



20 May 2020

(20-3717)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

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| 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): Benalaxyl (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 the non-renewal of approval of the active substance benalaxyl, 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: 4 https://members.wto.org/crnattachments/2020/SPS/EEC/20_3275_00_e.pdf |
| 6. Description of content: This draft Commission Implementing Regulation provides that the approval of the active substance benalaxyl is not renewed in accordance with Regulation (EC) No 1107/2009. EU Member States shall withdraw authorisations for plant protection products containing benalaxyl 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. 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. |
| 7. Objective and rationale: <input checked="" type="checkbox"/> food safety, [X] animal health, [X] plant protection, [X] protect humans from animal/plant pest or disease, [X] 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 benalaxyl, 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 Particular, the Authority could not exclude the potential groundwater contamination by relevant metabolites and identified as a critical area of concern a long-term risk to birds and earthworm-eating birds from secondary poisoning from benalaxyl. Additionally, the Authority identified concerns in relation to the risk to in-field and off-field non-target arthropods for all representative uses.

Finally, following the request by the Authority for additional information, the applicant confirmed that no additional studies would be performed or submitted. Consequently, the assessment of the endocrine disrupting potential of benalaxyl could not be finalised and it could not be concluded that the substance has no endocrine disrupting properties. These concerns mean that benalaxyl does not meet the approval criteria as outlined in Regulation (EC) No 1107/2009 and cannot be approved currently.

Existing authorisations will need to be withdrawn; EU Member States must withdraw existing plant protection products containing benalaxyl 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:

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:
<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, 11.6.2011, 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 benalaxyl.
- EFSA (European Food Safety Authority). 2019. Conclusion on the peer review of the pesticide risk assessment of the active substance benalaxyl. EFSA Journal 2020;18(1):5985, 41 pp. doi: 10.2903/j.efsa.2020.5985
- <https://www.efsa.europa.eu/en/efsajournal/pub/5985>
- This draft Commission Implementing Regulation was also notified under the TBT Agreement in notice G/TBT/N/EU/721.

10. Proposed date of adoption (dd/mm/yy): 3rd quarter 2020.

Proposed date of publication (dd/mm/yy): 3rd quarter 2020.

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 EU.
 Trade facilitating measure

12. Final date for comments: **Sixty days from the date of circulation of the notification and/or (dd/mm/yy):** 14 July 2020 - Comments are only to be addressed to the TBT Enquiry Point on notice G/TBT/N/EU/721.

Agency or authority designated to handle comments: **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: + (322) 299 8043
E-mail: grow-eu-tbt@ec.europa.eu

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

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