Commission Implementing Regulation (EU) 2018/1495 of 8 October 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance malathion (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1495

of 8 October 2018

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance malathion

(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 the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) The active substance malathion was included in Annex I to Council Directive 91/414/EEC[(2)] concerning the placing of plant protection products on the market by Commission Directive 2010/17/EU[(3)] under the condition that the Member States concerned ensure that the applicant at whose request malathion was approved provides inter alia further confirmatory information on the acute and long-term risk to insectivorous birds.

(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) On 25 April 2012 the applicant submitted additional information to address the confirmatory data requirements as regards the consumer risk assessment and the acute and long-term risk assessment for insectivorous birds and the quantification of the different potency of malaoxon and malathion to the rapporteur Member State, the United Kingdom, within the time period provided for its submission.

(4) The United Kingdom assessed the additional information submitted by the applicant and submitted its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission and the European Food Safety Authority ('the Authority'), on 11 May 2015.

(5) The other Member States, the applicant and the Authority were consulted and asked to provide comments on the assessment of the rapporteur Member State. The Authority published a technical report summarising the outcome of this consultation for malathion on 2 February 2016[(5)].

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1495. 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 draft assessment report, the addendum and the technical report of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised in January 2018 in the format of a Commission review report for malathion.

(7) The Commission invited the applicant to submit its comments on the review report for malathion. The applicant submitted its comments which have been carefully examined.

(8) However, the information submitted by the applicant is insufficient and prevents the Commission from concluding that the level of acute and long-term risks to birds arising from the use of malathion is acceptable. Furthermore, mitigating such risk with risk mitigation measures other than the applications in greenhouse cannot realistically be implemented.

(9) Therefore, taking into account the identified high risk for birds, it is appropriate to further restrict the conditions of use of malathion, and in particular to only allow for applications in greenhouses with a permanent structure. The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(10) Member States should be allowed sufficient time to amend or withdraw authorisations for plant protection products containing malathion.

(11) For plant protection products containing malathion, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 29 January 2020.

(12) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Transitional measures

Member States shall, in accordance with Regulation (EC) No 1107/2009, where necessary amend or withdraw existing authorisations for plant protection products containing malathion as active substance by 29 April 2019 at the latest.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1495. 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*

Article 3

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 29 January 2020 at the latest.

Article 4

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 8 October 2018.

For the Commission

The President

Jean-Claude JUNCKER