Commission Implementing Regulation (EU) 2018/1500 of 9 October 2018 concerning the non-renewal of approval of the active substance thiram, and prohibiting the use and sale of seeds treated with plant protection products containing 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1500

of 9 October 2018

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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/EEC[(1)], and in particular Article 20(1), Article 49(2) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2003/81/EC[(2)] included thiram 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 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 844/2012[(5)] 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.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1500. 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*

(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 conclusion[(6)] 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 application of thiram by foliar spraying. Furthermore, it identified a high risk to birds and mammals from all representative 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) On 18 May 2018 the applicant wrote to the Commission to withdraw from the renewal application the representative uses concerning application by foliar spraying.

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

(14) 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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1500. 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*

(15) The prohibition of placing on the market and use of treated seeds should apply as of 31 January 2020 in 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.

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

(17) 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 30 April 2019 for plant protection products used for foliar application and on 30 January 2020 for other plant protection products, including those used for seed treatment.

(18) Commission Implementing Regulation (EU) 2018/524[7] 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.

(19) 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.

(20) 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 thiram 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 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.