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):** Biocidal products and treated articles treated with or incorporating biocidal products |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Implementing Decision not approving d-Allethrin as an existing active substance for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council; (3 page(s), in English) |
| **6.** | **Description of content:** This draft Commission Implementing Decision does not approve d-Allethrin as an active substance for use in biocidal products of product-type 18.According to the opinion of the Agency, biocidal products of product-type 18 containing d-Allethrin cannot be expected to meet the criteria laid down in Article 19(1), points (b)(iii), and (iv), of Regulation (EU) No 528/2012.In its opinion, the Agency noted that the proposed reference specifications, established on the basis of data provided by one of the applicants, are not in line with the composition of the material that was used for testing to generate the toxicological data provided by the applicants. As a result, on the basis of the data provided in the applications, it could not be established whether the representative biocidal products could fulfil the criteria referred to in Article 19(1), point (b) of Regulation (EU) No 528/2012.According to the opinion of the Agency, based on the available toxicological data, an unacceptable risk has been identified for the general public due to secondary exposure to genotoxic photometabolites formed after the application of the representative products.In addition, according to the opinion of the Agency, an unacceptable risk to the environment has been identified for the aquatic compartment (surface water and sediment) and for soil.In conclusion, no safe use could be identified when considering the risks to human health and the environment for each of the representative biocidal products submitted in the applications. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Harmonisation of the EU market on biocidal products; Protection of human health or safety; Protection of the environment; Harmonization |
| **8.** | **Relevant documents:** Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1.). Available in all EU languages[EUR-Lex - 32012R0528 - EN - EUR-Lex (europa.eu)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0528&qid=1653319893936)The opinion of the European Chemicals Agency can be found on its website (<http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval>). |
| **9.** | **Proposed date of adoption:** January 2023**Proposed date of entry into force:** 20 days from publication in the Official Journal of the EU (Application 12 months after adoption) |
| **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/2022/TBT/EEC/22_7293_00_e.pdf> |