Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, 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) 2019/1090

of 26 June 2019

concerning the non-renewal of approval of the active substance dimethoate, 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) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2007/25/EC[(2)] included dimethoate 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 dimethoate, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2020.

(4) An application for the renewal of the approval of dimethoate 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 5 May 2017.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1090. 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*

(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 2 October 2018 the Authority communicated to the Commission its conclusion[6] on whether dimethoate can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented to the Standing Committee on Plants, Animal, Food and Feed the draft renewal report for dimethoate on 13 December 2018 and the draft regulation on 25 January 2019.

(9) The Authority identified specific concerns. In particular, it was not possible to exclude exposure risk to consumers, operators, workers, bystanders and residents due to their exposure to residues of dimethoate, for which the genotoxic potential could not be excluded, and its main metabolite omethoate which was concluded to be an in vivo mutagenic agent by the majority of experts in the peer review. Furthermore, the Authority concluded that a high risk to mammals, and to non-target arthropods for dimethoate. and to honeybees for both dimethoate and omethoate was concluded for all the assessed representative uses. In addition, the Authority concluded that the technical specification, whether the current or the revised one, is not supported by the (eco) toxicological assessment

(10) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, the Commission invited the applicant to submit comments on the draft renewal report. The applicant submitted their comments, which have been carefully examined.

(11) However, despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.

(12) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The approval of the active substance dimethoate should therefore not be renewed.

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

(14) Member States should be provided with sufficient time to withdraw authorisations for plant protection products containing dimethoate.

(15) For plant protection products containing dimethoate, 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 17 October 2019 for plant protection products used on cherries and on 17 July 2020 for plant protection products used on other crops.

(16) Commission Implementing Regulation (EU) 2019/707[7] extended the approval period of dimethoate to 31 July 2020 in order to allow the renewal process to be completed before the expiry of the approval period of that substance. Given that a decision on the non-renewal of the approval has been taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1090. 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*

(17) This Regulation does not prevent the submission of a further application for the approval of dimethoate pursuant to Article 7 of Regulation (EC) No 1107/2009.

(18) 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

Non-renewal of approval of active substance

The approval of the active substance dimethoate is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 149, on dimethoate, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing dimethoate as active substance by **[**[X1]31 December 2019**]** at the latest.

Editorial Information

X1 Substituted by Corrigendum to Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, 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 (Official Journal of the European Union L 173, 27 June 2019).

Article 4

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 **[**[X1]30 September 2019**]** for plant protection products used on cherries and by **[**[X1]30 June 2020**]** for plant protection products used on other crops, at the latest.

Editorial Information

X1 Substituted by Corrigendum to Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, in accordance with