



24 May 2023

(23-3533)

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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 [ ], 3.2 [ ], 7.2 [ ], 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> S-metolachlor (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 S-metolachlor, 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 the Annex to 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 S-metolachlor is not renewed in accordance with Regulation (EC) No 1107/2009. EU Member States shall withdraw authorisations for plant protection products containing S-metolachlor as an active substance. The non-renewal of 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 assessed and approved under Directive 91/414/ EEC.  This decision only concerns the placing on the market of this substance and plant protection products containing it. Following non-approval and the expiry of all grace periods for stocks of products containing this substance, separate action will likely be taken on MRLs and a separate notification will be made in accordance with SPS procedures.

**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 thereto) which must be met to enable approval.

During the evaluation and peer-review of S-metolachlor, a number of concerns and areas that could not be finalised were identified. These are detailed in the statement of the European Food Safety Authority (EFSA).

The decision is based on a risk assessment carried out by a rapporteur EU Member State and peer reviewed by the European Food Safety Authority together with all EU Member States, taking into account other factors legitimate to the matter.

In the case of S-metolachlor, the outcome of the risk assessment, as documented in the EFSA Conclusion, is not favourable and identifies critical areas of concern.

These critical areas of concern have been identified: 1) the representative uses are shown to contaminate groundwater (by both the active substance and the groundwater relevant metabolites) and 2) all the representative uses are shown to pose risk for mammals, since high risk to earthworm-eating mammals via secondary poisoning was concluded.

Moreover, part of the risk assessment could not be finalised by EFSA, thus precluding the renewal, such as an issue not finalised for the risk assessment of two human metabolites, the consumer dietary risk assessment (and the consequent livestock exposure assessment), and the consumer risk assessment regarding the treatment of surface water. For the environmental compartment, the risk assessment for aquatic and the one for non-target terrestrial plants could not be finalised.

Therefore, the outcome of the risk assessment is not favourable to the renewal given that it can be concluded that several application scenarios are not acceptable. These concerns mean that S-metolachlor does not meet the approval criteria as outlined in Regulation (EC) No 1107/2009.

Existing authorisations will need to be withdrawn; EU Member States must withdraw existing plant protection products containing S-metolachlor 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 (allowing for a final season of use).

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

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R1107>

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*)

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0540>

Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (*OJ L 67, 12.3.2015, p. 18–22*)

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32015R0408>

<p>EFSA (European Food Safety Authority), 2022. Statement concerning the assessment of environmental fate and behaviour and ecotoxicology in the context of the pesticides peer review of the active substance S-metolachlor. EFSA Journal 2022; 20(11): e07634  <a href="https://doi.org/10.2903/j.efsa.2022.7634">https://doi.org/10.2903/j.efsa.2022.7634</a></p>
<p><b>9. Proposed date of adoption:</b> 3rd quarter 2023  <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>          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>          The text is available on the EU-TBT Website : <a href="http://ec.europa.eu/growth/tools-databases/tbt/en/">http://ec.europa.eu/growth/tools-databases/tbt/en/</a>  <a href="https://members.wto.org/crnattachments/2023/TBT/EEC/23_09781_00_e.pdf">https://members.wto.org/crnattachments/2023/TBT/EEC/23_09781_00_e.pdf</a></p>