Commission Implementing Regulation (EU) 2019/989 of 17 June 2019 concerning the non-renewal of approval of the active substance chlorpropham, 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) 2019/989

of 17 June 2019

concerning the non-renewal of approval of the active substance chlorpropham, 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 2004/20/EC[(2)] included chlorpropham 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 chlorpropham, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2019.

(4) An application for the renewal of the approval of chlorpropham 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) A Task Force composed of three applicants 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 29 April 2016.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/989. 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 18 June 2017 the Authority communicated to the Commission its conclusion[(6)] on whether chlorpropham can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority concluded that a final consumer risk assessment through dietary intake cannot be performed due to several data gaps and uncertainties identified for the food crop uses. Nevertheless, a critical area of concern for chlorpropham was identified regarding the results of an indicative consumer risk assessment where acute and chronic dietary risks for consumers have been identified both for chlorpropham and for its major metabolite 3-chloroaniline. Moreover, the Authority also concluded that further scientific assessment of the potential endocrine disrupting properties of chlorpropham is needed and that the risk assessment for non-target arthropods for field uses could not be finalised.

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

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

(11) On 23 January 2019, one of the members of the Task Force that had submitted the application for renewal of approval of chlorpropham informed the Commission that it had decided to withdraw its support for the representative use of chlorpropham as a potato sprout suppressant. On 19 March 2019, the Task Force notified the Commission that it had withdrawn its support for all representative uses, except for non-edible crops, i.e. flower bulbs.

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

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

(14) Member States should be allowed sufficient time to withdraw authorisations for plant protection products containing chlorpropham.

(15) For plant protection products containing chlorpropham, 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 8 October 2020.

(16) Commission Implementing Regulation (EU) 2018/917[(7)] extended the expiry date of chlorpropham to 31 July 2019 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision has

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been taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

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

(18) 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

Non-renewal of approval of active substance

The approval of the active substance chlorpropham 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 78, on chlorpropham, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing chlorpropham as active substance by 8 January 2020.

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 8 October 2020 at the latest.

Article 5

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.