COMMISSION IMPLEMENTING REGULATION (EU) 2020/17

of 10 January 2020

concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, 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 2005/72/EC ([2]) included chlorpyrifos-methyl 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 chlorpyrifos-methyl, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2020.

(4) Applications for the renewal of the approval of the active substance chlorpyrifos-methyl were 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 applicants submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The applications were 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 3 July 2017.

(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 4 July 2018, the Authority requested that the applicants supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the form of an updated renewal assessment report.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances. (OJ L 279, 22.10.2005, p. 63).

([3]) 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).

([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]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

(9) The Authority organised an expert discussion in April 2019, to discuss certain elements related to the human health risk assessment. Due to concerns about genotoxicity and developmental neurotoxicity raised during that discussion, on 1 July 2019 the Commission sent a mandate to the Authority requesting a statement on the available outcomes of the human health assessment and an indication whether the active substance can be expected to meet the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009.

(10) On 31 July 2019, the Authority sent its initial statement ([6]) to the Commission on the available outcomes of the human health assessment. On 11 November 2019, the Authority sent its updated statement ([7]) to the Commission following an additional expert discussion held in September 2019. In its updated statement, the Authority confirmed its conclusions on the human health assessment that critical areas of concerns exist. A genotoxic potential of chlorpyrifos-methyl cannot be ruled out, when taking into account the concerns raised for chlorpyrifos and the available scientific open literature on chlorpyrifos-methyl in a weight of evidence approach. During the peer review, experts considered a read-across approach between the two substances justified as they are structurally similar and have similar toxicokinetic behaviour. Consequently, it is not possible to establish health-based reference values for chlorpyrifos-methyl and to conduct the relevant consumer and non-dietary risk assessments. Furthermore, concerns were identified concerning developmental neurotoxicity (DNT) for which epidemiological evidence exists, showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children. Moreover, the peer review experts indicated that it may be appropriate to classify chlorpyrifos-methyl as toxic for reproduction, category 1B, in accordance with the criteria established under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([8]).

(11) The Commission invited the applicants to submit their comments on the statements 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 applicants to submit comments on the draft renewal report. The applicants submitted their comments, which have been carefully examined.

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

(13) 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 environmental risk assessment, although not finalised, cannot alter this conclusion since the approval criteria related to the effects on human health are not satisfied and should therefore not delay further the decision-making on the renewal of the approval of the active substance. It is therefore appropriate not to renew the approval of the active substance chlorpyrifos-methyl in accordance with Article 20(1)(b) of that Regulation.

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

(15) Member States should be given sufficient time to withdraw authorisations for plant protection products containing chlorpyrifos-methyl.

(16) For plant protection products containing chlorpyrifos-methyl, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 3 months from the date of entry into force of this Regulation.

(17) Commission Implementing Regulation (EU) 2018/1796 ([9]) extended the approval period of chlorpyrifos-methyl to 31 January 2020, 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.

([6]) EFSA (European Food Safety Authority), 2019. Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. *EFSA Journal* 2019;17(5):5810. https://doi.org/10.2903/j.efsa.2019.5810.

([7]) European Food Safety Authority (EFSA), 2019. Updated statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. *EFSA Journal* 2019;17(11):5908, 21 pp. https://doi.org/10.2903/ j.efsa.2019.5908.

([8]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([9]) Commission Implementing Regulation (EU) 2018/1796 of 20 November 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflubenzuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, mecoprop-p, metiram, nicosulfuron, oxamyl, picloram, pyraclostrobin, pyriproxyfen and tritosulfuron (OJ L 294, 21.11.2018, p. 15).

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

(19) 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 chlorpyrifos-methyl 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 112, on chlorpyrifos-methyl, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing chlorpyrifos-methyl as an active substance by 16 February 2020.

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 16 April 2020.

Article 5

Entry into force

This Regulation shall enter into force on the third 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, 10 January 2020.

For the Commission
The President
Ursula VON DER LEYEN