

21 August 2024

Original: English

(24-5861) Page: 1/3

Committee on Sanitary and Phytosanitary Measures

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): Tritosulfuron (pesticide active substance)
- 4. Regions or countries likely to be affected, to the extent relevant or practicable:
 - [X] All trading partners
 - [] Specific regions or countries:
- **Title of the notified document:** Draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance ritosulfuron, 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). **Language(s):** English. **Number of pages:** 4
 - https://members.wto.org/crnattachments/2024/SPS/EEC/24 05520 00 e.pdf
- **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance tritosulfuron is not renewed in accordance with Regulation (EC) No 1107/2009. EU Member States shall withdraw authorisations for plant protection products containing tritosulfuron as an active substance.

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 tritosulfuron, areas that could not be finalised were identified. These are detailed in the conclusion of the European Food Safety Authority (EFSA). Moreover, the outcome of the risk assessment as documented in the EFSA Conclusion identifies the contamination of groundwater by the relevant metabolite TFA at level likely to be above the regulatory limit of 0.1 ug/L.

Therefore, and considering that by letter of 8 May 2024, the applicant informed the Commission of its decision to withdraw the application for the renewal of tritosulfuron, the approval should not be renewed.

Existing authorisations will need to be withdrawn; EU Member States must withdraw existing plant protection products containing tritosulfuron at the latest by 6 months from the date of entry into force. A period of grace in line with Article 46 of Regulation (EC) 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).

This decision only concerns the placing on the market of this substance and plant protection products containing it.

This draft Commission Implementing Regulation was also notified under the TBT Agreement in notice G/TBT/N/EU/1078.

- Objective and rationale: [X] food safety, [X] animal health, [X] plant protection, [] protect humans from animal/plant pest or disease, [X] protect territory from other damage from pests.
- 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):
 - [X] 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:

https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R1107

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*): https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0540

Conclusion on the peer review of the pesticide risk assessment of the active substance tritosulfuron EFSA Journal 2023;21(8):8142:

DOI https://doi.org/10.2903/j.efsa.2023.8142 (available in English)

10. Proposed date of adoption (dd/mm/yy): 4th quarter 2024

Proposed date of publication (dd/mm/yy): 4th guarter 2024

- 11. Proposed date of entry into force: [] Six months from date of publication, and/or (dd/mm/yy): 20 days following publication in the Official Journal of the European Union
 - [] Trade facilitating measure
- 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 welcomed on TBT related issues and to be addressed to the TBT Enquiry Point on notice G/TBT/N/EU/1078

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 8043

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:

European Commission EU-TBT Enquiry Point Fax: + (32 2) 299 8043

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