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[...] (2018) **XXX** draft

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

of **XXX**

concerning the non-renewal of approval of the active substance thiophanate-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)

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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 2005/53/EC² included thiophanate-methyl 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 thiophanate-methyl, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2019.
- (4) An application for the renewal of the approval of thiophanate-methyl was 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 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.

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Directive 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ L 241, 17.9.2005, p. 51).

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 1 November 2016.
- (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 17 January 2018 the Authority communicated to the Commission its conclusion⁶ on whether thiophanate-methyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for thiophanate-methyl to the Standing Committee on Plants, Animal, Food and Feed on 24 October 2018.
- (9) Specific concerns were identified. In particular, it was not possible to exclude exposure risk to consumers, operators, workers, bystanders and residents due to their exposure to residues of thiophanate-methyl (for which the genotoxic potential could not be excluded) and its main metabolite carbendazim (for which harmonised classification is mutagen category 1B and toxic for reproduction category 1B). The Authority also concluded that a high long-term risk was identified to birds and mammals for all representative uses. Finally, the Authority highlighted lack of toxicological data for the metabolites 2-AB, FH-432, DX-105 to which consumers might be exposed and for metabolite CM-0237 which might occur in surface and groundwater.
- (10) Furthermore, Authority concluded that there is enough evidence to conclude that the substance is an endocrine disruptor and that the mechanism is relevant to humans.
- (11) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, to submit comments on the draft renewal report. The applicant submitted its comments, which have been carefully examined.
- (12) However, despite the arguments put forward by the applicant, the concerns referred to in recital 9 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 approval of the active substance thiophanate-methyl should therefore not be renewed.
- (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 thiophanate-methyl.
- (16) For plant protection products containing thiophanate-methyl, 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 [*Office of Publications please insert date 12 months from the date of entry into force*].

⁶ EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance thiophanate-methyl EFSA Journal 2018;16(1):5133. <https://www.efsa.europa.eu/en/efsajournal/pub/5133>.

- (17) Commission Implementing Regulation (EU) 2018/1262⁷ extended the approval period of thiophanate-methyl to 31 October 2019 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.
- (18) This Regulation does not prevent the submission of a further application for the approval of thiophanate-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 approval of active substance

The approval of the active substance thiophanate-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 105, on thiophanate-methyl, is deleted.

Article 3
Transitional measures

Member States shall withdraw authorisations for plant protection products containing thiophanate-methyl as active substance by [*Office of Publications please insert date 6 months from the date of entry into force*] at the latest.

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 12 months from the date of entry into force*] at the latest.

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*.

⁷ Commission Implementing Regulation (EU) 2018/1262 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, clomazone, cypermethrin, daminozide, deltamethrin, dimethenamid-p, diuron, fludioxonil, flufenacet, flurtamone, fosthiazate, indoxacarb, MCPA, MCPB, prosulfocarb, thiophanate-methyl and tribenuron (OJ L 238, 21.9.2018, p. 62).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER