



6 July 2022

(22-5221)

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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/en/">http://ec.europa.eu/growth/tools-databases/tbt/en/</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], 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 and thiamethoxam (pesticide active substances)
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Commission Regulation amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products; (7 page(s), in English), (1 page(s), in English), (13 page(s), in English)
<b>6. Description of content:</b> The proposed draft Regulation addresses an environmental concern of global nature, that it is the decline of pollinators worldwide. It concerns the review of all existing maximum residue levels (MRLs) for clothianidin and thiamethoxam to the limit of quantification in accordance with Regulation (EC) No 396/2005. This draft Regulation follows the non-renewal of the approval, due to the withdrawal of all applications for renewal, and expiry of all grace periods provided by Member States for stocks of plant protection products (PPP) on 31 January 2019 for clothianidin and on 30 April 2019 for thiamethoxam. Prior to the non-renewal of approval, the outdoor uses of clothianidin and thiamethoxam were already severely restricted in 2013 (Regulation (EU) No 485/2013) and completely banned in 2018 (Regulation (EU) 2018/784 and Regulation (EU) 2018/785) following the risk assessments performed by European Food Safety Authority concluding that due to their intrinsic properties, the exposure from outdoor use of clothianidin and thiamethoxam leads to unacceptable risks for bees, or such risks could not be excluded based on the available data.  Such measures were previously notified to the World Trade Organization through the notifications G/TBT/N/EU/497, G/TBT/N/EU/499 and G/SPS/N/EU/39

**7. Objective and rationale, including the nature of urgent problems where applicable:** Clothianidin and thiamethoxam were included in Annex I to Directive 91/414/EEC on 1 August 2006 and 1 February 2007, respectively, and, therefore, before the entry into force of Regulation (EU) No 1107/2009. The most recent risk assessments for bees from the exposure to these substances conducted by the Authority under Regulation (EC) No 1107/2009 found that, due to their intrinsic properties, the exposure from outdoor use of clothianidin and thiamethoxam leads to unacceptable risks for bees, or such risks could not be excluded based on the available data. Therefore, Commission Implementing Regulations (EU) 2018/784 and 2018/785 restricted the approval of clothianidin and thiamethoxam, respectively, to uses in permanent greenhouses only and required that the resulting crops stayed within a permanent greenhouse during their entire life cycle. Following the adoption of these restrictions, all applications for the renewal of the approval of the active substances clothianidin and thiamethoxam were withdrawn.

Adverse effects of clothianidin and thiamethoxam on bees are directly linked to the intrinsic properties of those substances. Therefore, the risks for bees from outdoor uses of these substances are unlikely to be limited to the European Union. Given the global nature of pollinator decline, there is a need to ensure that also commodities imported into the European Union do not contain residues resulting from good agricultural practices based on outdoor uses of clothianidin and/or thiamethoxam, in order to avoid the transfer of adverse effects on bees from food production in the European Union to production of food in other parts of the world that is then imported into the European Union.

The MRLs for clothianidin and thiamethoxam were set in Annex II to Regulation (EC) No 396/2005, including some MRLs which were based on Codex maximum residue limits (CXLs). All authorisations for plant protection products containing clothianidin and/or thiamethoxam in the European Union have been revoked. It is therefore appropriate to delete the MRLs based in obsolete EU uses and CXLs currently set out in Annex II of Regulation (EC) No 396/2005.

A reasonable period would be allowed to elapse before the modified MRLs become applicable in order to permit operators in third countries, especially in least developed and developing countries, and food business operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs. Such adaptation can be reasonably expected to be achieved after three growing seasons in both hemispheres (equivalent to 36 months); Protection of animal or plant life or health; Protection of the environment

**8. Relevant documents:**

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. *OJ L 31, 1.2.2002, p. 1*

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>

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (*OJ L 070 16.3.2005, p. 1*)

[EUR-Lex - 02005R0396-20220516 - EN - EUR-Lex \(europa.eu\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&uri=CELEX:32005R0396)

Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (OJ L 132, 30.5.2018, p. 35).

Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam (OJ L 132, 30.5.2018, p. 40).

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for clothianidin and thiamethoxam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(12):3918, 120 pp. doi:10.2903/j.efsa.2014.3918 <https://www.efsa.europa.eu/en/efsajournal/pub/3918>

European Food Safety Authority; Peer review of the pesticide risk assessment for bees for the active substance clothianidin considering the uses as seed treatments and granules. EFSA Journal 2018;16(2):5177. <https://www.efsa.europa.eu/en/efsajournal/pub/5179>

European Food Safety Authority; Peer review of the pesticide risk assessment for bees for the active substance thiamethoxam considering the uses as seed treatments and granules. EFSA Journal 2018;16(2):5179. <https://www.efsa.europa.eu/en/efsajournal/pub/5179>

Relevant international standards :

· Codex Maximum Residue Limits for clothianidin (238): [https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p\\_id=238](https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=238)

· Codex Maximum Residue Limits for clothianidin (245): [https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p\\_id=245](https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=245)

Additional information for comparison purposes - old and new values of clothianidin and thiamethoxam (see Section 11 below).

**9. Proposed date of adoption:** 2nd quarter 2023.

**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/2022/TBT/EEC/22\\_4547\\_00\\_e.pdf](https://members.wto.org/crnattachments/2022/TBT/EEC/22_4547_00_e.pdf)

[https://members.wto.org/crnattachments/2022/TBT/EEC/22\\_4547\\_01\\_e.pdf](https://members.wto.org/crnattachments/2022/TBT/EEC/22_4547_01_e.pdf)

[https://members.wto.org/crnattachments/2022/TBT/EEC/22\\_4547\\_02\\_e.pdf](https://members.wto.org/crnattachments/2022/TBT/EEC/22_4547_02_e.pdf)

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