



30 November 2021

(21-8993)

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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> Isopyrazam (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 withdrawing the approval of the active substance isopyrazam 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, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Implementing Regulation (EU) No 1037/2012. <b>Language(s):</b> English. <b>Number of pages:</b> 4 <a href="https://members.wto.org/crnattachments/2021/SPS/EEC/21_7410_00_e.pdf">https://members.wto.org/crnattachments/2021/SPS/EEC/21_7410_00_e.pdf</a>
<b>6. Description of content:</b> This draft Commission Implementing Regulation provides that the approval of the active substance isopyrazam is withdrawn in accordance with Regulation (EC) No 1107/2009. <p>Member States shall withdraw authorisations for plant protection products containing isopyrazam as an active substance.</p> <p>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.</p> <p>Active substances may be reviewed at any time where in the light of new scientific and technical knowledge there are indications that the substance no longer satisfies the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.</p> <p>Substances that are or have to be classified as toxic for reproduction category 1B (R1B) according to Regulation (EC) No 1272/2008 cannot be approved unless exposure to humans is demonstrated to be negligible under realistic conditions of use.</p> <p>In December 2020, the ECHA Committee for Risk Assessment concluded that isopyrazam meets the criteria to be classified as R1B. Negligible exposure is not demonstrated since residues are expected in crops (therefore there is no negligible exposure demonstrated for consumers).</p> <p>This means that isopyrazam no longer fulfils the approval criteria as outlined in Regulation (EC) No 1107/2009 and the approval should therefore be withdrawn.</p>

Existing authorisations will need to be withdrawn; Member States must withdraw existing plant protection products containing isopyrazam 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.

This decision only concerns the placing on the market of this substance and plant protection products containing it. Following withdrawal of approval and the expiry of all grace periods for stocks of products containing this substance, separate action may 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/857.

**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

<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 June 2011, p. 1-186)

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442928512004&uri=CELEX:32011R0540>

– Opinion of the Committee for Risk Assessment, adopted on 10 December 2020

<https://echa.europa.eu/documents/10162/095e630c-18d9-994c-4d8f-82c4c28e3238>

– Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1272>

– Notification G/TBT/N/EU/826

<http://tbtims.wto.org/en/RegularNotifications/View/173586?FromAllNotifications=True>

**10. Proposed date of adoption (dd/mm/yy):** 1<sup>st</sup> quarter 2022

**Proposed date of publication (dd/mm/yy):** 1<sup>st</sup> quarter 2022

**11. Proposed date of entry into force:**  **Six months from date of publication, and/or (dd/mm/yy):** 20 days following publication in the Official Journal of the European Union.  
 **Trade facilitating measure**

**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/857.

**Agency or authority designated to handle comments:**  **National Notification Authority,  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:**  **National Notification Authority,  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