



30 July 2021

(21-5999)

Page: 1/3

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): Cypermethrin (pesticide active substance)
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 renewing the approval of the active substance cypermethrin as a candidate for substitution 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: 5+7 https://members.wto.org/crnattachments/2021/SPS/EEC/21_4996_00_e.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_4996_01_e.pdf
6. Description of content: This draft Commission Implementing Regulation provides that the approval of the active substance cypermethrin is renewed in accordance with Regulation (EC) No 1107/2009. It is however, necessary to include certain conditions and restrictions for spray applications outdoors to ensure the required protection level for aquatic organisms and non-targeted arthropods including bees is met. Existing authorised plant protection products containing cypermethrin will be reviewed in accordance with the conditions and restrictions set in this act. The conditions and restrictions are based on the first evaluation of the substance for use as a pesticide active substance in the European Union under Regulation (EC) No 1107/2009. The substance was formerly approved under Directive 91/414/EEC. 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 thereto) which must be met to enable approval. During the evaluation and peer-review of cypermethrin, 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). In its Statement on risk mitigation measures on cypermethrin published on 4 October 2019, EFSA presented the levels of the necessary drift reduction and the measures that would be needed to demonstrate low risk to the non-target organisms, in particular aquatic organisms and non-target arthropods, including bees.

<p>This means that cypermethrin meets the approval criteria as outlined in Regulation (EC) No 1107/2009 only if appropriate mitigation measures to ensure the required protection level for aquatic organisms, non-targeted arthropods including bees are put in place for spray applications outdoors.</p> <p>Existing authorisations will need to be amended or withdrawn following renewal of authorisation in accordance with Article 43 of Regulation (EC) No 1107/2009.</p> <p>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 active substance. Any action on MRLs will be subject to notification under the SPS procedure.</p> <p>This draft Commission Implementing Regulation was also notified under the TBT Agreement in notice G/TBT/N/EU/825.</p>
<p>7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input checked="" type="checkbox"/> animal health, <input checked="" type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input checked="" type="checkbox"/> protect territory from other damage from pests.</p>
<p>8. Is there a relevant international standard? If so, identify the standard:</p> <p><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
<p>9. Other relevant documents and language(s) in which these are available:</p> <ul style="list-style-type: none"> - 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 June 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 cypermethrin: EFSA Journal 2018;16(8):5402. Conclusion on the peer review of the pesticide risk assessment of the active substance cypermethrin. Available online http://www.efsa.europa.eu - EFSA Statement on risk mitigation measures on cypermethrin https://www.efsa.europa.eu/en/efsajournal/pub/5822
<p>10. Proposed date of adoption (dd/mm/yy): Fourth quarter of 2021</p> <p>Proposed date of publication (dd/mm/yy): Fourth quarter of 2021</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 European Union.</p> <p><input type="checkbox"/> Trade facilitating measure</p>

12. Final date for comments: [] Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable. Comments are only to be addressed to the TBT Enquiry Point on notice G/TBT/N/EU/825 and on TBT aspects of the notified draft legislation.

Agency or authority designated to handle comments: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (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

13. Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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