



1 March 2018

(18-1307)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: European Commission Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: grow-eu-tbt@ec.europa.eu Website: http://ec.europa.eu/growth/tools-databases/tbt/en/
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Thiram (pesticide active substance)
5. Title, number of pages and language(s) of the notified document: Draft Commission Implementing Regulation 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 (6 page(s), in English)
6. Description of content: This draft Commission Implementing Regulation provides that the approval of the active substance thiram is not renewed in accordance with Regulation (EC) No 1107/2009. Existing authorised plant protection products containing thiram will be withdrawn from the market. The non-approval is based on the first evaluation of the substance for use as a pesticide active substance in the EU under Regulation (EC) No 1107/2009. The substance was formerly approved under Directive 91/414/ EEC. This decision only concerns the placing on the market of this substance and does not affect the Maximum Residue Levels (MRLs) for residues of the concerned pesticide. However, following non-approval, separate action may be taken on MRLs. Any subsequent action on MRLs will be subject to notification under the SPS procedure.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety; protection of animal or plant life or health; protection of the environment. In order for an active substance to be approved in accordance with Regulation (EC) No 1107/2009 (concerning the placing of plant protection products on the market), it must be demonstrated that the substance is not harmful to human health, animal health or

the environment. Criteria are listed in Article 4 of the Regulation (and also detailed in Annex II) which must be met to enable approval.

During the evaluation and peer-review of thiram, a number of concerns and areas that could not be finalised were identified. These are detailed in the conclusion of the European Food Safety Authority (EFSA).

Specific concerns were identified as follows: 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.

These concerns mean that thiram does not meet the approval criteria as outlined in Regulation (EC) No 1107/2009 and cannot be approved currently.

Existing authorisations will need to be withdrawn; Member States must withdraw existing plant protection products containing thiram at the latest by 6 months from the date of entry into force. A period of grace in line with Article 46 of Regulation 1107/2009 is allowed for and shall expire at the latest 15 months from the entry into force.

Furthermore, a transitional period for placing on the market and use of seeds treated with thiram is provided for (for a period of 15 months from the date of entry into force).

8. Relevant documents:

- 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: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&qid=1437730988988&from=EN>
- 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. 1-186*). <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&uri=CELEX:32011R0540>
- 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. <https://www.efsa.europa.eu/en/efsajournal/pub/4700>

9. Proposed date of adoption: June 2018

Proposed date of entry into force: 20 days following publication in the Official Journal of the EU

10. Final date for comments: 60 days from notification

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

European Commission
EU-TBT Enquiry Point
Fax: + (32) 2 299 80 43
E-mail: grow-eu-tbt@ec.europa.eu

The text is available on the EU-TBT Website:

<http://ec.europa.eu/growth/tools-databases/tbt/en/>

https://members.wto.org/crnattachments/2018/TBT/EEC/18_1142_00_e.pdf