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):** Methoxyfenozide (pesticide active substance) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Implementing Regulation renewing the approval of the active substance methoxyfenozide, as a candidate for substitution, 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 (and its accompanying annexes) (4 pages + Annexes 3 pages, in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance methoxyfenozide is renewed in accordance with Regulation (EC) No 1107/2009 under restricted conditions and for a period of 7 years. Existing authorised plant protection products containing methoxyfenozide will have to be re-authorised in accordance with the proposed restrictions. The 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 approved under Directive 91/414/ EEC.  This regulation 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 and if so 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 the substance, a number of issues that could not be finalised and an area of concern were identified. These are detailed in the conclusion of the European Food Safety Authority (EFSA).  In particular, the Authority identified as an area of concern the potential groundwater contamination above the parametric drinking water limit of 0.1 µg/L by methoxyfenozide and its toxicologically relevant metabolite. Moreover, several data gaps lead to non- finalised risk assessment in the area of consumer and non-target organisms and to uncertainty as to whether thyroid toxicity effects in rats could be endocrine-mediated. It is therefore necessary to restrict the uses to fruiting vegetables of solanaceae in greenhouses for which sufficient evidence allows for the conclusion that there will be limited consumer exposure and limited potential environmental exposure. In addition, considering the remaining uncertainties, further data are required to confirm the overall conclusion that the substance satisfies the approval criteria of Article 4 of Regulation No 1107/2009. Existing authorisations of plant protection products containing methoxyfenozide will need to be re-examined by Member States in accordance with Article 43 of Regulation No 1107/2009. |
| **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 methoxyfenozide EFSA Journal 2017;15(8):4978  <https://www.efsa.europa.eu/en/efsajournal/pub/4978>  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](http://eur-lex.europa.eu/legal-content/EN/AUTO/?uri=OJ:L:2008:353:TOC)).  <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2008:353:TOC> |
| **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_4677_00_e.pdf>  <https://members.wto.org/crnattachments/2018/TBT/EEC/18_4677_01_e.pdf> |