.

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

Done at Brussels, 9 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

([9]) Commission Implementing Regulation (EU) 2019/707 of 7 May 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, desmedipham, dimethoate, dimethomorph, diuron, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, metalaxyl-m, methiocarb, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, s-metolachlor and tebuconazole (OJ L 120, 8.5.2019, p. 16).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
alpha-cypermethrin CAS No 67375-30-8 CIPAC No 454	Racemate comprising: (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (R)-α-cyano-3 phenoxybenzyl-(1S)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3 phenoxybenzyl-(1R)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	≥ 980 g/kg The manufacturing impurity hexane is considered to be of toxicological concern and must not exceed 1 g/kg in the technical material.	1 November 2019	31 October 2026	For the implementation of the uniform principles, as referred to in Article 9(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on alpha-cypermethrin, 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 operators, ensuring that the conditions of use prescribe the application of adequate personal protective equipment; — the consumer risk assessment; — the protection of aquatic organisms, bees and non-target arthropods. 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: 1. the toxicological profile of the metabolites bearing the 3-phenoxybenzoyl moiety; 2. the potential 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 of Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605. The applicant shall submit the information referred to in point 1 by 30 October 2020; the information referred to in point 2 within two years from the date of publication, by the Commission, of a guidance document on evaluation of isomer mixtures; and the

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
					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. As regards Points 3.6.5 and 3.8.2 of Annex II of 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 androgenic endocrine activity shall be submitted by 30 October 2021.

(1) Further details on identity and specification of 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 A, entry 83 on alpha-cypermethrin is deleted;

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

No	Common Name, Identification Numbers	IUPAC Name	Purity (')	Date of approval	Expiration of approval	Specific provisions
'12	alpha-cypermethrin CAS No 67375-30-8 CIPAC No 454	Racemate comprising: (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (R)-α-cyano-3 phenoxybenzyl-(1S)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3 phenoxybenzyl-(1R)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	≥ 980 g/kg The manufacturing impurity hexane is considered to be of toxicological concern and must not exceed 1 g/kg in the technical material	1 November 2019	31 October 2026	For the implementation of the uniform principles, as referred to in Article 9(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on alpha-cypermethrin, 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 operators, ensuring that the conditions of use prescribe the application of adequate personal protective equipment; — the consumer risk assessment; — the protection of aquatic organisms, bees and non-target arthropods. 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: 1. the toxicological profile of the metabolites bearing the 3-phenoxybenzoyl moiety; 2. the potential 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;

No	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
						4. Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605. The applicant shall submit the information referred to in point 1 by 30 October 2020; the information referred to in point 2 within two years from the date of publication, by the Commission, of a guidance document on evaluation of isomer mixtures; 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. As regards Points 3.6.5 and 3.8.2 of Annex II of 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 androgenic endocrine activity shall be submitted by 30 October 2021.'

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

COMMISSION REGULATION (EU) 2019/1691

of 9 October 2019

amending Annex V to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([1]), and in particular Article 131 thereof,

Whereas:

(1) Annex V to Regulation (EC) No 1907/2006 contains a list of substances that are exempt from the obligation to register in accordance with Article 2(7)(b) of that Regulation.

(2) Digestate is a residual semisolid or liquid material that has been sanitised and stabilised by a biological treatment process, of which the last step is an anaerobic digestion step, and where the inputs used in that process are biodegradable materials originating only from non-hazardous source segregated materials, such as food waste, manure and energy crops. Biogas resulting from the same process as digestate or from other anaerobic digestion processes, as well as compost resulting from the aerobic decomposition process of similar biodegradable materials, are already listed in Annex V to Regulation (EC) No 1907/2006. Therefore, digestate that is either not waste or has ceased to be waste should also be listed in that Annex, as it is inappropriate and unnecessary to require that substance to be registered and as its exemption from Titles II, V and VI of Regulation (EC) No 1907/2006 does not prejudice the objectives of that Regulation.

(3) So far, no registrations have been submitted for digestate. The listing of digestate in Annex V of Regulation (EC) No 1907/2006 should clarify that digestate is exempted from registration, for reasons analogous to those that justify the existing exemption of compost and biogas, thereby removing uncertainties encountered by producers and users of digestate and by enforcement authorities.

(4) Annex V to Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

([1]) OJ L 396, 30.12.2006, p. 1.