



24 April 2020

(20-3227)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved:
2. Agency responsible: European Commission, Health and Food Safety Directorate-General
3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Mancozeb (pesticide active substance used as fungicide)
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance mancozeb, 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. Language(s): English . Number of pages: 4 https://members.wto.org/crnattachments/2020/SPS/EEC/20_2907_00_e.pdf
6. Description of content: <p>This draft Commission Implementing Regulation provides that the approval of the active substance mancozeb is not renewed in accordance with Regulation (EC) No 1107/2009. Existing authorisations of plant protection products containing mancozeb will be withdrawn and such products can then no longer be placed on the market. The non-renewal of the approval is based on a scientific assessment conducted under Regulation (EC) No 1107/2009 by experts from the Member States of the European Union and the European Food Safety Authority (EFSA).</p> <p>This decision only concerns the placing on the market of mancozeb and plant protection products containing it. Following non-renewal of approval and the expiry of all grace periods for stocks of products containing this substance, separate action will be taken to swiftly lower all existing MRLs to the limit of quantification and a separate notification will be made in accordance with SPS procedures. As soon as the lowered MRLs will be applicable (expected in the third quarter of 2020), foodstuffs with higher levels of mancozeb will become non-compliant and can no longer be placed on the EU market.</p> <p>This draft Commission Implementing Regulation was also notified under the TBT Agreement in notice G/TBT/N/EU/712.</p>

7. Objective and rationale: food safety, animal health, plant protection, protect humans from animal/plant pest or disease, protect territory from other damage from pests. 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 further detailed in Annex II) which must be met to enable approval. During the evaluation and peer-review of mancozeb, a number of concerns were identified. These are detailed in a statement of the European Food Safety Authority (EFSA):

- A reprotoxic potential of mancozeb, classified as Toxic for reproduction cat. 1B in accordance with the criteria set out in Commission Regulation (EC) No 1272/2008.
- The non-dietary exposure estimates exceed the reference values for tomatoes, potatoes, cereals and grapevines.
- Moreover, endocrine disruptors criteria are met for humans and likely for non-target species.
- This means that mancozeb does not meet the approval criteria as outlined in Article 4 of Regulation (EC) No 1107/2009 and cannot be approved currently.
- Existing authorisations will need to be withdrawn; EU Member States must withdraw existing authorisations for plant protection products containing mancozeb at the latest by 3 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 6 months from the entry into force.

Protection of human health or safety; Protection of animal or plant life or health; Protection of the environment.

8. Is there a relevant international standard? If so, identify the standard:

Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):

World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):

International Plant Protection Convention (e.g. ISPM number):

None

Does this proposed regulation conform to the relevant international standard?

Yes No

If no, describe, whenever possible, how and why it deviates from the international standard:

9. Other relevant documents and language(s) in which these are available:

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>

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*).

<p>https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272</p> <p>EFSA conclusions on the peer review of the active substance mancozeb. EFSA Journal 2019;17(7):5755. DOI: 10.2903/j.efsa.2019.5755.</p> <p>https://www.efsa.europa.eu/en/efsajournal/pub/5755</p>
<p>10. Proposed date of adoption (dd/mm/yy): 3rd quarter 2020. Proposed date of publication (dd/mm/yy): 3rd quarter 2020.</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 20 days following publication in the Official Journal of the EU. <input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 17 June 2020 - Comments are to be addressed to the TBT Enquiry Point.</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission EU-TBT Enquiry Point Fax: +(322) 299 8043 E-mail: grow-eu-tbt@ec.europa.eu</p>
<p>13. Text(s) available from: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission EU-TBT Enquiry Point Fax: +(322) 299 8043 E-mail: grow-eu-tbt@ec.europa.eu</p>