



22 January 2018

(18-0532)

Page: 1/2

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> Oxasulfuron (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 approval of the active substance oxasulfuron, 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 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 oxasulfuron is not renewed in accordance with Regulation (EC) No 1107/2009. Existing authorised plant protection products containing oxasulfuron will be withdrawn from the market.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 and if so a separate notification will be made in accordance with SPS procedures.
<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 the substance, 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).

The Authority identified numerous deficiencies in the dossier resulting in a large number of data gaps and areas in which the risk assessment could not be finalised. In particular, the available information on oxasulfuron and its metabolites did not allow finalising the assessment of the overall consumer exposure, the groundwater exposure, the risk to aquatic organisms, earthworms, soil macro- and microorganisms and non-target terrestrial plants. The situation where a large number of fundamental parts of risk assessment were not finalised created insecurity which lead to the non-renewal.

These concerns mean that oxasulfuron 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; EU Member States must withdraw existing plant protection products containing oxasulfuron 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 15 months from the entry into force (allowing for a final season of use).

**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 pesticide risk assessment of the active substance oxasulfuron. EFSA Journal 2017;15(3):4722,25 pp. doi:10.2903/j.efsa.2017.4722 <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4722/epdf>

**9. Proposed date of adoption:** 1st quarter 2018

**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\\_0472\\_00\\_e.pdf](https://members.wto.org/crnattachments/2018/TBT/EEC/18_0472_00_e.pdf)