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):** Metalaxyl-M (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 renewing the approval of the active substance metalaxyl-M, and restricting the use of seeds treated with plant protection products containing it, 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 pages plus Annexes 4 pages, in English) |
| **6.** | **Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance metalaxyl-M is renewed in accordance with Regulation (EC) No 1107/2009, subject to certain restrictions including to the use of seeds treated with product containing metalaxyl-M. Use as seed treatment is permitted, however, treated seeds shall only be sown in greenhouses. Other uses e.g. foliar spraying can still be authorised by EU Member States.  Existing authorised plant protection products containing metalaxyl-M will be reviewed 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 decision only concerns the placing on the market and use of metalaxyl-M and plant protection products containing it. The decision does not affect existing Maximum Reside Levels (MRLs). |
| **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 metalaxyl-M, a number of concerns were identified. These are detailed in the conclusion of the European Food Safety Authority (EFSA). EFSA concluded that based on the information available, the genotoxic potential of one impurity (2-[(2,6-dimethyl-phenyl)-(2-methoxyacetyl)-amino]-propionic acid 1-methoxycarbonyl-ethyl ester) in the technical active substance as manufactured could not be ruled out. However, the evaluation showed that if the impurity is present below a certain level (0.18 g/kg) that a concern does not exist.  Furthermore, two other impurities (2,6-dimethylphenylamine and 4-methoxy-5-methyl-5H-[1,2]oxathiole 2,2-dioxide) are considered toxicologically relevant. It is therefore necessary to establish maximum levels for those three impurities in the technical active substance as manufactured.   EFSA also identified a high risk to birds and mammals from the use of metalaxyl-m as a seed treatment. In order to address this concern, seeds treated with metalaxyl-M shall only be sown in greenhouses. The risk from consumption of seedlings was considered acceptable for the two representative crops considered (sunflowers and spinach). For the use on spinach, residue data allow to conclude that seedlings can be planted in the field after 21 days. For other crops, such data are not available. EU Member States therefore need to pay particular attention to the period before seedlings can be planted in open fields. Existing authorisations will need to be amended or withdrawn following renewal of authorisation in accordance with Article 43 of Regulation (EC) 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>](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>](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 metalaxyl-M. EFSA Journal 2015;13(3):3999. DOI: 10.2903/j.efsa.2015.3999  [<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.3999>](https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.3999) |
| **9.** | **Proposed date of adoption:** 1st quarter 2020  **Proposed date of entry into force:** 20 days following publication in the Official Journal of the EU. The Regulation will apply from 1 April 2020.  The restriction to sowing of treated seeds in greenhouses will apply from 1 November 2020. |
| **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/2019/TBT/EEC/19_6145_01_e.pdf> <https://members.wto.org/crnattachments/2019/TBT/EEC/19_6145_00_e.pdf> |