EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11271/2018
[…](2018) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

renewing the approval of the active substance tolclofos-methyl 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)

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(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 2006/39/EC[2] included tolclofos-methyl 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 tolclofos-methyl, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2020.

(4) An application for the renewal of the approval of tolclofos-methyl 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. 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.

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1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2006/39/EC of 12 April 2006 amending Council Directive 91/414/EEC to include clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole as active substances as active substance **(**OJ L 104, 13.4.2006, p. 30).

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 amending 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).

(5) 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 11 November 2016.

(6) 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.

(7) On 8 December 2017, the Authority communicated to the Commission its conclusion[6] on whether tolclofos-methyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. An amended version of this conclusion was adopted by the Authority on 5 October 2018 and re-published on 15 November 2018 with an explanation concerning the partially acceptable risk for aquatic organisms (one FOCUS scenario out of the 3 is considered as acceptable) from the representative uses in ornemental crops for protected structures. The initial version of the conclusions was removed from EFSA Journal. The Commission presented the draft renewal report for tolclofos-methyl to the Standing Committee on Plants, Animals, Food and Feed on 24 October 2018.

(8) As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[7], which became applicable on 10 November 2018, the conclusion of the Authority, based on the fact that there was no evidence of endocrine-mediated effects *in vivo*, infers that it is unlikely that tolclofos-methyl is an endocrine disrupter. Thus, the Commission considers that tolclofos-methyl is not to be considered as having endocrine disrupting properties.

(9) The Commission invited the applicant to submit its comments on the amended version of the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EC) No 844/2012, on the draft renewal report. The applicant submitted its comments, which have been carefully examined.

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

(11) It is therefore appropriate to renew the approval of tolclofos-methyl.

(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 restrict the use of plant protection products containing tolclofos-methyl in order to minimise the exposure for consumers to certain metabolites and to reduce the exposure of aquatic organisms and wild mammals to this substance by approving its use in ornamentals and potatoes only.

(13) The risk assessment for the renewal of the approval of tolclofos-methyl is based on a limited number of representative uses, which, however, do not restrict the uses for

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6 EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance tolclofos-methyl. EFSA Journal 2018;16(1):5130 [25 pp.]. doi: 10.2903/j.efsa.2018.5130.

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, 20.04.2018, p. 33).

which plant protection products containing tolclofos-methyl may be authorised. It is therefore appropriate to remove the restriction for use only as a fungicide.

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

(15) Implementing Regulation (EU) 2019/168[8] extended the expiry date of tolclofos-methyl to 30 April 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 apply from 1 August 2019.

(16) 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 approval of active substance

The approval of the active substance tolclofos-methyl 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 2019.

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

[8] Commission Implementing Regulation (EU) 2019/168 of 31 January 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, Bacillus subtilis (Cohn 1872) Strain QST 713, Bacillus thuringiensis subsp. Aizawai, Bacillus thuringiensis subsp. israeliensis, Bacillus thuringiensis subsp. kurstaki, Beauveria bassiana, benfluralin, clodinafop, clopyralid, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, epoxiconazole, fenpyroximate, fluazinam, flutolanil, fosetyl, Lecanicillium muscarium, mepanipyrim, mepiquat, Metarhizium anisopliae var. Anisopliae, metconazole, metrafenone, Phlebiopsis gigantea, pirimicarb, Pseudomonas chlororaphis strain: MA 342, pyrimethanil, Pythium oligandrum, rimsulfuron, spinosad, Streptomyces K61, thiacloprid, tolclofos-methyl, Trichoderma asperellum, Trichoderma atroviride, Trichoderma gamsii, Trichoderma harzianum, triclopyr, trinexapac, triticonazole, Verticillium albo-atrum and ziram (*OJ L 33, 5.2.2019, p. 1).*

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

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ANNEXES 1 to 2

ANNEXES

to the

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ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity[1]	Date of approval	Expiration of approval	Specific provisions
Tolclofos-methyl CAS No 57018-04-9 CIPAC No 479	O-2,6-dichloro-p-tolylO,O-dimethyl phosphorothioate O-2,6-dichloro-4-methylphenyl O,O-dimethyl phosphorothioate	≥ 960 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material: Methanol max. 1 g/kg	1 August 2019	31 July 2034	Only for use on ornamentals and on potatoes. 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 tolclofos-methyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the risk to aquatic organisms and mammals; - the risk to consumers, in particular the potential risk from metabolite DM-TM-CH_2OH in potatoes; - the risk to operators, workers and bystanders. Conditions of use shall include risk mitigation measures, where appropriate.

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

ANNEX II

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

(1) in Part A, entry 126 on tolclofos-methyl is deleted;

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

No.	Common Name, Identification Numbers	IUPAC Name	Purity[2]	Date of approval	Expiration of approval	Specific provisions
"XXX	Tolclofos-methyl CAS No 57018-04-9 CIPAC No 479	O-2,6-dichloro-p-tolylO,O-dimethyl phosphorothioate O-2,6-dichloro-4-methylphenyl O,O-dimethyl phosphorothioate	≥ 960 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material: Methanol max. 1 g/kg	1 August 2019	31 July 2034	Only for use on ornamentals and on potatoes. 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 tolclofos-methyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the risk to aquatic organisms and mammals; - the risk to consumers, in particular the potential risk from metabolite DM-TM-CH_2OH in potatoes; - the risk to operators to operators, workers and bystanders; Conditions of use shall include risk mitigation measures, where appropriate."

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