Establishing Import Tolerances for Spices

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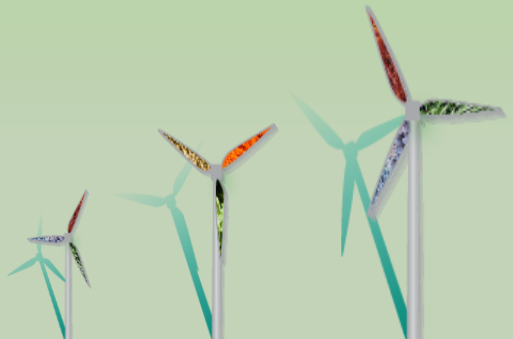
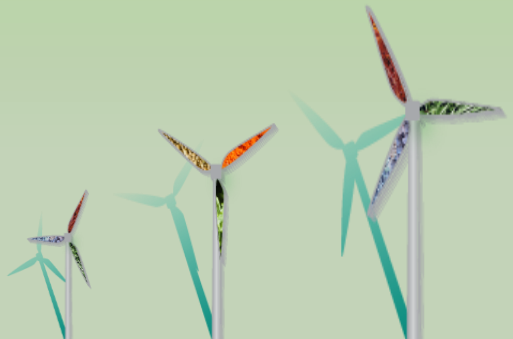
Tolerances (Maximum Residue Limits)

- The Federal Food Drug and Cosmetic Act (FFDCA) requires that tolerances (MRLs) for a residue of a pesticide be established for a pesticide residue to be present on any food commodity. The Environmental Protection Agency has the authority to establish tolerances for pesticides in the U.S.
- A tolerance is the maximum residue level (MRL) of a pesticide (usually measured in parts per million (ppm)) that legally can be present in food or feed.
- Tolerances in the absence of a US registration are often referred to as “import tolerances”.
- There is no legal definition for import tolerances under FFDCA and no specific requirements in FFDCA for import tolerances.
- The Code of Federal Regulations (40 CFR 180) usually will include a footnote for a commodity that specifies “There are no U.S. registrations..”
- EPA’s Office of Pesticide Programs (OPP) may be petitioned to establish import tolerances to help facilitate the importation of food commodities into the U.S. when a chemical is not registered for use on those commodities in the U.S.



Establishing Import Tolerances in the U.S.

- In order to establish an import tolerance in the U.S., a petition must be submitted to EPA's Office of Pesticide Programs requesting the establishment of the tolerance.
- The petition should include an informative summary of the petition with the information required in 40 CFR 180.7.
- The petitioner is also required to provide the residue field trial data in accordance with the *NAFTA guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada.*
- https://www.epa.gov/sites/production/files/2015-10/documents/nafta-guidance.pdf



Establishing Import Tolerances in the U.S.: Spices

- Spices generally are not grown in the U.S. and obtaining residue data from domestic field trials to support the establishment of a tolerance for spices is unlikely.
- Current practice for the last decade by Codex is to use monitoring data to establish Codex MRLs on spices. This was adopted because: limited availability of field trial data reflecting pesticide use on spices; consumption of spices is low in the overall diet; and, spices are a blended commodity. Codex experience has found the use of monitoring data to be a useful tool.
- EPA was requested in May 2017 to consider the use of monitoring data to support the establishment of import tolerances for spices. Subsequently EPA adopted a policy allowing the use of monitoring data to support the establishment of import tolerances for spices following the Codex requirements and guidance.
- Residue data on the representative commodities is still needed to establish a domestic tolerance (with a registered use) on spices.

Current Initiative: Establishing Import Tolerances for Spices

- ASTA has been pursuing initiatives to establish import tolerances for spices over the last few years. Focus has been primarily on pepper, black.
- Candidate pesticides were identified along with possible regulatory pathways.
  - Monitoring data available for some pesticides.
  - EPA's pilot project to rely on data reviews from the Joint Meeting on Pesticide Residues (JMPR), European Food Safety Authority (EFSA), or a national authority rather than conduct a *de novo* U.S. review. Requirements:
    - In-depth review of report from competent authority
    - Compound generally must have food-use registration in the U.S.
    - Tolerance = MRL from Codex, EU, or exporting country (No "extra" run through the OECD MRL Calculator)
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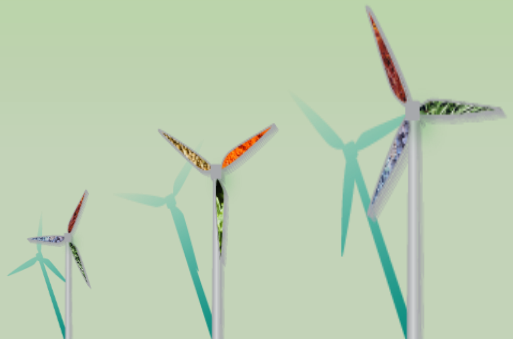

Progress Towards Establishment of Import MRLS: Spices

- Two candidates were identified as having adequate and available monitoring data in accordance with the guidance laid out by Codex's Joint Meeting on Pesticide Residues (JMPR): metalaxyl and difenocoanazole.
- Metalaxyl petition for pepper, black was submitted to EPA on 12/3/2019 and has a PRIA completion date of 3/3/2021. This is the first petition to be submitted using monitoring data. The scientific review is currently in progress.
- Difenoconazole petition for pepper, black was submitted to EPA on 3/31/2020 and we are awaiting an official PRIA completion date. (Review time = 15 months).
- Currently working to identify an additional candidate either with monitoring data or for submission under EPA's pilot project for submission in ASTA's next fiscal year.