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):** Famoxadone (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 concerning the non-renewal of approval of the active substance famoxadone, 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 (4 page(s), in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance famoxadone is not renewed in accordance with Regulation (EC) No 1107/2009. EU Member States shall withdraw authorisations for plant protection products containing famoxadone 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 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 thereto) which must be met to enable approval. During the evaluation and peer-review of famoxadone, 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) and reported hereafter: * the estimated worker exposure levels during crop hand-harvesting exceed the AOEL (112 % of the AOEL) even when the use of PPE (trousers, long-sleeved shirt and gloves) is considered;
* the high long-term risk for mammals;
* the high risk for aquatic organisms.

Furthermore, the available information is insufficient to satisfy the requirements set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009 concerning the long-term risk assessments for birds. These concerns and areas that could not be finalised mean that famoxadone 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 famoxadone 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>Conclusion on the peer review of the pesticide risk assessment of the active substance famoxadone. EFSA Journal 2015;13(7):4194 [116 pp.]. Conclusion on the peer review of the pesticide risk assessment of the active substance famoxadone. doi:10.2903/j.efsa.2015.4194. |
| **9.** | **Proposed date of adoption:** 2nd quarter 2021**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 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/2021/TBT/EEC/21_1858_00_e.pdf> |