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):** Propiconazole (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 propiconazole, 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 Commission Implementing Regulation (EU) No 540/2011 (5 pages, in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance propiconazole is not renewed in accordance with Regulation (EC) No 1107/2009. Existing authorised plant protection products containing propiconazole will be withdrawn from the market. The non-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 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 pesticide. However, following non-approval, separate action may be taken on MRLs. Any subsequent action on MRLs will be subject to notification under the SPS procedure. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; protection of animal or plant life or health; protection of the environment.  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) which must be met to enable approval.  During the evaluation and peer-review of propiconazole, 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).  Propiconazole is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council.  Based on the data available in the dossier the Authority concluded that Maximum Residue Levels (‘MRLs’) in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council could not be confirmed for plant and animal products since data on the magnitude and toxicity of metabolites that are included in the residue definition for risk assessment was not available. The current MRLs for the proposed uses of propiconazole are above the default value in the meaning of Article 18(1)(b) of Regulation (EC) No 396/2005. For those reasons, it cannot be considered that exposure of humans to the active substance is negligible.  Therefore, the requirements set out in Point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 are not fulfilled.  A critical concern was identified by the Authority in relation to the contamination of groundwater by metabolites of propiconazole. In particular, metabolite NOA436613 is predicted to occur above the paramteric value of 0.1 μg/L in all pertinent scenarios for all proposed uses of propiconazole, even when the substance is used biennally. Two other metabolites are predicted to occur in groundwater above 0.1 μg/L in the majority of pertinent scenarios.  Additionally, the Authority concluded that propiconazole caused toxic effects on endocrine organs. However, the scientific assessment to determine the endocrine disrupting potential of propiconazole could not be finalised by the Authority based on the information available in the dossier.  Furthermore, the assessment of several aspects necessary to conclude on the risk to consumers through dietary intake could not be finalised based on the information available in the dossier.  These concerns mean that propiconazole 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; EU Member States must withdraw existing plant protection products containing propiconazole 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 15 months from the entry into force. |
| **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>  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/TXT/?qid=1528730328713&uri=CELEX:32005R0396>   EFSA (European Food Safety Authority), Arena M, Auteri D, Barmaz S, Bellisai G, Brancato A, Brocca D, Bura L, Byers H, Chiusolo A, Court Marques D, Crivellente F, De Lentdecker C, De Maglie M, Egsmose M, Erdos Z, Fait G, Ferreira L, Goumenou M, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Magrans JO, Medina P, Miron I, Molnar T, Nougadere A, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Serafimova R, Sharp R, Stanek A, Streissl F, Sturma J, Szentes C, Tarazona J, Terron A, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017.  Conclusion on the peer review of the pesticide risk assessment of the active substance propiconazole. EFSA Journal 2017;15(7):4887, 28 pp.  <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4887> |
| **9.** | **Proposed date of adoption:**  4th quarter 2018  **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/2018/TBT/EEC/18_3018_00_e.pdf> |