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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the non-renewal of the approval of the active substance chlorpyrifos, 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)

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(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/EEC¹, and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2005/72/EC² included chlorpyrifos as an active substance in Annex I to Council Directive 91/414/EEC³.
- (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 540/2011⁴.
- (3) The approval of the active substance chlorpyrifos, 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 were submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012⁵ 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.

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).

- (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 applicant 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.
- (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 statement⁶ to the Commission. In its statement, the Authority confirmed that its conclusions on the human health assessment indicate that critical areas of concerns exist. Based on the information available, it cannot be excluded that chlorpyrifos has a genotoxic potential, since positive results were found in a number of *in vitro* and *in vivo* studies. Consequently, it is not possible to establish health-based reference values for chlorpyrifos and to conduct the relevant consumer and non-dietary risk assessments. Furthermore, developmental neurotoxicity (DNT) effects were observed in the available study on developmental neurotoxicity in rats and epidemiological evidence exists showing an association between exposure to chlorpyrifos during development and adverse neurodevelopmental outcomes in children. Moreover, it is indicated that the peer review experts considered it appropriate to classify chlorpyrifos 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 Council⁷.
- (11) The Commission invited the applicants to submit their comments on the statement 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.

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. EFSA Journal 2019;17(5):5809.

⁷ 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).

- (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 active substance. It is therefore appropriate not to renew the approval of the active substance chlorpyrifos 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.
- (16) For plant protection products containing chlorpyrifos, 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) 2018/1796⁸ extended the approval period of chlorpyrifos 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.
- (18) This Regulation does not prevent the submission of a further application for the approval of chlorpyrifos 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 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 111, on chlorpyrifos, is deleted.

Article 3

Transitional measures

⁸ 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).

Member States shall withdraw authorisations for plant protection products containing chlorpyrifos as an active substance by ... [*Office of Publications please insert date 1 month from the date of entry into force*].

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 ... [*Office of Publications please insert date 3 months from the date of entry into force*].

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,

For the Commission
The President
[Name to be inserted]