WORLD TRADE ORGANIZATION

G/SPS/N/EU/608

16 January 2023

(23-0368)

Page: 1/3

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1.	**Notifying Member:** EUROPEAN UNION **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):** Ipconazole (pesticide active substance)
4.	**Regions or countries likely to be affected, to the extent relevant or practicable:** **[X] All trading partners** **[ ] Specific regions or countries:**
5.	**Title of the notified document:** Draft Commission Implementing Regulation withdrawing the approval of the active substance ipconazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Commission Implementing Regulation (EU) No 571/2014 (Text with EEA relevance). **Language(s):** English. **Number of pages:** 5 https://members.wto.org/crnattachments/2023/SPS/EEC/23_0435_00_e.pdf
6.	**Description of content:** This draft Commission Implementing Regulation provides that the approval of the active substance ipconazole is withdrawn in accordance with Regulation (EC) No 1107/2009. 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. 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. 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. Commission Delegated Regulation (EU) 2020/1182 amended Annex VI to Regulation (EC) No 1272/2008 and classified ipconazole as toxic for reproduction category 1B. Negligible exposure to ipconazole for humans could not be concluded due to limitations with the available data. Furthermore, a high long-term risk to birds from the representative uses of ipconazole was concluded by the European Food Safety Authority. This means that ipconazole no longer fulfils the approval criteria as outlined in Regulation (EC) No 1107/2009 and the approval should therefore be withdrawn.

Existing authorizations will need to be withdrawn; EU member States must withdraw existing plant protection products containing ipconazole 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 in which case 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/944.

7. Objective and rationale: [X] food safety, [ ] animal health, [X] plant protection, [X] protect humans from animal/plant pest or disease, [X] 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)*:

[X] 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
- EFSA Panel (European Food Safety Authority), 2022. Statement concerning the review of the approval of the active substance ipconazole. EFSA Journal 2022;20(8):7133, 26 pp. https://doi.org/10.2903/j.efsa.2022.7133
- 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
- Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (*OJ L 261, 11 August 2020, p. 2)* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R1182
- 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

10.	**Proposed date of adoption *(dd/mm/yy)*:** 2nd quarter 2023 **Proposed date of publication *(dd/mm/yy)*:** 2nd quarter 2023
11.	**Proposed date of entry into force: [ ] Six months from date of publication, and/or *(dd/mm/yy)*:** 20 days following its 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/944. **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:** European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: grow-eu-tbt@ec.europa.eu