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  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):** Tolclofos‑methyl (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 tolclofos-methyl, 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 pages + annexes 3 pages, in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance tolclofos-methyl is renewed in accordance with Regulation (EC) No 1107/2009. It is, however, necessary to include certain conditions and restrictions. In particular, only the use on ornamentals and on potatoes can be approved. Existing authorised plant protection products containing tolclofos-methyl will be amended or withdrawn from the market. The restriction 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 approved under Directive 91/414/EEC.  Following the use restriction of products containing this substance, separate action will likely 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:** 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 tolclofos-methyl, a number of concerns and areas that could not be finalised were identified. These are detailed inthe conclusion of the European Food Safety Authority (EFSA).  In particular, the consumer risk assessment could not be finalised for lettuces which were initially proposed as representative use considering the outstanding data to finalise the residue definitions for risk assessment. In order to minimise the exposure for consumers to certain metabolites and to reduce the exposure for aquatic organisms and wild mammals, only the use in ornamentals and potatoes are considered acceptable.  These concerns mean that tolclofos-methyl can only meet the approval criteria as outlined in Regulation (EC) No 1107/2009 if the approval is restricted to use in ornamentals and on potatoes only.  Existing authorisations of plant protection products containing tolclofos-methyl will be re-examined by Member States in accordance with Article 43 of Regulation No 1107/2009. Uses that do not comply with the conditions of approval of tolclofos-methyl, in particular uses on crops other than ornamentals and potatoes must be withdrawn. ; 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> * EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance tolclofos-methyl. EFSA Journal EFSA Journal 2018;16(1):5130, 25 pp. doi: 10.2903/j.efsa.2018.5130 <https://www.efsa.europa.eu/en/efsajournal/pub/5130> |
| **9.** | **Proposed date of adoption:** 3rd quarter 2019.  **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/2019/TBT/EEC/19_1547_00_e.pdf>  <https://members.wto.org/crnattachments/2019/TBT/EEC/19_1547_01_e.pdf> |