



14 May 2020

(20-3591)

Page: 1/3

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: European Commission Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: grow-eu-tbt@ec.europa.eu Website: http://ec.europa.eu/growth/tools-databases/tbt/en/
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Benalaxyl (pesticide active substance)
5. Title, number of pages and language(s) 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 (4 page(s), in English)
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.	<p>Objective and rationale, including the nature of urgent problems where applicable: 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</p>
8.	<p>Relevant documents:</p> <ul style="list-style-type: none"> • 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 (<i>OJ L 153, 11.6.2011, p. 1–186</i>) 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
9.	<p>Proposed date of adoption: 3rd quarter 2020</p> <p>Proposed date of entry into force: 20 days following publication in the Official Journal of the EU</p>
10.	<p>Final date for comments: 60 days from notification</p>

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, 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

The text is available on the EU-TBT Website : <http://ec.europa.eu/growth/tools-databases/tbt/en/>

https://members.wto.org/crnattachments/2020/TBT/EEC/20_3204_00_e.pdf