



9 January 2025

(25-0253)

Page: 1/3

Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

|  |
|--|
| <b>1. Notifying Member:</b> <u>EUROPEAN UNION</u><br><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> Flufenacet (pesticide active substance)  |
| <b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b><br><input checked="" type="checkbox"/> <b>All trading partners</b><br><input type="checkbox"/> <b>Specific regions or countries:</b>  |
| <b>5. Title of the notified document:</b> Draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance flufenacet, 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 and Commission Implementing Regulation (EU) 2015/408 (Text with EEA relevance). <b>Language(s):</b> English. <b>Number of pages:</b> 6<br><a href="https://members.wto.org/crnattachments/2025/SPS/EEC/25_00450_00_e.pdf">https://members.wto.org/crnattachments/2025/SPS/EEC/25_00450_00_e.pdf</a>  |
| <b>6. Description of content:</b> This draft Commission Implementing Regulation provides that the approval of the active substance flufenacet is not renewed in accordance with Regulation (EC) No 1107/2009. EU member States shall withdraw authorizations for plant protection products containing flufenacet 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 EU under Regulation (EC) No 1107/2009. The substance was formerly assessed and approved under Directive 91/414/ EEC.<br><br>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 <a href="#">G/TBT/N/EU/1105</a> - 2 - 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.<br><br>During the evaluation and peer-review of flufenacet, a number of concerns and areas that could not be finalized were identified. These are detailed in the statement of the European Food Safety Authority (EFSA).<br><br>Flufenacet meets the criteria in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 to be identified as an endocrine disruptor for the thyroid (T)-modality for humans and non-target organisms and it has not been demonstrated that the exposure of humans and non-target organisms to that active substance in a plant protection product, under realistic proposed conditions of use, is negligible.<br><br>High potential for contamination of ground water with trifluoroacetic acid was identified and that metabolite is considered to be to toxicologically relevant. |

|  |
|--|
| <p>The risk assessment could not be finalized with respect to the non-relevance assessment of groundwater metabolites and the risks for the consumers.</p> <p>These concerns mean that flufenacet does not meet the approval criteria as outlined in Regulation (EC) No 1107/2009.</p> <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 MRLs 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 <a href="#">G/TBT/N/EU/1105</a>.</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 checked="" 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<br/><a href="https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R1107">https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R1107</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)<br/><a href="https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0540">https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0540</a></li> <li>– Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (OJ L 67, 12 March 2015, p. 18–22)<br/><a href="https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32015R0408">https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32015R0408</a></li> <li>– EFSA (European Food Safety Authority), 2024. Peer review of the pesticide risk assessment of the active substance flufenacet. EFSA Journal 2024; 22(9): e08997<br/><a href="https://doi.org/10.2903/j.efsa.2024.8997">https://doi.org/10.2903/j.efsa.2024.8997</a></li> </ul> |
| <p><b>10. Proposed date of adoption (dd/mm/yy):</b> April 2025</p> <p><b>Proposed date of publication (dd/mm/yy):</b> May 2025</p>   |

|            |   |
|------------|---|
| <b>11.</b> | <b>Proposed date of entry into force:</b> <input type="checkbox"/> <b>Six months from date of publication, and/or (dd/mm/yy):</b> 20 days following publication in the Official Journal of the European Union.<br><br><input type="checkbox"/> <b>Trade facilitating measure</b>  |
| <b>12.</b> | <b>Final date for comments:</b> <input type="checkbox"/> <b>Sixty days from the date of circulation of the notification and/or (dd/mm/yy):</b> Not applicable. Comments are only welcomed on TBT related issues and to be addressed to the TBT Enquiry Point on notice <a href="#">G/TBT/N/EU/1105</a> .<br><br><b>Agency or authority designated to handle comments:</b> <input checked="" type="checkbox"/> <b>National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</b><br><br>European Commission<br>EU-TBT Enquiry Point<br>Fax: +(32) 2 299 80 43<br>E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a> |
| <b>13.</b> | <b>Text(s) available from:</b> <input checked="" type="checkbox"/> <b>National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</b><br><br>European Commission<br>EU-TBT Enquiry Point<br>Fax: +(32) 2 299 80 43<br>E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a>  |