NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** European Union  **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](mailto: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):** Fenpyrazamine (pesticide active substance) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance fenpyrazamine (4 page(s), in English; 2 page(s), in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance fenpyrazamine is amended in accordance with Regulation (EC) No 1107/2009. EU Member States shall review authorisations for plant protection products containing fenpyrazamine as an active substance, where relevant. The amendment of the conditions of approval is based on the evaluation to clarify the technical specification proposed in the approval of fenpyrazamine for use as a pesticide active substance in the EU under Regulation (EC) No 1107/2009.  This decision only concerns the placing on the market of this substance and plant protection products containing it and does not affect the Maximum Residue Levels (MRLs) for residues of the concerned pesticide; the impurity was considered not to be new in the commercial produced batches. |
| **7.** | **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. The reference specification as established at the time of first approval of fenpyrazamine was updated based on batch data from the technical material as commercially manufactured. The review has established that for the active substance notified by the applicant, the minimum purity is higher and there is one toxicologically relevant impurity, hydrazine. The content of hydrazine in the active substance as manufactured shall be a maximum concentration of 0.0001% (1 mg/kg). These are detailed in the conclusion of the European Food Safety Authority (EFSA). Existing authorisations will need to be adapted accordingly; EU Member States must ensure that the placing on the market of fenpyrazamine and the plant protection products containing it are in compliance with Part B of the Annex to Implementing Regulation (EU) No 540/2011 as replaced by this draft Commission Implementing Regulation; Protection of human health or safety; Protection of animal or plant life or health; Protection of the environment |
| **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:   <https://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:32009R1107&qid=1590756186915&rid=1>   * 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/AUTO/?uri=CELEX:32011R0540&qid=1590756246146&rid=1>   * Outcome of the consultation on the pesticide risk assessment of confirmatory data for the active substance fenpyrazamine. EFSA Journal (2012) 10(1):2496. doi:10.2903/j.efsa.2012.2496.   <http://www.efsa.europa.eu/en/supporting/pub/en-630> |
| **9.** | **Proposed date of adoption:** Fourth quarter 2020  **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/2020/TBT/EEC/20_5315_00_e.pdf>  <https://members.wto.org/crnattachments/2020/TBT/EEC/20_5315_01_e.pdf> |