



12 August 2021

(21-6186)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved:
2. Agency responsible: European Commission, Health and Food Safety Directorate-General
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): Indoxacarb (pesticide active substance); Pesticides and other agrochemicals (ICS Code: 65.100)
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance indoxacarb, 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 (Text with EEA relevance). Language(s): English. Number of pages: 5 https://members.wto.org/crnattachments/2021/SPS/EEC/21_5151_00_s.pdf
6. Description of content: This draft Commission Implementing Regulation provides that the approval of the active substance indoxacarb is not renewed in accordance with Regulation (EC) No 1107/2009. EU Member States shall withdraw authorisations for plant protection products containing indoxacarb 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. 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 indoxacarb, 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 EFSA identified a critical concern in relation to the high long-term risk to wild mammals for all representative uses and, additionally, a high risk to consumers and workers for the representative use in lettuce and a high risk to bees for the representative use in maize, sweet corn and lettuce for seed production. Furthermore, there are several areas of the risk assessment not finalised due to lack of data in the dossier. These concerns mean that indoxacarb 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 indoxacarb 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

<p>shall expire at the latest six months from the entry into force.</p> <p>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.</p> <p>This draft Commission Implementing Regulation was also notified under the TBT Agreement in notice G/TBT/N/EU/827.</p>
<p>7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input checked="" type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input checked="" type="checkbox"/> protect territory from other damage from pests.</p>
<p>8. Is there a relevant international standard? If so, identify the standard:</p> <p><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
<p>9. Other relevant documents and language(s) in which these are available:</p> <ul style="list-style-type: none"> - 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: EUR-Lex - 32009R1107 - EN - EUR-Lex (europa.eu) - 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) EUR-Lex - 32011R0540 - EN - EUR-Lex (europa.eu) - Conclusion on the peer review of the pesticide risk assessment of the active substance indoxacarb - EFSA (European Food Safety Authority). 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance indoxacarb. EFSA Journal 2018; 16(1):5140,29pp. https://www.efsa.europa.eu/en/efsajournal/pub/5140 - EFSA (European Food Safety Authority), 2019. Statement on the updated peer review concerning the risk to mammals and bees for the active substance indoxacarb. EFSA Journal 2019;17(10):5866, 10 pp https://www.efsa.europa.eu/en/efsajournal/pub/5866
<p>10. Proposed date of adoption (dd/mm/yy): 4th quarter 2021</p> <p>Proposed date of publication (dd/mm/yy): 4th quarter 2021</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 20 days following publication in the Official Journal of the European Union.</p> <p><input type="checkbox"/> Trade facilitating measure</p>

12. Final date for comments: [] Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 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/827.

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:

European Commission
EU-TBT Enquiry Point
Fax: +(32) 2 299 80 43
E-mail: grow-eu-tbt@ec.europa.eu

13. Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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