

II

(Non-legislative acts)

REGULATIONS

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⁾.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ 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).

⁽³⁾ Commission Directive 2010/17/EU of 9 March 2010 amending Council Directive 91/414/EEC to include malathion as active substance (OJ L 60, 10.3.2010, p. 17).

⁽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⁾ EFSA, Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment of confirmatory data for malathion. EFSA Supporting publication 2016:EN-951. 61 pp.

- (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.

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

ANNEX

The column 'Specific provisions' of row 300, malathion, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

PART A

Only uses as an insecticide in greenhouses with a permanent structure may be authorised. Authorisations shall be limited to professional users.

PART B

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on malathion, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed shall be taken into account.

In this overall assessment, Member States must pay particular attention to:

- (a) releases from greenhouses, such as condensation water, drain water, soil or artificial substrate, in order to preclude risks to aquatic organisms;
- (b) the protection of pollinator colonies purposely placed in the greenhouse;
- (c) the protection of operators and workers, so as to ensure that the conditions of use prescribe the use of adequate personal protective equipment, where appropriate;
- (d) the protection of consumers in the case of processed commodities.

Member States shall ensure that malathion-based formulations are accompanied by the necessary instructions to avoid any risk of formation of isomalathion in excess of the permitted maximum quantities during storage and transport.

Conditions of authorisation shall include risk mitigation measures and provide for adequate labelling of plant protection products.'
