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 CommissionEU-TBT Enquiry PointFax: +(32) 2 299 80 43E-mail: grow-eu-tbt@ec.europa.euWebsite: <http://ec.europa.eu/growth/tools-databases/tbt/>  |
| **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):** Mepanipyrim (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 mepanipyrim 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 mepanipyrim 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 in greenhouses can be approved. Existing authorised plant protection products containing mepanipyrim will be amended or withdrawn from the market.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.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.  |
| **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 mepanipyrim, 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 considering the outstanding data to finalise the residue definitions for risk assessment in primary crops and in processed commodities, except for tomatoes in greenhouses.Furthermore, the endocrine disrupting potential of mepanipyrim could not be ruled out and further clarification is needed.Finally, A high long-term risk was identified for wild mammals exposed to mepanipyrim via dietary exposure.In order to avoid exposure of wild mammals to mepanipyrim, it is necessary to restrict the approval to uses in greenhouses only.These concerns mean that mepanipyrim can only meet the approval criteria as outlined in Regulation (EC) No 1107/2009 if the approval is restricted to use in greenhouse only.Existing authorisations will need to be amended or withdrawn; EU Member States must amend or withdraw existing plant protection products containing mepanipyrim 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 15 months from the entry into force. |
| **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), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance mepanipyrim. EFSA Journal 2017;15(6):4852, 22 pp. doi: 10.2903/j.efsa.2017.4852<https://www.efsa.europa.eu/en/efsajournal/pub/4852>  |
| **9.** | **Proposed date of adoption:**1st 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 Website: <http://ec.europa.eu/growth/tools-databases/tbt/><https://members.wto.org/crnattachments/2018/TBT/EEC/18_4706_00_e.pdf><https://members.wto.org/crnattachments/2018/TBT/EEC/18_4706_01_e.pdf> |