Pesticide Import Tolerances

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Topics

- Import tolerance pilot project
  - Status, challenges, successes, next steps
- Related topics
  - PRIA fees for import tolerances
  - Import tolerances for spices based on monitoring data
“Import tolerance” = a tolerance that exists in the U.S. for which there is no accompanying U.S. registration.

Import tolerances are based on the same safety standards as “regular” U.S. tolerances.

Import tolerances generally require the same types of data as are needed to establish tolerances associated with U.S. registrations.
Import Tolerance Standard Practice

- Investigate consumption and % imported
- Determine number of field trials needed
- Evaluate field trial data (and supporting data such as methods, storage stability)
- Calculate import tolerance level
Import Tolerance Pilot Strategy

- Rely on data reviews from JMPR, EFSA, or National Authority rather than a *de novo* U.S. review
  - In-depth review of report from competent authority
  - Tolerance = MRL from Codex, EU, or exporting country
    (No “extra” run through the OECD MRL Calculator)
  - Compound generally must have food-use registration in the U.S.
Import Tolerance Pilot Strategy (1 of 2)

Review Process

Is there a suitable method for enforcement of the MRL residue definition?

Yes

Are there residue estimates for the US residues of concern for risk assessment?

Yes

Refine Inputs

No

Are data available to refine the RA?

Yes

Pass?

No

Conduct RA

Yes

Contact RD/Submitter
Does the US tolerance expression match the MRL residue definition?

- **Yes**
  - Prepare dietary and aggregate RA documents and recommend for tolerance at petitioned-for level in 40 CFR180.xxx paragraph (a)

- **No**
  - Prepare dietary and aggregate RA documents and recommend for tolerance at petitioned-for level in a *sub-paragaph* in 40 CFR180.xxx paragraph (a) using the MRL residue definition

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**Import Tolerance Pilot Strategy (2 of 2)**

**Tolerance/MRL Process**
Import Tolerance Pilot Status

- 14 chemical/crop combinations submitted
- 3 additional chemical/crop combinations were self-identified by the Agency
- 10 commodities: banana, barley, coffee, ginseng, hops, legumes, olive, oats, tea, and wheat
Import Tolerance Pilot Status

- MRLs have been established for 11 chemical/crop combos:
  - Boscalid on edible-podded legumes (subgroup 6A)
  - Ametocradin on hops
  - Chlormequat chloride on cereals (3 separate MRLs)
  - Tebuconazole on ginseng
  - Abamectin on tea (+ banana, but not under pilot)
  - Spinetoram on tea
  - Pyrifluquinazon on tea
  - Methoxyfenozide on tea

- One petition (2 crops) had risk issues, so on hold

- Four additional chemical/crop combinations are in progress
Import Tolerance Pilot Challenges

❑ Reluctance
  ❑ Registrants – Time concerns and translation costs
  ❑ Science reviewers – Trust concerns
Import Tolerance Pilot Successes

- Most submissions to-date have been successfully reviewed
- All reviewers reported a positive experience
- Significant savings over “traditional” reviews
  - ~ 50 hours shorter science review time
- Some decisions have been faster
- Experience with EFSA, JMPR & national authority reviews
Import Tolerance Pilot Next Steps

- Continue pilot
  - Need experience with reviews by other national authorities
  - Use experience from current work to determine
    - Potential for a standard business practice
    - Boundaries for a revised import tolerance policy
Points of Contact

- Technical Questions
  - Mike Doherty (doherty.michael@epa.gov)

- Registration Questions
  - Nancy Fitz (fitz.nancy@epa.gov)
## Relevant PRIA Fees – PRIA 3 and PRIA 4

<table>
<thead>
<tr>
<th>PRIA</th>
<th>Category</th>
<th>Action</th>
<th>Decision Time (Months)</th>
<th>Fee ($)</th>
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<td>3</td>
<td>R280</td>
<td>Establish import tolerance; new active ingredient or first food use</td>
<td>21</td>
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<td>Same as PRIA 3</td>
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<td>R290</td>
<td>Establish import tolerance; additional food use</td>
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<td>R291</td>
<td>Establish import tolerances; additional food uses; 6 or more crops submitted in one petition</td>
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<td>Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated</td>
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<td>R292</td>
<td>Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex MRLs; domestic or import; applicant-initiated</td>
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Monitoring Data for Import Tolerances on Spices

- Policy of establishing “import tolerances” for pesticide residues in spices based on monitoring data
- Consistent with current Codex practice
- Only applies to spices and “import tolerances”
  - Residue data on the representative commodities is still needed to establish a domestic tolerance (and register the use) on spices.