



11 April 2018

(18-2166)

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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 [ ], 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> Dithianon (pesticide active substance)  Pesticides and other agrochemicals (ICS 65.100)
<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 dithianon (and its accompanying annex) (4 + 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 dithianon are amended. Existing authorisations for plant protection products containing dithianon will be amended or withdrawn from the market. The amendment is based on evaluation of confirmatory information submitted following the approval of the substance for use as a pesticide active substance in the EU under Regulation (EC) No 1107/2009.  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.
<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.  During the evaluation and peer-review of the confirmatory data provided on dithianon following its approval (Commission Implementing Directive 2011/41/EU), it was identified that the consumer exposure assessment could not be concluded given the data gaps identified for storage stability data on dithianon residues in grape wine, and for the magnitude of the metabolites Reg. No. 4107273, Reg. No. 31062, Reg. No. 4005234 (Phthalic acid) and Reg. No. 4110933 in apple and grapes processed commodities. This is indicated as a critical area of concern in the conclusion of the European Food Safety

<p>Authority (EFSA) published in August 2015.</p> <p>In order to ensure the protection of consumers it is necessary to amend the approval to include a restriction of use. Dithianon will be restricted to use on non-edible crops only.</p> <p>Existing authorisations will need to be amended or withdrawn; EU Member States must amend or withdraw existing plant protection products containing dithianon 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 15 months from the date of withdrawal of the authorisation.</p>
<p><b>8. Relevant documents:</b></p> <p>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</p> <p><a href="http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1521642425074&amp;uri=CELEX:32009R1107">http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1521642425074&amp;uri=CELEX:32009R1107</a></p> <p>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 (<i>OJ L 153, 11.6.2011, p. 1–186</i>)</p> <p><a href="http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&amp;uri=CELEX:32011R0540">http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&amp;uri=CELEX:32011R0540</a></p> <p>Commission Implementing Directive 2011/41/EU of 11 April 2011 amending Council Directive 91/414/EEC to include dithianon as active substance and amending Commission Decision 2008/934/EC (<i>OJ L 97, 12.4.2011, p. 38–41</i>)</p> <p><a href="http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011L0041">http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011L0041</a></p> <p>EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment for the active substance dithianon in light of confirmatory data. EFSA Journal 2015;13(11):4278 20 pp. doi: 10.2903/j.efsa.2015.4278</p> <p><a href="https://www.efsa.europa.eu/en/efsajournal/pub/4278">https://www.efsa.europa.eu/en/efsajournal/pub/4278</a></p>
<p><b>9. Proposed date of adoption:</b> 4th quarter 2018</p> <p><b>Proposed date of entry into force:</b> 20 days following publication in the Official Journal of the EU</p>
<p><b>10. Final date for comments:</b> 60 days from notification</p>
<p><b>11. Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b></p> <p>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></p> <p>The text is available on the EU-TBT Website :</p> <p><a href="http://ec.europa.eu/growth/tools-databases/tbt/en/">http://ec.europa.eu/growth/tools-databases/tbt/en/</a></p> <p><a href="https://members.wto.org/crnattachments/2018/TBT/EEC/18_1951_00_e.pdf">https://members.wto.org/crnattachments/2018/TBT/EEC/18_1951_00_e.pdf</a></p> <p><a href="https://members.wto.org/crnattachments/2018/TBT/EEC/18_1951_01_e.pdf">https://members.wto.org/crnattachments/2018/TBT/EEC/18_1951_01_e.pdf</a></p>