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/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):** Copper compounds (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 substances copper compounds, as candidates 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 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 substances copper compounds are renewed in accordance with Regulation (EC) No 1107/2009 under restricted conditions and for a period of 5 years. Existing authorised plant protection products containing copper compounds will have to be re-authorised in accordance with the proposed restrictions. The renewal of approval is based on the first evaluation of the substances for use as pesticide active substances in the EU under Regulation (EC) No 1107/2009. The substances were formerly approved under Directive 91/414/ EEC.This regulation only concerns the placing on the market of these substances 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 substances, 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). In particular, the Authority identified some areas of concern with respect to high risk for birds and mammals, aquatic organisms and soil macro-organisms. It is therefore necessary to restrict the uses to the maximum application rate per year and per hectare to 4 Kg/ha/year of copper to limit the potential environmental exposure due to its use in plant protection products. In addition, copper is a metal, which occurs in nature and as other metals shows a distinct chemical behaviour in the environment for which the Authority has recognised that the current scientific guidance for pesticides risk assessment might not be fully appropriate. Hence, given that specific guidance is available under the European regulatory framework concerning biocides, the Commission will request the Authorityto develop guidance on environmental risk assessment of metals and metals compounds used in plant protection products to take into account the new scientific approach already incorporated in other European regulatory framework. In view of the above it is hence considered appropriate to propose the renewal of copper for a limited period of 5 years ensuring a priority re-assessment of copper compounds over other active substances as soon as specific guidance for environmental risk assessment of metals and metal compounds will be available. Existing authorisations of plant protection products containing copper compounds 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 copper compounds EFSA Journal 2018;16(1):5152<https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2018.5152>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=uriserv:OJ.L_.2008.353.01.0001.01.ENG&toc=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 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/2018/TBT/EEC/18_4676_00_e.pdf><https://members.wto.org/crnattachments/2018/TBT/EEC/18_4676_01_e.pdf> |