WORLD TRADE ORGANIZATION

G/TBT/N/EU/994

14 July 2023

(23-4753)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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 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 [ ], 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):** Clofentezine (pesticide active substance)
5.	**Title, number of pages and language(s) 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; (5 page(s), in English)
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 EU 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.

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 clofentezine, 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).

In particular, based on the available information submitted in the dossier, clofentezine has endocrine disrupting properties that may cause adverse effects in humans, as set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009. Negligible exposure cannot be demonstrated for clofentezine since residues above the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005 may be expected to occur. Therefore, the requirement set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 is not fulfilled.

Furthermore, a high long-term risk to birds and wild mammals for the representative uses not grown in permanent greenhouses was identified. The consumer risk assessment could not be performed and maximum residue levels cannot be proposed based on the available data. Finally, the risk assessment for non-target arthropods could also not be finalised for the representative uses not grown in permanent greenhouses.

Derogation in accordance with Article 4(7) to Regulation (EC) No 1107/2009 does not apply for the reasons set out in the draft Regulation.

These concerns mean that clofentezine does not meet the approval criteria as outlined in Regulation (EC) No 1107/2009 and cannot be approved currently.

Existing authorisations will need to be withdrawn; Member States must withdraw existing plant protection products containing clofentezine at the latest by 6 months from the date of entry into force. A period of grace in line with Article 46 of Regulation 1107/2009 is allowed for and shall expire at the latest 12 months from the entry into force (allowing for a final season of use).

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

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, 20.4.2018, 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, 16.3.2005, 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
9.	**Proposed date of adoption:** 4th quarter 2023 **Proposed date of entry into force:** 3 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 The text is available on the EU-TBT Website : http://ec.europa.eu/growth/tools-databases/tbt/en/ https://members.wto.org/crnattachments/2023/TBT/EEC/23_10999_00_e.pdf