

4 August 2017

Original: English

(17-4226) Page: 1/2

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>EUROPEAN UNION</u>

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

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): Thiamethoxam (pesticide active substance)
- **Title, number of pages and language(s) of the notified document:** Draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam (5 pages + Annex 2 pages, in English)
- **6. Description of content:** This draft Commission Implementing Regulation provides that the conditions of approval of the active substance thiamethoxam are amended. Existing authorisations for plant protection products containing thiamethoxam will be amended or withdrawn from the market.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 thiamethoxam (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.

7. Objective and rationale, including the nature of urgent problems where applicable: Protection of animal or plant life or health; Protection of the environment; During the evaluation of the confirmatory data on thiamethoxam, provided following the amendment of its conditions of approval (Regulation (EU) No 485/2013), the submitted additional information was considered not sufficient in view of the requirements set in Regulation (EU) No 485/2013 and therefore an unacceptable risk to bees and other pollinators cannot be excluded unless further restrictions would be provided.

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 thiamethoxam 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 thiamethoxam 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 thiamethoxam 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&gid=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. Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for thiamethoxam in light of confirmatory data. EFSA Supporting publication 2016:EN-1020

http://www.efsa.europa.eu/en/supporting/pub/1020e

9. Proposed date of adoption: 4th 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

The text is available on the EU-TBT Website: <a href="http://ec.europa.eu/growth/tools-table-page-4/background-color="http://ec.eu/growth/tools-table-page-4/background-color="http://ec.eu/growth/tools-table-page-4/background-color="http://ec.eu/growth/tools-page-4/background-color="http://ec.eu/growth/tools-page-4/ba

databases/tbt/en/

https://members.wto.org/crnattachments/2017/TBT/EEC/17 3485 00 e.pdf https://members.wto.org/crnattachments/2017/TBT/EEC/17 3485 01 e.pdf