



13 June 2023

(23-4021)

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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> 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
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> <b>All trading partners</b> <input type="checkbox"/> <b>Specific regions or countries:</b>
<b>5. Title of the notified document:</b> 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 (Z)-13-hexadecen-11-yn-1-yl acetate, (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isoburyrate, acrinathrin, azimsulfuron, famoxadone, methyl nonyl ketone, prochloraz and sodium hypochlorite in or on certain products (Text with EEA relevance). <b>Language(s):</b> English. <b>Number of pages:</b> 5+ Annexes <a href="https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_00_e.pdf">https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_00_e.pdf</a> <a href="https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_01_e.pdf">https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_01_e.pdf</a> <a href="https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_02_e.pdf">https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_02_e.pdf</a> <a href="https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_03_e.pdf">https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_03_e.pdf</a> <a href="https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_04_e.pdf">https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_04_e.pdf</a> <a href="https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_05_e.pdf">https://members.wto.org/crnattachments/2023/SPS/EEC/23_10185_05_e.pdf</a>
<b>6. Description of content:</b> The proposed draft Regulation concerns the update of existing MRLs for (Z)-13-hexadecen-11-yn-1-yl acetate, (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isoburyrate, acrinathrin, azimsulfuron, famoxadone, methyl nonyl ketone, prochloraz and sodium hypochlorite in certain food commodities. MRLs for these substances in certain commodities are changed. Lower MRLs are set after deleting old uses which are not authorised any more in the European Union as the approval of the use of the active substance has expired.
<b>7. Objective and rationale:</b> <input checked="" type="checkbox"/> <b>food safety</b> , <input type="checkbox"/> <b>animal health</b> , <input type="checkbox"/> <b>plant protection</b> , <input type="checkbox"/> <b>protect humans from animal/plant pest or disease</b> , <input type="checkbox"/> <b>protect territory from other damage from pests.</b>

**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 famoxadone (208) [https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p\\_id=208](https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=208)
- Codex Maximum Residue Limits for prochloraz (142) [https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p\\_id=142](https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=142)

**[ ] 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 current EU policy is to align EU MRLs with CXLs if the following conditions are fulfilled: (i) that the European Union sets MRLs for the commodity under consideration; (ii) that the current EU MRL is lower than the CXL; and (iii) that the CXL is acceptable to the European Union with respect to its policy objective of ensuring a high level of consumer protection, including aspects on supporting data and extrapolations. Where the European Union considers that a proposed CXL is not acceptable, it makes a reservation to the Codex Committee on Pesticide Residues (CCPR). Reservations made by the European Union, concerning some of the active substances envisaged by the draft Regulation, are listed in the relevant CCPR reports:

<http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-meetings/en/?committee=CCPR>.

For famoxadone, based on the Statement of European Food Safety Authority on famoxadone (<https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.7932>), the current MRL for table grapes could not exclude the risk for consumers and should be therefore lowered.

Prochloraz is no longer approved as an active substance in the European Union since 31 December 2021. Prochloraz MRLs were last reviewed in 2020 by Commission Regulation (EU) 2020/192 in accordance with Article 12(1) of Regulation (EC) No 396/2005. The review was based on the European Food Safety Authority's (EFSA) reasoned opinion on the existing MRLs (<https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5401>). EFSA proposed to change the residue definition for enforcement to the sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz. In the reasoned opinion EFSA noted that the definition differs from the residue definition (Sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz) set by Codex Alimentarius.

For that reason, the Commission established tentative MRLs based on CXLs with specific footnotes requiring the missing information on residue trials in relation with the new residue definition to be submitted by 13 February 2022. The information was not submitted by that deadline. Therefore, with the current draft Regulation it is proposed to delete the MRLs, including the ones based on CXLs.

**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>
- "Commission Implementing Regulation (EU) 2016/638 of 22 April 2016 withdrawing the approval of the active substance Z-13-hexadecen-11-yn-1-yl acetate, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the

<p>Council, and amending Commission Implementing Regulation (EU) No 540/2011"  <a href="http://data.europa.eu/eli/reg_impl/2016/638/oj">http://data.europa.eu/eli/reg_impl/2016/638/oj</a></p> <ul style="list-style-type: none"> <li>- "Commission Implementing Regulation (EU) 2016/636 of 22 April 2016 withdrawing the approval of the active substance Z,Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011"  <a href="https://eur-lex.europa.eu/eli/reg_impl/2016/636/oj">https://eur-lex.europa.eu/eli/reg_impl/2016/636/oj</a></li> <li>- "European Food Safety Authority Statement on the pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005" (12 February 2019)  <a href="https://doi.org/10.2903/j.efsa.2019.5591">https://doi.org/10.2903/j.efsa.2019.5591</a></li> <li>- "Commission Implementing Regulation (EU) 2021/1450 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances acrinathrin and prochloraz"  <a href="https://eur-lex.europa.eu/eli/reg_impl/2021/1450/oj">https://eur-lex.europa.eu/eli/reg_impl/2021/1450/oj</a></li> <li>- "European Food Safety Authority opinion on the review of the existing maximum residue levels for prochloraz according to Article 12 of Regulation (EC) No 396/2005"  <a href="http://data.europa.eu/eli/reg/2020/192/oj">http://data.europa.eu/eli/reg/2020/192/oj</a></li> <li>- "Commission Implementing Regulation (EU) 2021/1379 of 19 August 2021 concerning the non-renewal of approval of the active substance famoxadone, 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 Commission Implementing Regulation (EU) No 540/2011"  <a href="https://eur-lex.europa.eu/eli/reg_impl/2021/1379/oj">https://eur-lex.europa.eu/eli/reg_impl/2021/1379/oj</a></li> <li>- "European Food Safety Authority Statement on the targeted risk assessment for famoxadone"  <a href="https://doi.org/10.2903/j.efsa.2023.7932">https://doi.org/10.2903/j.efsa.2023.7932</a></li> <li>- "Commission Implementing Regulation (EU) 2017/781 of 5 May 2017 withdrawing the approval of the active substance methyl nonyl ketone, 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 Commission Implementing Regulation (EU) No 540/2011"  <a href="https://eur-lex.europa.eu/eli/reg_impl/2017/781/oj">https://eur-lex.europa.eu/eli/reg_impl/2017/781/oj</a></li> <li>- "European Food Safety Authority Statement on the pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005" (12 December 2017)  <a href="https://doi.org/10.2903/j.efsa.2017.5080">https://doi.org/10.2903/j.efsa.2017.5080</a></li> </ul>
<p><b>10. Proposed date of adoption (dd/mm/yy):</b> 19 January 2024  <b>Proposed date of publication (dd/mm/yy):</b> 19 February 2024</p>
<p><b>11. Proposed date of entry into force:</b> <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 8 September 2024  <input type="checkbox"/> Trade facilitating measure</p>
<p><b>12. Final date for comments:</b> <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 12 August 2023</p> <p><b>Agency or authority designated to handle comments:</b> <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission  DG Health and Food Safety, Unit A4-Multilateral International Relations  Rue Froissart 101  B-1049 Brussels  Tel: +(32 2) 29 54263  E-mail: <a href="mailto:sps@ec.europa.eu">sps@ec.europa.eu</a></p>

**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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