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

of **XXX**

concerning the non-renewal of approval of the active substance thiram, 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 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 2003/81/EC² included thiram 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 thiram, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2019.
- (4) An application for the renewal of the approval of thiram 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 2003/81/EC of 5 September 2003 amending Council Directive 91/414/EEC to include molinate, thiram and ziram as active substances (OJ L 224, 6.9.2003, p. 29).

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 20 January 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 27 January 2017 the Authority communicated to the Commission its conclusion⁶ on whether thiram can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority identified a high acute risk to consumers and to workers from the foliar uses assessed and a high risk to birds and mammals from all uses assessed, including as a seed treatment, even taking into account the application of higher tier refinements in the risk assessment. Residue definitions for risk assessment purposes could not be derived from the incomplete information available on metabolite M1, consequently the assessment of consumer risk through dietary intake could not be completed and maximum residue levels could not be established. Furthermore, the formation of N-N-dimethylnitrous amide (NDMA), a substance of concern given its intrinsic hazard, in drinking water when surface water and groundwater containing thiram and its metabolite DMCS is subject to water treatment processes could not be excluded by the Authority based on the available information and in addition a high risk to aquatic organisms from exposure to DMCS was concluded by the Authority based on the limited information available. Also, based on the information available the Authority could not conclude on the endocrine disrupting potential of thiram.
- (9) 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 draft renewal report. The applicant submitted its comments, which have been carefully examined.
- (10) However, despite the arguments put forward by the applicant, the concerns related to the substance could not be eliminated.
- (11) 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 thiram in accordance with Article 20(1)(b) of that Regulation.
- (12) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (13) Taking into account the risk identified for birds and wild mammals from treated seeds the placing on the market and the use of seeds treated with plant protection products containing thiram should be prohibited.
- (14) The prohibition of placing on the market and use of treated seeds should apply as of [publications office insert date 15 months + 1 day from the date of entry into force] in

⁶ EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance thiram. EFSA Journal 2017;15(7):4700 [29 pp.]. doi:10.2903/j.efsa.2017.4700.

order to allow for a sufficient period of transition for the seed supply chain taking into account the limited availability of seeds that are not treated with products containing thiram.

- (15) Member States should be allowed sufficient time to withdraw authorisations for plant protection products containing thiram.
- (16) For plant protection products containing thiram, 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 *[publications office insert date 15 months from the date of entry into force]*.
- (17) Commission Implementing Regulation (EU) 2017/XXX⁷ extended the expiry date of thiram to 30 April 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 is 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 thiram in accordance with 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 thiram is not renewed.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 73, on thiram, is deleted.

Article 3

Prohibition of placing on the market of treated seeds

Seeds which have been treated with plant protection products containing thiram shall not be used or placed on the market.

Article 4

Transitional measures

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

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Commission Implementing Regulation (EU) 2017/XXX (...) (OJ L XXX)

Article 5
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 [*insert date* 15 months] from the date of entry into force] at the latest.

Article 6
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*.

Article 3 shall apply as of [*publications office insert date* 15 months + 1 day] from the date of entry into force].

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