WORLD TRADE ORGANIZATION

G/SPS/N/EU/763

8 May 2024

(24-3641)

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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):** Cereals (HS codes: 1001, 1002, 1003, 1004, 1005, 1006, 1007, 1008), foodstuffs of animal origin (HS codes: 0201, 0202, 0203, 0204, 0205, 0206, 0207, 0208, 0209, 0210) and certain products of plant origin, including fruit and vegetables
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 Regulation amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for thiacloprid in or on certain products (Text with EEA relevance). **Language(s):** English. **Number of pages:** 4+1+8 https://members.wto.org/crnattachments/2024/SPS/EEC/24_03130_00_e.pdf https://members.wto.org/crnattachments/2024/SPS/EEC/24_03130_01_e.pdf https://members.wto.org/crnattachments/2024/SPS/EEC/24_03130_02_e.pdf
6.	**Description of content:** The proposed draft Regulation concerns the review of existing MRLs for thiacloprid in certain food commodities following the non-approval of thiacloprid in the European Union. The proposed Draft Regulation proposes to provisionally lower to the limit of determination all the MRLs for thiacloprid, ensuring a precautionary approach towards consumer protection based on the indications that the substance may be an endocrine disruptor, while seeking to obtain additional information.
7.	**Objective and rationale: [X] 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:** **[X] Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:** Codex Maximum Residue Limits for thiacloprid in some commodities. CODEX MRLs LIST is available at https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=223. **[ ] 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 [X] No

If no, describe, whenever possible, how and why it deviates from the international standard: The European Food Safety Authority published a peer review in the framework of the renewal of the approval of thiacloprid in the European Union. It identified several areas of concern, and it was considered no necessary to finalize the assessment of the possible endocrine disrupting properties of thiacloprid on the basis of the most recent criteria in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009. The recent MRL risk assessment carried out by the European Food Safety Authority did not identify an acute risk for the consumers but concluded that further consideration by risk managers was required. Since this assessment was based on the existing toxicological reference values which were established before the most recent Union criteria on endocrine disruptors were adopted, they do not necessarily reflect endocrine-related effects. Therefore, there remain reasonable grounds for concern that the existing MRLs have potentially harmful effects on human health and are inconsistent with the high level of consumer protection in the European Union. Pending the conclusion of an additional risk assessment by the European Food Safety Authority, and given the available pertinent information with regard to potentially harmful effects on human health, it is appropriate to provisionally lower the all the MRLs for thiacloprid to the product-specific limits of determination.

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

- Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC https://eur-lex.europa.eu/eli/reg/2005/396/oj
- 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/eli/reg/2009/1107/oj
- EFSA (European Food Safety Authority), 2019. Conclusion on pesticides peer review. Peer review of the pesticide risk assessment of the active substance thiacloprid. EFSA Journal 2019;17(3): e05595 https://www.efsa.europa.eu/en/efsajournal/pub/5595
- EFSA (European Food Safety Authority) 2023; Statement on the short-term (acute) dietary risk assessment and evaluation of confirmatory data for certain maximum residue levels (MRLs) for thiacloprid. EFSA Journal 2023;21(3):7888 https://www.efsa.europa.eu/en/efsajournal/pub/7888

(available in English)

10. Proposed date of adoption *(dd/mm/yy)*: 11 November 2024

Proposed date of publication *(dd/mm/yy)*: 11 December 2024

11. Proposed date of entry into force: [X] Six months from date of publication, and/or *(dd/mm/yy)*:

[ ] Trade facilitating measure

12. Final date for comments: [X] Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*: 7 July 2024

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
DG Health and Food Safety, Unit A4-Multilateral International Relations
Rue Froissart 101
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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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