Commission Implementing Regulation (EU) 2019/1101 of 27 June 2019 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1101

of 27 June 2019

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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.

(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.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1101. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(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 ornamental 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 criteria to identify endocrine-disrupting properties introduced by Commission Regulation (EU) 2018/605[(7)], the conclusion of the Authority, based on the fact that there was no evidence of endocrine-mediated effects *in vivo*, indicates that it is highly unlikely that tolclofos-methyl is an endocrine disrupter. Thus, the Commission concludes 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 (EU) 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 of that Regulation 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 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 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) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1101. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(15) Commission Implementing Regulation (EU) 2019/168[8] extended the approval period 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 September 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 September 2019.

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

Done at Brussels, 27 June 2019.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1101. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**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 September 2019	31 August 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

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