NOTIFICATION

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** EUROPEAN UNION**If applicable, name of local government involved:**  |
| **2.** | **Agency responsible:** European Commission, Health and Food Safety Directorate-General |
| **3.** | **Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):** Clofentezine (pesticide active substance) |
| **4.** | **Regions or countries likely to be affected, to the extent relevant or practicable:****[****X]** **All trading partners** **[****]** **Specific regions or countries:**  |
| **5.** | **Title of the notified document:** Draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance clofentezine, 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.**Language(s):** English. **Number of pages:** 5[https://members.wto.org/crnattachments/2023/SPS/EEC/23\_11175\_00\_e.pdf](https://members.wto.org/crnattachments/2023/SPS/EEC/23_11175_00_e.pdf%22%20%5Ct%20%22_blank) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance clofentezine is not renewed in accordance with Regulation (EC) No 1107/2009. Member States shall withdraw authorisations for plant protection products containing clofentezine as an active substance. The non-renewal of approval is based on the first evaluation of the substance for use as a pesticide active substance in the European Union under Regulation (EC) No 1107/2009. The substance was formerly assessed and approved under Directive 91/414/ EEC.This decision only concerns the placing on the market of this substance and plant protection products containing it. Following non-approval and the expiry of all grace periods for stocks of products containing this substance, separate action may be taken on MRLs and a separate notification will be made in accordance with SPS procedures.This draft Commission Implementing Regulation was also notified under the TBT Agreement in notice G/TBT/N/EU/994 |
| **7.** | **Objective and rationale: [****X]****food safety, [****X]****animal health, [****X]****plant protection, [****]****protect humans from animal/plant pest or disease, [****X]****protect territory from other damage from pests.**  |
| **8.** | **Is there a relevant international standard? If so, identify the standard:****[****]** **Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:** **[****]** **World Organization for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*:** **[****]** **International Plant Protection Convention *(e.g. ISPM number)*:** **[****X]** **None****Does this proposed regulation conform to the relevant international standard?** **[****]** **Yes [****]** **No****If no, describe, whenever possible, how and why it deviates from the international standard:**  |
| **9.** | **Other relevant documents and language(s) in which these are available:** * 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 June 2011, p. 1–186*)

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&uri=CELEX:32011R0540>* Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (*OJ L 101, 20 April 2018, p. 33)*

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R0605>* Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16 March 2005, p. 1)

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32005R0396>* EFSA (European Food Safety Authority), Alvarez F, Arena M, Auteri D, Borroto J,Brancato A, Carrasco Cabrera L, Castoldi AF, Chiusolo A, Colagiorgi A, Colas M, Crivellente F, DeLentdecker C, Egsmose M, Fait G, Gouliarmou V, Ferilli F, Greco L, Ippolito A, Istace F, Jarrah S,Kardassi D, Kienzler A, Leuschner R, Lava R, Linguadoca A, Lythgo C, Magrans O, Mangas I, Miron I,Molnar T, Padovani L, Parra Morte JM, Pedersen R, Reich H, Santos M, Sharp R, Szentes C, Terron A,Tiramani M, Vagenende B and Villamar-Bouza L, 2021. Conclusion on the peer review of the pesticiderisk assessment of the active substance clofentezine. EFSA Journal 2021;19(8):6817, 35 pp.

<https://doi.org/10.2903/j.efsa.2021.6817>(available in English) |
| **10.** | **Proposed date of adoption *(dd/mm/yy)*:** 4th quarter 2023.**Proposed date of publication *(dd/mm/yy)*:** 4th quarter 2023. |
| **11.** | **Proposed date of entry into force: [****]****Six months from date of publication**, **and/or** ***(dd/mm/yy)*:** Three days following publication in the Official Journal of the European Union.**[****]** **Trade facilitating measure**  |
| **12.** | **Final date for comments: [****]****Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** Not applicable. Comments are only welcomed on TBT related issues and to be addressed to the TBT Enquiry Point on notice G/TBT/N/EU/994.**Agency or authority designated to handle comments: [****X]****National Notification Authority, [****X]****National Enquiry Point.** **Address, fax number and e‑mail address (if available) of other body:** European CommissionEU-TBT Enquiry PointFax: +(32) 2 299 80 43E-mail: grow-eu-tbt@ec.europa.eu |
| **13.** | **Text(s) available from: [****X]****National Notification Authority, [****X]****National Enquiry Point.** **Address, fax number and e‑mail address (if available) of other body:** European CommissionEU-TBT Enquiry PointFax: +(32) 2 299 80 43E-mail: grow-eu-tbt@ec.europa.eu |