



24 April 2020

(20-3222)

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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> Bromoxynil (pesticide active substance)
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> <b>All trading partners</b> <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 approval of the active substance bromoxynil, 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. <b>Language(s):</b> English. <b>Number of pages:</b> 5 <a href="https://members.wto.org/crnattachments/2020/SPS/EEC/20_2900_00_e.pdf">https://members.wto.org/crnattachments/2020/SPS/EEC/20_2900_00_e.pdf</a>
<b>6. Description of content:</b> <p>This draft Commission Implementing Regulation provides that the approval of the active substance bromoxynil is not renewed in accordance with Regulation (EC) No. 1107/2009. EU Member States shall withdraw authorisations for plant protection products containing bromoxynil 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.</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 may 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 G/TBT/N/EU/710.</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 also detailed in Annex II thereto) which must be met to enable approval.

During the evaluation and peer-review of bromoxynil, 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).

The conclusion of the Authority indicates that, during the peer review, experts from Member States and the Authority suggested that bromoxynil, currently subject to harmonised classification and labelling in accordance with Regulation (EC) No 1272/2008 as toxic for reproduction category 2, should be classified as toxic for reproduction category 1B in accordance with the criteria laid down in that Regulation. The Commission therefore requested the Authority to consider whether negligible exposure in accordance with Point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 could be demonstrated. On 8 November 2018, the Authority communicated to the Commission its conclusion (EFSA Journal 2018;16 (12):5490, 15 pp.) that, for the representative uses considered, non-dietary exposure to bromoxynil cannot be considered negligible. In that conclusion, the Authority identified a risk to child residents from the representative uses of bromoxynil even when taking into account available mitigation measures.

In its conclusion from 2017, the Authority also identified a high risk to wild mammals from dietary exposure to bromoxynil. Furthermore, the Authority concluded that the consumer risk assessment for products of animal origin and the risk assessment for aquatic organisms could not be finalized.

Derogation in accordance with Article 4(7) of Regulation (EC) No 1107/2009 does not apply for the reasons set out in the draft Regulation.

These concerns mean that bromoxynil does not meet the approval criteria as outlined in Regulation (EC) No 1107/2009 and cannot be approved currently. Existing authorizations will need to be withdrawn; EU Member States must withdraw existing plant protection products containing bromoxynil 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 12 months from the entry into force (allowing for a final season of use).

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:**

<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="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&amp;qid=1437730988988&amp;from=EN">http://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, 11.6.2011, p. 1-186): <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&amp;uri=CELEX:32011R0540">http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&amp;uri=CELEX:32011R0540</a></li> <li>- 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). <a href="https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32008R1272">https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32008R1272</a></li> <li>- EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance bromoxynil (variant evaluated bromoxynil octanoate). EFSA Journal 2017;15(6):4790, 24 pp. <a href="https://doi.org/10.2903/j.efsa.2017.4790">https://doi.org/10.2903/j.efsa.2017.4790</a></li> <li>- EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment for the active substance bromoxynil in light of negligible exposure data submitted. EFSA Journal 2018;16 (12):5490, 15 pp.</li> <li>- EFSA (European Food Safety Authority), 2018. Scientific report on evaluation of data concerning the necessity of bromoxynil as herbicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. EFSA Journal 2018;16(8):5391, 80 pp.</li> </ul>
<p><b>10. Proposed date of adoption (dd/mm/yy):</b> 4th quarter 2020. <b>Proposed date of publication (dd/mm/yy):</b> 4th quarter 2020.</p>
<p><b>11. Proposed date of entry into force: [ ] Six months from date of publication, and/or (dd/mm/yy):</b> 3 days following publication in the Official Journal of the EU. <b>[ ] Trade facilitating measure</b></p>
<p><b>12. Final date for comments: [ ] Sixty days from the date of circulation of the notification and/or (dd/mm/yy):</b> 17 June 2020 Comments are to be addressed to the TBT Enquiry Point. <b>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:</b>  European Commission EU-TBT Enquiry Point Fax: + (322) 299 8043 E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a></p>
<p><b>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:</b>  European Commission EU-TBT Enquiry Point Fax: + (322) 299 8043 E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a></p>