



Updates on Spice Tolerance Applications

Lois Rossi, ASTA Consultant



ASTA's Progress to Obtain Import Tolerances

- ASTA is continuing to work to obtain new U.S. pesticide tolerances (also referred to as MRLs) for spices to reduce the regulatory risk for importers.
- Presentation will cover the approach to obtaining pesticide tolerances and progress on specific pesticide tolerance applications (petitions).
- Applications (petitions) are submitted to the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP).
- Petitions submitted to date have been for import tolerances.
- An import tolerance is the maximum residue level of a pesticide permitted in or on food or feed treated with a pesticide in foreign countries to be lawfully imported into the United States. The term "import tolerance" is used as a convenience to refer to a tolerance that exists in the U.S. for which there is no accompanying U.S registration but that meets U.S. Food safety standards.



ASTA's Progress to Obtain Import Tolerances

- Identify from solicitation of ASTA's membership pesticides whose use could result in detectable residues and possible violations because a tolerance does not exist in the U.S.
- Utilize Monitoring Data to support the establishment of import tolerances
 - ASTA requested EPA to accept spice monitoring data similar to Codex practices in setting MRLs for spices.
 - On 5/10/17 the Chemistry Science Advisory Council (ChemSAC) of EPA's Office of Pesticide Programs considered the use of monitoring data in place of field trial data to establish import tolerances for residues of pesticides in/on imported spices.
 - ChemSAC concurred that monitoring data could be used to support the establishment of an import tolerance for spices following the criteria utilized by Codex's Joint Meeting on Pesticide Residues (JMPR) that the monitoring data set must have at least 59 samples with detectable residues.
- Utilize the EPA Pilot Project for establishing import tolerances.
 - EPA Pilot Project: Instead of submitting the currently required residue chemistry field trial data, the petitioner would submit the final review of the residue chemistry data from the JMPR or a national authority;
 - EPA would rely on these reviews to determine the appropriate tolerance level with the intent of harmonizing with the established Codex or national authority MRL, provided the required safety finding can be made.



ASTA's Progress to Obtain Import Tolerances

- Import tolerance petitions submitted to EPA:
 - Metalaxyl, black pepper
 - Difenoconazole, black pepper
- Import tolerance petitions to be submitted:
 - Cypermethrin for two Codex crop subgroups:
 - Spices, fruits and berries: 0.5 ppm (2011)
 - Spices, roots and rhizomes: 0.2 ppm (2005)
- Import tolerance petitions under discussion:
 - Azoxystrobin to include black pepper in the current tolerance which excludes black pepper.



ASTA's Progress to Obtain Import Tolerances

- Metalaxyl (fungicide): Black pepper
 - Import tolerance petition submitted to EPA on 10/10/2019. Pesticide Registration Improvement Act (PRIA) decision R290 timeline for decision = 15 months. Fee = \$67,007 (ASTA qualified for the small business waiver, fee = 25% of total amount).
 - Requested an import tolerance of 1.0 ppm based on monitoring data from several countries including:
 - 380 samples from Vietnam collected from 2011-2015.
 - 151 samples from Brazil, Ecuador, India, Indonesia, Malaysia, and Sri Lanka collected from 2013-2015.
 - EPA came back with the determination that the monitoring data submitted would support a tolerance of 0.3ppm
 - Original EPA due date for a decision: 3/3/2021; EPA requested date to be renegotiated to 7/3/2021; EPA recently asked for a two-month extension but consent given only until 7/23/2021.



ASTA's Progress to Obtain Import Tolerances

- Difenoconazole (fungicide): Black pepper
 - Import tolerance petition submitted to EPA on 3/27/2021. Pesticide Registration Improvement Act (PRIA) decision R290 timeline for decision = 15 months.
Fee = \$67,007 (ASTA qualified for the small business waiver, fee was 25% of total amount).
 - Requested an import tolerance of 0.1 ppm based on monitoring data from several countries including:
 - 378 samples from Argentina, Brazil, Ecuador, India, Indonesia, Malaysia, Sri Lanka, and Vietnam collected from 2009-2015.
 - 1007 samples from Brazil, Cambodia, Indonesia, Malaysia, and Vietnam collected in 2017.
 - 535 samples from Brazil, Cambodia, Indonesia, Malaysia, and Vietnam collected in 2018.
 - EPA PRIA date for a decision: 8/9/2021; import tolerance issued on 6/3/2021 (two months early) at 0.1 ppm for black pepper.
 - First import tolerance to be established on monitoring data!
 - Using monitoring data to support an import tolerance could be the better approach.



ASTA's Progress to Obtain Import Tolerances

- Cypermethrin
 - Approach: To use the JMPR evaluation report associated with two Codex MRLs for spices to support the establishment of U.S. spice import tolerances.
 - Work supported by Crop Life America, Food and Beverage Committee.
 - Codex has established MRLs for two spice subgroups:
 - Spices, fruits and berries: 0.5 ppm (2011)
 - Spices, roots and rhizomes: 0.2 ppm (2005)
 - EPA has one crop group (not subgroups) for spices as of November 2019 and the representative crop is dill seed; while the two subgroups overlap considerably with the EPA spice crop group, they are not the same.
 - To obtain the entire EPA spice crop group sufficient data on dill seed are required; the JMPR data set includes only 2 samples on dill seed.
 - Codex crop groups are not harmonized with EPA; EPA has determined that the PRIA fee will need to be based on the individual spices in the two Codex subgroups resulting in the maximum PRIA fee for the R290 category (6 or more uses) of approximately \$400K (before the 25% small business waiver).
 - Discussions currently taking place with EPA/OPP senior management challenging the decision and finding a path to proceed.



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- Azoxystrobin
 - EPA has a tolerance established for Spice Subgroup 19B, except black pepper. (former spice subgroups) as does Canada.
 - Some monitoring exists but there is an insufficient number of detects (need 59 minimum).
 - ASTA worked with Syngenta to prepare a tolerance petition.
 - Trying to determine from EPA the reason black pepper was excluded and the data needed to support establishing the tolerance to cover black pepper.



Updated Spice & Herbs Crop Group

- EPA published a Final Rule updating the spice and herb crop groups in November 2020, which went into effect in January 2021
 - Intention to “reduce regulatory burden” on industry
 - Crop groups allow tolerances to be established on multiple related crops based on data submitted by one representative commodity
 - Rule splits current spices and herbs crop group 19 into two new crop groups – crop group 25 herbs & crop group 26 spices
- The good:
 - Expands the number of spices and herbs covered by a crop group tolerance
 - Codifies the new monitoring data policy for spices
 - However, monitoring data is only allowed for individual crop tolerances NOT the whole spice group
- The bad:
 - Requires all spice crop group tolerances to be based on dill seed field trial data, of which there is very little
 - Does indicate monitoring data on subgroups may be used to obtain a tolerance for related commodities
- ASTA is meeting with EPA leadership to voice concerns



ASTA's Progress to Obtain Import Tolerances

- Codex Committee on Pesticide Residues (CCPR) Update
 - CCPR will meet virtually July 26-31, 2021.
 - Consider recommending adoption of the MRLs recommended by JMPR from their May 2019 extraordinary meeting to the Codex Alimentarius Commission.
 - MRLs under consideration related to spices:
 - Acetamiprid, spices, seed subgroup: 2.0 ppm
 - Carbendazim, spices, seed subgroup: 5.0 ppm



Thank You for Your Attention