



31 May 2023

(23-3695)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved:</b>
<b>2. Agency responsible:</b> European Commission, Health and Food Safety Directorate-General
<b>3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):</b> S-metolachlor (pesticide active substance)
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
<b>5. Title 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 (Text with EEA relevance). <b>Language(s):</b> English. <b>Number of pages:</b> 5 <a href="https://members.wto.org/crnattachments/2023/SPS/EEC/23_09918_00_e.pdf">https://members.wto.org/crnattachments/2023/SPS/EEC/23_09918_00_e.pdf</a>
<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 European Union under Regulation (EC) No 1107/2009. The substance was formerly assessed and approved under Directive 91/414/EEC.  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 three 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 six months from the entry into force (allowing for a final season of use).

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.

This draft Commission Implementing Regulation was also notified under the TBT Agreement in notice G/TBT/N/EU/982.

**7. Objective and rationale:  food safety,  animal health,  plant protection,  protect humans from animal/plant pest or disease,  protect territory from other damage from pests.**

**8. Is there a relevant international standard? If so, identify the standard:**

**Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):**

**World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):**

**International Plant Protection Convention (e.g. ISPM number):**

**None**

**Does this proposed regulation conform to the relevant international standard?**

Yes  No

**If no, describe, whenever possible, how and why it deviates from the international standard:**

**9. Other relevant documents and language(s) in which these are available:**

– 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 June 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

	<p>the market and establishing a list of candidates for substitution (OJ L 67, 12 March 2015, p. 18–22)  <a href="https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32015R0408">https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32015R0408</a></p> <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>          (available in English)</p>
<p><b>10.</b></p>	<p><b>Proposed date of adoption (dd/mm/yy):</b> 3<sup>rd</sup> quarter 2023.  <b>Proposed date of publication (dd/mm/yy):</b> 3<sup>rd</sup> quarter 2023.</p>
<p><b>11.</b></p>	<p><b>Proposed date of entry into force: [ ] Six months from date of publication, and/or (dd/mm/yy):</b> 20 days following publication in the Official Journal of the European Union.  <b>[ ] Trade facilitating measure</b></p>
<p><b>12.</b></p>	<p><b>Final date for comments: [ ] Sixty days from the date of circulation of the notification and/or (dd/mm/yy):</b> Not applicable. Comments are only welcomed on TBT related issues and to be addressed to the TBT Enquiry Point on notice G/TBT/N/EU/982.</p> <p><b>Agency or authority designated to handle comments: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (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><b>13.</b></p>	<p><b>Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (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>