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):** Bifenazate (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 renewing the approval of the active substance bifenazate 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 (5 page(s), in English; 4 page(s), in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance bifenazate is renewed in accordance with Regulation (EC) No 1107/2009. It is however, necessary to include certain conditions and restrictions, i.e. to restrict the use of plant protection products containing bifenazate to non-edible crops in permanent greenhouses and to require further confirmatory information.  Existing authorised plant protection products containing bifenazate will be reviewed in accordance with the conditions and restrictions set in this act. The conditions and restrictions are 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. Following restriction of the approval and the consequent expiry of all grace periods for stocks of products, separate legal action may be taken on Maximum Residue Levels and a separate notification will be made in accordance with SPS procedures in due time. |
| **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 bifenazate, 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). This means that bifenazate meets the approval criteria as outlined in Regulation (EC) No 1107/2009 only if its use is restricted to non-edible crops in permanent greenhouses. The restriction to use on non-edible crops will exclude dietary exposure of consumers and is required since the consumer risk assessment could not be finalised. As a high risk was identified to birds via long term exposure to bifenazate, a restriction to use in greenhouses as defined in Article 3 of Regulation (EC) No 1107/2009 will ensure that birds are not exposed to bifenazate. 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 bifenazate EFSA Journal 2017;15(1):4693. EFSA Updated peer review of the pesticide risk assessment of the active substance bifenazate EFSA Journal 2021;19(8):6818 Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu) |
| **9.** | **Proposed date of adoption:** 2nd quarter 2022.  **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/2022/TBT/EEC/22_0730_00_e.pdf> <https://members.wto.org/crnattachments/2022/TBT/EEC/22_0730_01_e.pdf> |