COMMISSION IMPLEMENTING REGULATION (EU) 2018/710

of 14 May 2018

renewing the approval of the active substance silthiofam 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 2003/84/EC ([2]) included silthiofam 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 silthiofam, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2018.

(4) An application for the renewal of the approval of silthiofam 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 22 June 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 1 August 2016 the Authority communicated to the Commission its conclusion ([6]) on whether silthiofam 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 for silthiofam to the Standing Committee on Plants, Animals, Food and Feed on 22 March 2018.

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

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2003/84/EC of 25 September 2003 amending Council Directive 91/414/EEC to include flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam as active substances (OJ L 247, 30.9.2003, p. 20).

([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 silthiofam. EFSA Journal 2016;14(8):4574, 59 pp. doi:10.2903/j.efsa.2016.4574; Available online: www.efsa.europa.eu.

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

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

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

(14) Commission Implementing Regulation (EU) 2017/1511 [1] extended the approval period of silthiofam to 31 October 2018 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 apply from 1 July 2018.

(15) 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 silthiofam 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 July 2018.

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

Done at Brussels, 14 May 2018.

For the Commission
The President
Jean-Claude JUNCKER

[1] Commission Implementing Regulation (EU) 2017/1511 of 30 August 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, cypermethrin, daminozide, deltamethrin, dimethenamid-p, flufenacet, flurtamone, forchlorfenuron, fosthiazate, indoxacarb, iprodione, MCPA, MCPB, silthiofam, thiophanate-methyl and tribenuron (OJ L 224, 31.8.2017, p. 115).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Silthiofam CAS No 175217-20-6 CIPAC No 635	N-allyl-4,5-dimethyl-2-(trimethylsilyl)thiophene-3-carboxamide	≥ 980 g/kg	1 July 2018	30 June 2033	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 silthiofam and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the protection of operators, — the protection of groundwater in vulnerable regions, — the protection of birds, mammals and earthworms. 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 effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water; 2. the relevance of the metabolites M2 and M6 taking into account any relevant classification for silthiofam in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council (2), in particular as reprotoxic category 2. The applicant shall submit the information mentioned in point (1) within two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater is made public by the Commission and the information requested under point (2) within one year after the publication in the European Chemicals Agency (ECHA) webpage of the opinion adopted by the Committee for risk assessment of the ECHA in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to silthiofam.

(1) Further details on identity and specification of active substance are provided in the review report.
(2) 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).

ANNEX II

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

(1) in Part A, the entry 70 for Silthiofam is deleted;

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

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'121	Silthiofam CAS No 175217-20-6 CIPAC No 635	N-allyl-4,5-dimethyl-2-(trimethylsilyl)thiophene-3-carboxamide	≥ 980 g/kg	1 July 2018	30 June 2033	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 silthiofam and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the protection of operators, — the protection of groundwater in vulnerable regions, — the protection of birds, mammals and earthworms. 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 effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water; 2. the relevance of the metabolites M2 and M6 taking into account any relevant classification for silthiofam in accordance with Regulation (EC) No 1272/2008, in particular as reprotoxic category 2. The applicant shall submit the information mentioned in point (1) within two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater is made public by the Commission and the information requested under point (2) within one year after the publication in the European Chemicals Agency (ECHA) webpage of the opinion adopted by the Committee for risk assessment of the ECHA in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to silthiofam.'

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