



U.S. EPA Update

2021 MRL Harmonization Workshop Webinar

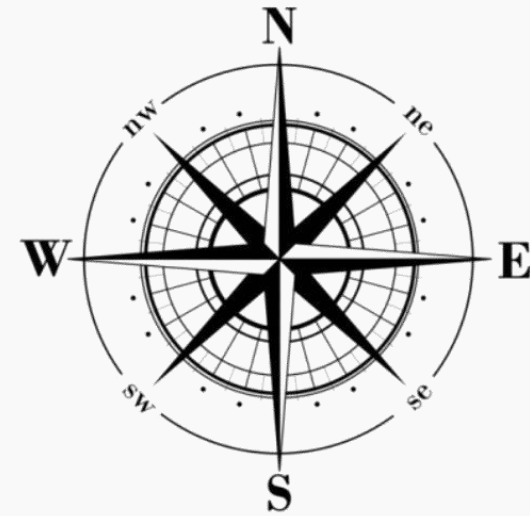
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Topics

- Crop group rulemaking
- Import tolerance updates
- Import tolerance pilot project: updates, lessons learned and next steps





Crop Group Rulemaking

Crop Grouping Phase V final rule was published November 6, 2020.

Previous Crop Group: § 180.41(c)(28)	New Crop Groups § 180.41(c)(34) & (35)
Crop Group 19: Herbs and Spices Group <ul style="list-style-type: none">• 68 commodities• Rep crops: basil (fresh & dried); black pepper; chive; celery seed or dill seed	No equivalent
Herb Subgroup 19A <ul style="list-style-type: none">• 36 commodities• Rep crops: basil (fresh & dried); chive	Crop Group 25: Herb Group <ul style="list-style-type: none">• 418 commodities• Rep crops: basil, dried leaves; basil, fresh leaves; mint, dried leaves; mint, fresh leaves
Spice Subgroup 19B <ul style="list-style-type: none">• 32 commodities• Rep crops: black pepper; celery seed or dill seed	Crop Group 26: Spice Group <ul style="list-style-type: none">• 209 commodities• Rep crops: Dill seed or celery seed



Monitoring Data for Import Tolerances on Spices

- ❑ Policy of establishing “import tolerances” for pesticide residues in spices based on monitoring data
- ❑ See [November 6, 2020 Crop Grouping Phase V rule](#)
- ❑ 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.



Relevant Tolerance Fees under PRIA 4

PRIA	Category	Action	Decision Time (Months)	Fee (\$)
4	R280	Establish import tolerance; new active ingredient or first food use	21	335,026
4	R290	Establish import tolerance; additional food use	15	67,007
4	R291	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition	15	402,031
3	R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	11	41,124
4	R292	Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex MRLs ; domestic or import; applicant-initiated	11	47,609



Import Tolerance Pilot Project

- Summary of pilot project
- Import tolerances established
- Lessons learned, successes, next steps



Import Tolerance Standard Practice – Residue Chemistry Data

- 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 – Residue Chemistry Data

- 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
- Compound generally must have food-use registration in the U.S.

* JMPR = Joint FAO/WHO Meeting on Pesticide Residues; EFSA = European Food Safety Authority



Import Tolerance Pilot Status

- More than 30 chemical/crop combinations submitted
- 4 additional chemical/crop combinations were self-identified by the Agency
- Commodities: apple, barley, cacao, citrus, coffee, ginseng, grape, hops, legumes, melon, olive, oats, Japanese persimmon, tea, and wheat
- Evaluations from Brazil, Canada, Japan, JMPR, EFSA
- Participation by the major agrochemical companies



Import Tolerance Pilot Status

- 24 MRLs have been established:
 - Boscalid on edible-podded legumes (subgroup 6A)
 - Ametoctradin on hops
 - Chlormequat chloride on cereals (3 separate MRLs)
 - Tebuconazole on ginseng
 - Abamectin, difenoconazole, fenbuconazole, fluxametamide, hexythiazox, methoxyfenozide, pyrifluquinazon, spinetoram, spinosad and trifloxystrobin on tea
 - Ethiprole on coffee
 - Mandipropamid on cacao
 - Diquat on dried shelled legumes (subgroup 6C)
 - Metaflumizone on apple, citrus, coffee, grape and melon (subgroup 9A)
- Several are in progress, two were withdrawn



Import Tolerance Pilot Lessons Learned

- Initial reluctance
 - Registrants – Time concerns and translation costs
 - Science reviewers – Trust concerns
- No reduction in PRIA registration fee



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
 - Scope of a revised import tolerance policy



Points of Contact

- ❑ Technical Questions
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- ❑ Registration Questions
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