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.euWebsite: <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 [****], 3.2 [****], 7.2 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** metconazole (pesticide active substance) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Implementing Regulation renewing the approval of the active substance metconazole as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011; (6 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 metconazole is renewed in accordance with Regulation (EC) No 1107/2009. It is, however, necessary to include certain conditions and restrictions including in particular a restriction to use only by professional users.Existing authorised plant protection products containing metconazole will be reviewed in accordance with the conditions and restrictions set in this act. The outcome of the assessment 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 active substance. Any action on MRLs will be subject to notification under the SPS procedure. |
| **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.During the evaluation and peer-review of metconazole, a number of concerns and areas that could not be finalised were identified, and experts considered the potential link between the occurrence of azole-resistant *A. fumigatus* in the environment and the spread of azole-resistant *Aspergillus* in infected patients. In the light of this potential concern for an increasing prevalence of azole-resistant strains in *A. fumigatus* and taking into account the precautionary principle, restricting the use of products containing metconazole to professional users only is considered appropriate.Existing authorisations will need to be amended or withdrawn following renewal of authorisation in accordance with Article 43 of Regulation (EC) No 1107/2009; 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: <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 metconazole EFSA Journal 2023, doi: 10.2903/j.efsa.2023.8141. |
| **9.** | **Proposed date of adoption:** 3rd quarter 2024**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.euThe text is available on the EU-TBT Website : <http://ec.europa.eu/growth/tools-databases/tbt/en/><https://members.wto.org/crnattachments/2024/TBT/EEC/24_01674_00_e.pdf><https://members.wto.org/crnattachments/2024/TBT/EEC/24_01674_01_e.pdf> |