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):** Terbuthylazine (pesticide active substance); Pesticides and other agrochemicals (ICS 65.100) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Implementing Regulation amending Implementing Regulations (EU) No 540/2011 and 820/2011 as regards the conditions of approval of the active substance terbuthylazine (5 page(s), in English; 5 page(s), in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance terbuthylazine is amended to set revised limits for two toxicologically relevant impurities in the technical material and to introduce a restriction to the rate and frequency of use of the substance. EU Member States shall review authorisations for plant protection products containing terbuthylazine as an active substance. The amendment of the conditions of approval is based on the evaluation of the confirmatory information required in the approval of terbuthylazine 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. |
| **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. Based on the assessment of the confirmatory information related to the specification of the technical material as manufactured, it is concluded that revised maximum levels for propazine and simazine in the technical material as manufactured should be established. EFSA also identified a risk to infants and toddlers under some conditions of use from exposure to metabolites of terbuthylazine through food and drinking water, according to the additional information provided by the applicant and based on the use of terbuthylazine at a rate of 850 g/ha each year on the same field. Furthermore, where terbuthylazine is applied every year at a maximum rate of 850 g/ha, two metabolites of terbuthylazine, LM3 and LM6, are predicted to occur in groundwater above 0.75 µg/L in all scenarios, triggering the need for a consumer risk assessment which, however, could not be carried out since health-based reference values could not be derived based on the available data. Therefore, it is necessary and appropriate to restrict the approval of terbuthylazine to use only every third year on the same field at a maximum rate of 850 g/ha. It is also necessary to amend the maximum levels of the relevant impurities propazine and simazine (to a maximum of 9 g/kg). Existing authorisations will need to be adapted accordingly; EU Member States must ensure that the placing on the market of terbuthylazine and the plant protection products containing it are in compliance with the amended conditions of approval as introduced 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> * Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011 approving the active substance terbuthylazine, 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 and Commission Decision 2008/934/EC  <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0820&from=EN> * EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for terbuthylazine in light of confirmatory data. EFSA supporting publication 2016:EN-919. 54 pp. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2016.EN-919> * EFSA (European Food Safety Authority), 2019. Conclusion on the updated peer review of the pesticide risk assessment for the active substance terbuthylazine in light of conﬁrmatory data submitted. EFSA Journal 2019;17(9):5817, 21 pp. [https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5817c](https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5817) |
| **9.** | **Proposed date of adoption:** Second quarter 2021  **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/2021/TBT/EEC/21_0624_00_e.pdf>  <https://members.wto.org/crnattachments/2021/TBT/EEC/21_0624_01_e.pdf> |