



20 June 2018

(18-3868)

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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): 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: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Draft Commission Regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridaben in or on certain products (Text with EEA relevance). Language(s): English. Number of pages: 5+ Annexes https://members.wto.org/crnattachments/2018/SPS/EEC/18_3194_00_e.pdf https://members.wto.org/crnattachments/2018/SPS/EEC/18_3194_01_e.pdf https://members.wto.org/crnattachments/2018/SPS/EEC/18_3194_02_e.pdf https://members.wto.org/crnattachments/2018/SPS/EEC/18_3194_03_e.pdf https://members.wto.org/crnattachments/2018/SPS/EEC/18_3194_04_e.pdf https://members.wto.org/crnattachments/2018/SPS/EEC/18_3194_05_e.pdf
6. Description of content: The proposed draft Regulation concerns the review of existing MRLs for bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridaben in certain food commodities. MRLs for these substances in certain commodities are changed: either increased or lowered. Lower MRLs are set after updating the limits of determination and/or deleting old uses which are not authorised any more in the European Union or for which a human health concern may not be excluded. The residue definition for some substances has also been updated.
7. Objective and rationale: <input checked="" type="checkbox"/> food safety , <input type="checkbox"/> animal health , <input type="checkbox"/> plant protection , <input type="checkbox"/> protect humans from animal/plant pest or disease , <input type="checkbox"/> 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):

Codex Maximum Residue Limits for fenbutatin oxide.

The list of Codex MRLs is available at: <http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticides/en/>

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: The European Food Safety Authority published a reasoned opinion on the review of the existing maximum residue levels for fenbutatin oxide in which it does not recommend to maintain CXL values as toxicological data for the active substance and its metabolite, di-hydroxy fenbutatin oxide, were not provided and the risk to consumers could not be assessed. Commission Implementing Regulation (EU) No 486/2014 provided for the withdrawal of the approval of fenbutatin oxide as the further confirmatory information for this active substance required by Commission Directive 2011/30/EU had not been submitted. All existing national authorisations for plant protection products containing fenbutatin oxide have been revoked.

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"

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32005R0396>

"Reasoned opinion on the review of the existing maximum residue levels for bromuconazole according to Article 12 of Regulation (EC) No 396/2005". EFSA Journal 2017;15(9):4986.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4986/epdf>

"Reasoned opinion on the review of the existing maximum residue levels for carboxin according to Article 12 of Regulation (EC) No 396/2005". EFSA Journal 2017;15(10):5019.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5019/epdf>

"Reasoned opinion on the review of the existing maximum residue levels for fenbutatin oxide according to Article 12 of Regulation (EC) No 396/2005". EFSA Journal 2017;15(12):5091.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5091/epdf>

"Reasoned opinion on the review of the existing maximum residue levels for fenpyrazamine according to Article 12 of Regulation (EC) No 396/2005". EFSA Journal 2017;15(12):5072.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5072/epdf>

"Reasoned opinion on the review of the existing maximum residue levels for pyridaben according to Article 12 of Regulation (EC) No 396/2005". EFSA Journal 2017;15(11):5054.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5054/epdf> (available in English)

10. Proposed date of adoption (dd/mm/yy): January 2019

Proposed date of publication (dd/mm/yy): March 2019

11. Proposed date of entry into force: Six months from date of publication, and/or (dd/mm/yy): Twenty days after 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): 19 August 2018

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:

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DG Health and Food Safety, Unit D2-Multilateral International Relations
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13. Text(s) available from: National Notification Authority, National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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