



31 January 2023

(23-0702)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved:</b>
<b>2. Agency responsible:</b> European Commission, Health and Food Safety Directorate-General
<b>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):</b> Oxamyl (pesticide active substance)
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
<b>5. Title of the notified document:</b> Draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance oxamyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance). <b>Language(s):</b> English. <b>Number of pages:</b> 5 <a href="https://members.wto.org/crnattachments/2023/SPS/EEC/23_0781_00_e.pdf">https://members.wto.org/crnattachments/2023/SPS/EEC/23_0781_00_e.pdf</a>
<b>6. Description of content:</b> This draft Commission Implementing Regulation provides that the approval of the active substance oxamyl is not renewed in accordance with Regulation (EC) No 1107/2009. EU member States shall withdraw authorisations for plant protection products containing oxamyl as an active substance. The non-renewal of approval is 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 assessed and 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 oxamyl, 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) and reported here after: The operators' exposure is unacceptable (min 112% of the AEOL and min 389% of the AAOEL) even when the use of PPE is considered; The preliminary consumer dietary risk assessment did indicate a large exceedance of the acute reference dose (ARfD) for all the representative uses: 1,538% (potatoes, children), 1,223% (watermelons, children), 656% (cucumbers, children) and 581% (tomatoes, children) even when oxamyl residues at the LOQ of 0.01mg/kg were considered. These concerns and areas that could not be finalised mean that oxamyl does not meet the approval criteria as outlined in Regulation (EC) No 1107/2009 and its approval cannot be renewed. Existing authorisations will need to be withdrawn. EU member States must withdraw existing plant protection products containing oxamyl at the latest by six months from the date of entry into force. A period of grace in line with Article 46 of Regulation No 1107/2009 is allowed for and shall expire at the latest 12 months from the entry into force (allowing for a final season of use).

<p>This decision only concerns the placing on the market of this substance and plant protection products containing it. Following non-approval and the expiry of all grace periods for stocks of products containing this substance, separate action will likely be taken on Maximum Residue Limits and a separate notification will be made in accordance with SPS procedures.</p> <p>This draft Commission Implementing Regulation was also notified under the TBT Agreement in notice G/TBT/N/EU/945.</p>
<p><b>7. Objective and rationale:</b> <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><b>8. Is there a relevant international standard? If so, identify the standard:</b></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><b>Does this proposed regulation conform to the relevant international standard?</b></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>If no, describe, whenever possible, how and why it deviates from the international standard:</b></p>
<p><b>9. Other relevant documents and language(s) in which these are available:</b></p> <ul style="list-style-type: none"> <li>- 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 <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&amp;qid=1437730988988&amp;from=EN">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&amp;qid=1437730988988&amp;from=EN</a></li> <li>- 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) <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&amp;uri=CELEX:32011R0540">https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&amp;uri=CELEX:32011R0540</a></li> <li>- Conclusion on the peer review of the pesticide risk assessment of the active substance oxamyl</li> <li>- EFSA Journal 2022;20(5):7296 [36 pp.]. Conclusion on the peer review of the pesticide risk assessment of the active substance oxamyl <a href="https://doi.org/10.2903/j.efsa.2022.7296">https://doi.org/10.2903/j.efsa.2022.7296</a> (available in English)</li> </ul>
<p><b>10. Proposed date of adoption (dd/mm/yy):</b> 2<sup>nd</sup> quarter 2023</p> <p><b>Proposed date of publication (dd/mm/yy):</b> 2<sup>nd</sup> quarter 2023</p>
<p><b>11. Proposed date of entry into force:</b> <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>
<p><b>12. Final date for comments:</b> <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable. Comments are only welcomed on TBT related issues and to be addressed to the TBT Enquiry Point on notice G/TBT/N/EU/945.</p>

**Agency or authority designated to handle comments:  National Notification Authority,  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](mailto:grow-eu-tbt@ec.europa.eu)

**13. Text(s) available from:  National Notification Authority,  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  
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