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):** Sulfoxaflor (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 amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor (5 page(s), in English; 2 page(s), in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval conditions of the active substance sulfoxaflor are amended in accordance with Regulation (EC) No 1107/2009 based on the evaluation of confirmatory data as required in Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor for use in the EU. Existing authorised plant protection products containing sulfoxaflor will be reviewed in accordance with the restriction set in this act.  This decision however only concerns the placing on the market of this substance. Following restriction of the approval and the consequent expiry of all grace periods for stocks of products, separate legal action will likely be taken on Maximum Residue Levels and a separate notification will be made in accordance with SPS procedures in due time. |
| **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. Regulation (EU) No 2015/1295 approved sulfoxaflor as active substance for use in plant protection products and required the applicant to provide confirmatory information with regard to bees. Following the assessment of confirmatory information, the information provided did not demonstrate absence of risks to bees, in particular bumble bees and solitary bees, from outdoor use. Consequently, the notified draft Implementing Regulation aims at restricting the conditions of approval of the active substance sulfoxaflor to uses in permanent greenhouses only in order to protect bees. The decision is based on a risk assessment peer reviewed at EU level, under the lead of the European Food Safety Authority. EU Member States shall, where necessary, withdraw or amend authorisations for plant protection products containing sulfoxaflor as active substance at the latest by 6 months from the date of entry into force. EU Member States may grant a period of grace in line with Article 46 of Regulation No 1107/2009 which shall expire at the latest 12 months from the entry into force of the notified draft Implementing Regulation.; 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. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment of confirmatory data for sulfoxaflor in light of confirmatory data. EFSA supporting publication 2018:EN-1474. 73 pp. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1474> * EFSA (European Food Safety Authority), 2019. Conclusion on the peer review of the pesticide risk assessment for the active substance sulfoxaflor in light of confirmatory data submitted. EFSA Journal 2019;17(3):5633, 14 pp. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5633> * EFSA (European Food Safety Authority), 2020. Conclusion on the peer review of the pesticide risk assessment for the active substance sulfoxaflor in light of confirmatory data submitted. EFSA Journal 2020;18(3):6056, 15 pp.  <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6056> |
| **9.** | **Proposed date of adoption:** 1st Quarter 2022.  **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/2021/TBT/EEC/21_7189_00_e.pdf> <https://members.wto.org/crnattachments/2021/TBT/EEC/21_7189_01_e.pdf> |