



15 February 2016

(16-0937)

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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

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| 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/ |
| 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): Triasulfuron (pesticide active substance) |
| 5. | Title, number of pages and language(s) of the notified document: Draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance triasulfuron, 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 (4 pages, in English). |
| 6. | Description of content: This draft Commission Implementing Regulation provides that the approval of the active substance triasulfuron is not renewed in accordance with Regulation (EC) No 1107/2009. Existing authorised plant protection products containing triasulfuron will be withdrawn from the market.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 will be taken to lower MRLs to the limit of quantification (LOQ). |
| 7. | Objective and rationale, including the nature of urgent problems where applicable: 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); most importantly the Authority concluded that, due to an incomplete genotoxic assessment of triasulfuron and its manufacturing impurity CGA 150829, it has not been possible to set the health based toxicological reference values. As a consequence, the assessment of the risk to consumers, operators, workers and bystanders could not be conducted. Furthermore, the Authority concluded that there is a high potential for the representative uses assessed to result in groundwater exposure above the parametric drinking water limit of 0.1 µg/l either by triasulfuron itself or by its soil metabolite CGA 150829. In addition, a high risk to aquatic plants was identified.

These concerns imply that triasulfuron 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 triasulfuron 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 on 30 November 2016 (allowing for a final season of use).

Protection of animal or plant life or health; Protection of human health or safety; Protection of the environment

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>

9. Proposed date of adoption: 2nd quarter 2016

Proposed date of entry into force: 20 days from publication in the Official Journal of the European Union (Withdrawal of authorisations by 3 months after entry into force. Grace period for products at the latest until 30 November 2016 for final season of use)

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 Website: <http://ec.europa.eu/growth/tools-databases/tbt/>
https://members.wto.org/crnattachments/2016/TBT/EEC/16_0586_00_e.pdf