



20 March 2018

(18-1690)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> European Commission <b>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:</b>  European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a> Website: <a href="http://ec.europa.eu/growth/tools-databases/tbt/en/">http://ec.europa.eu/growth/tools-databases/tbt/en/</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Fenamidone (pesticide active substance)
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance fenamidone, 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 (5 page(s), in English)
<b>6. Description of content:</b> This draft Commission Implementing Regulation provides that the approval of the active substance fenamidone is not renewed in accordance with Regulation (EC) No 1107/2009. Existing authorised plant protection products containing fenamidone will be withdrawn from the market. The non-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 approved under Directive 91/414/ EEC.  This decision only concerns the placing on the market of this substance and does not affect the Maximum Residue Levels (MRLs) for residues of the concerned pesticide. However, following non-approval, separate action may be taken on MRLs. Any subsequent action on MRLs will be subject to notification under the SPS procedure.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health or safety; Protection of animal or plant life or health; Protection of the environment; 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) which must be met to enable approval.

During the evaluation and peer-review of fenamidone, 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 it was not possible to conclude on the genotoxic potential of fenamidone and no health-based reference values could be set. Consequently, the consumer and non-dietary risk assessments could not be conducted. Furthermore, a high potential for groundwater contamination above the parametric drinking water limit of 0.1 µg/L by a toxicologically relevant metabolite (RPA 412708) was indicated in all pertinent scenarios for crops grown in soils of predominantly pH 7 or above.

In addition, the consumer risk assessment for exposure to another groundwater metabolite (RPA 412636) which is also found in food of plant and animal origin could not be finalised. Furthermore, the residue definitions for risk assessment in plant and livestock commodities are not finalised in terms of the inclusion of potentially relevant metabolites.

Finally, the risk assessment for wild mammals could not be concluded and a high risk to aquatic organisms from exposure to the metabolite acetophone could not be excluded based on the available information.

These concerns mean that fenamidone 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; Member States must withdraw existing plant protection products containing fenamidone 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 15 months from the entry into force.

**8. Relevant documents:**

- 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 fenamidone. EFSA Journal 2016;14(2)4406:, 102 pp. doi:10.2903/j.efsa.2016.4406. <https://www.efsa.europa.eu/en/efsajournal/pub/4406>

**9. Proposed date of adoption:** 3rd quarter 2018

**Proposed date of entry into force:** 20 days following publication in the Official Journal of the EU

**10. Final date for comments:** 60 days from notification

**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](mailto: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/2018/TBT/EEC/18\\_1506\\_00\\_e.pdf](https://members.wto.org/crnattachments/2018/TBT/EEC/18_1506_00_e.pdf)