Commission Implementing Regulation (EU) 2020/1246 of 2 September 2020 concerning the non-renewal of the approval of the active substance fenamiphos, 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) 2020/1246

of 2 September 2020

concerning the non-renewal of the approval of the active substance fenamiphos, 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 2006/85/EC[(2)] included fenamiphos 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 fenamiphos, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2021.

(4) An application for the renewal of the approval of the active substance fenamiphos 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 2 October 2017.

Changes to legislation: *Commission Implementing Regulation (EU) 2020/1246 is up to date with all changes known to be in force on or before 27 February 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

(8) On 10 December 2018, the Authority communicated to the Commission its conclusion[(6)] on whether fenamiphos can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Authority identfied a number of concerns. In particular, the overall consumer risk assessment was considered to be provisional since the data package for metabolities M01 and M02 on genotoxicity was incomplete, leading to a provisional residue definition for risk assessment for crops on which fenamiphos is intended to be used. However, even if the consumer risk assessment could not be finalised, an acute risk for consumers was identified for all the representative uses concerning fruiting vegetables.

(10) Additionally, for the chronic intake consumer exposure, if the calculated maximum residue levels (MRLs) resulting from the available residue dataset submitted for the renewal process are used in the exposure assessment, the maximum theoretical daily intake (TMDI) would account for 172 % of the acceptable daily intake (ADI).

(11) Furthermore, as regards the remaining uses of the substance on ornamentals and nursery stock, given that those plants can be grown in rotation with food crops, an acute consumer risk deriving from these uses could not be excluded considering the possible uptake of residues in rotational crops.

(12) Finally, the risk assessment to unique human metabolities could not be finalised since an in vitro comparative metabolism study was not submitted.

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

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

(15) 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. It is therefore appropriate not to renew the approval of the active substance fenamiphos in accordance with Article 20(1)(b) of that Regulation.

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

(17) Member States should be given sufficient time to withdraw authorisations for plant protection products containing fenamiphos.

***Changes to legislation:** Commission Implementing Regulation (EU) 2020/1246 is up to date with all changes known to be in force on or before 27 February 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(18) For plant protection products containing fenamiphos, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 12 months from the date of entry into force of this Regulation.

(19) Commission Implementing Regulation (EU) 2020/869[7] extended the approval period of fenamiphos to 31 July 2021 in order to allow the renewal process to be completed before the expiry of the approval period of that substance. However, given that a decision on the non-renewal of the approval is being taken ahead of the expiry of that extended approval period, this Regulation should apply as soon as possible.

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

(21) 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 the approval of the active substance

The approval of the active substance fenamiphos 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 141, on fenamiphos, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing fenamiphos as an active substance by 23 March 2021.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 23 September 2021.