



4 December 2018

(18-7666)

Page: 1/3

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 [ ], 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> Chlorothalonil (pesticide active substance)
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance chlorothalonil, 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 Commission Implementing Regulation (EU) No 540/2011 (5 page(s), in English)
<b>6. Description of content:</b> This draft Commission Implementing Regulation provides that the approval of the active substance chlorothalonil is not renewed in accordance with Regulation (EC) No 1107/2009. Existing authorised plant protection products containing chlorothalonil will be withdrawn from the market. The non-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 of this substance 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. Any subsequent action on MRLs will be subject to notification under the SPS procedure.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> 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 chlorothalonil, 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, a genotoxicity concern could not be excluded for residues to which consumers will be exposed. Several toxicologically relevant metabolites have been identified which are predicted to occur above the parametric value of 0.1 µg/L in groundwater for all scenarios evaluated. A high risk to amphibians and fish was identified.

Furthermore, the Authority concluded that the analytical methods used in the toxicological studies were not identified and therefore not validated, this questions the validity of the studies, in particular repeated-dose dietary studies. Also several other areas of the risk assessment could not be finalised due to insufficient data in the dossier. In particular, the assessment of consumer risk from dietary exposure could not be completed because of a lack of data to confirm the definition of the residue in plants and the livestock exposure assessment, including the toxicological assessment of a metabolite.

Additionally, chlorothalonil is classified as carcinogen category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council while in the conclusion of the Authority it is indicated that chlorothalonil should be classified as carcinogen category 1B. For the representative uses considered, residue levels as referred to in point (b) of Article 18(1) of Regulation (EC) No 396/2005 could not be confirmed for plant and animal products due to lack of missing data on the magnitude and toxicity of metabolites that are included in the residue definition for risk assessment. Consequently, the requirement set out in Points 3.6.3 of Annex II to Regulation (EC) No 1107/2009 is not fulfilled.

These concerns mean that chlorothalonil does not meet the approval criteria as outlined in Regulation (EC) No 1107/2009 and cannot be approved currently.

Existing authorisations will need to be withdrawn; Member States must withdraw existing plant protection products containing chlorothalonil at the latest by 6 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 12 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>
- Conclusion on the peer review of the peer review of the pesticide risk assessment of the active substance chlorothalonil. EFSA Journal 2018;16(1):5126, 40 pp. <https://doi.org/10.2903/j.efsa.2018.5126>

#### **9. Proposed date of adoption:** 1<sup>st</sup> quarter 2019

**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/2018/TBT/EEC/18\\_6220\\_00\\_e.pdf](https://members.wto.org/crnattachments/2018/TBT/EEC/18_6220_00_e.pdf)