



4 August 2017

(17-4224)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> European Commission <b>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:</b>  European Commission, EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a> Website: <a href="http://ec.europa.eu/growth/tools-databases/tbt/">http://ec.europa.eu/growth/tools-databases/tbt/</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Clothianidin (pesticide active substance)
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (5 pages + Annex 2 pages, in English)
<b>6. Description of content:</b> This draft Commission Implementing Regulation provides that the conditions of approval of the active substance clothianidin are amended. Existing authorisations for plant protection products containing clothianidin will be amended or withdrawn from the market. The amendment is based on the evaluation of confirmatory information submitted following the amendment of the conditions of approval of clothianidin (Regulation (EU) No 485/2013).  This decision concerns the placing on the market of this substance and does not affect the Maximum Residue Levels (MRLs) for residues of the concerned pesticide.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> During the evaluation of the confirmatory data on clothianidin, provided following the amendment of its conditions of approval (Regulation (EU) No 485/2013), for most crops, high acute risks for bees were identified from plant protection products containing the active substance clothianidin. In particular, as regards exposure via dust, high acute risks for bees were identified for winter cereals and high chronic risks to bees cannot be excluded for sugar beets. For the consumption of residues in contaminated pollen and nectar, high acute and chronic risks were identified or a high risk cannot be excluded for most field uses. Chronic and acute risks to bees were also identified in the succeeding crops for all field uses. For forestry nursery, no data was provided by the applicants and risks to bees can therefore not be excluded.

In order to ensure the protection of bees, it is necessary to amend the approval conditions to include a further restriction of use. In particular, the use of clothianidin should be limited to permanent greenhouses where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside.

Seeds treated with plant protection products containing clothianidin may not be placed on the market or used, with the exception of seeds to be used in permanent greenhouses where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside.

Existing authorisations will need to be amended or withdrawn; Member States must amend or withdraw existing authorisations for plant protection products containing clothianidin at the latest by 3 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 6 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>

Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (*OJ L 139, 25.5.2013, p. 238–252*)

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1491312449480&uri=CELEX:32013R0485>

EFSA (European Food Safety Authority), 2016. Peer review of the pesticide risk assessment for the active substance clothianidin in light of confirmatory data submitted. EFSA Journal 2016;14(11):4606 [34 pp.].

<http://www.efsa.europa.eu/en/efsajournal/pub/4606>

**9. Proposed date of adoption:** 4<sup>th</sup> quarter 2017

**Proposed date of entry into force:** 20 days following publication in the OJ

**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 Website: <http://ec.europa.eu/growth/tools-databases/tbt/>

[https://members.wto.org/crnattachments/2017/TBT/EEC/17\\_3483\\_00\\_e.pdf](https://members.wto.org/crnattachments/2017/TBT/EEC/17_3483_00_e.pdf)

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