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 CommissionEU-TBT Enquiry PointFax: +(32) 2 299 80 43E-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 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Thiacloprid (pesticide active substance) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance thiacloprid, 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 page(s), in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance thiacloprid is not renewed in accordance with Regulation (EC) No 1107/2009. EU Member States shall withdraw authorisations for plant protection products containing thiacloprid as active substance. The non-renewal of the 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-renewal of approval and the expiry of all grace periods for stocks 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:** 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 thiacloprid, 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). EFSA identified acritical concern in relation to the contamination of groundwater by metabolites of thiacloprid. In particular, metabolites M30, M34 and M46 are predicted to occur above the parametric drinking water limit of 0,1 μg/L in all pertinent scenarios for all proposed uses of thiacloprid. These metabolites are considered *a priori* of concern since it cannot be excluded that they share the same carcinogenic properties of the parent active substance thiacloprid, which is clasified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council as carcinogenic category 2. Therefore, it cannot currently be established that the presence of metabolites of thiacloprid in groundwater will not result in unacceptable effects on groundwater and in harmful effects on human health. Furthermore, issues were raised as regards the consumer risk assessment and the risk assessment for birds and mammals (from the relevant plant metabolites on maize), aquatic organisms, bees and terrestrial non-target plants was not finalised. Additionally, thiacloprid is classified in accordance with Regulation (EC) No 1272/2008  also as toxic for reproduction category 1B. The applicant provided information attempting to demonstrate that exposure of humans to thiacloprid can be considered negligible. The Authority presented the outcome of the assessment of that informaiton in its conclusion. Nevertheless, given the concerns identified (as outlined in recital 9 of the draft Implementing Regulation), a conclusion on whether exposure to humans is negligible for the purposes of point 3.6.4 of Annex II to Regulation (EC) No 1107/2009, is not necessary for the decision on whether the approval of thiacloprid can be renewed. These concerns mean that thiacloprid does not meet the approval criteria as outlined in Article 4 of 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 thiacloprid 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>](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 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1). [<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272>](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272)
* Conclusion on the peer review of the pesticide risk assessment of the active substance thiacloprid. EFSA Journal 2019;17(3):5595. DOI: 10.2903/j.efsa.2019.5595 <http://www.efsa.europa.eu/en/efsajournal/pub/5595>
 |
| **9.** | **Proposed date of adoption:** 4th 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 CommissionEU-TBT Enquiry PointFax: + (32) 2 299 80 43E-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/2019/TBT/EEC/19_4261_00_e.pdf> |