

## ASTA Update for International Pepper Association

February 2022

### Collaboration with International Counterparts is Crucial



ASTA build relationships with international organizations and collaborates to identify and address food safety and compliance issues



#### Key Regulatory Issues

- Pesticide Regulations
  - Overview of U.S. Regulatory Environment
  - Chlorpyrifos Update
  - Additional Pesticide Tolerances
- Update on Heavy Metals
- Salmonella Requirements
- General Food Import Requirements
- Other Emerging Regulatory Issues





- The U.S. Environmental Protection Agency (EPA) issues tolerances for pesticide residues in food -40 CFR Part 180
- The U.S. Food and Drug Administration (FDA) enforces the tolerances
  - FDA screens imported foods for pesticide residues
- Under the Federal Food Drug and Cosmetics Act, a food that contains pesticide residues not covered by a tolerance or tolerance exemption, or with residues in excess of the tolerance, is deemed adulterated
- If there is no tolerance, the tolerance is interpreted as zero, with no allowance for *de minimis* levels regardless of the level, even if there is no health or safety concern
  - Therefore, it is in the best interest of U.S. industry to obtain tolerances for pesticides to ensure they can be legally imported and ensure that no residues of chemicals for which there are no tolerances occur on spices

#### Chlorpyrifos Ban



- The U.S. Government took steps to ban chlorpyrifos under the Obama Administration – Trump Administration halted the ban
  - This is in response to health concerns related to neurological development
- In August, Biden Administration announced it was revoking U.S. chlorpyrifos tolerances – effective Feb 28, 2022
- There are several expiring chlorpyrifos tolerances on spices in the U.S. including chilis, peppermint, spearmint, and onion
  - There is no existing tolerance on black pepper any detectable levels of chlorpyrifos on black pepper are not allowed



- ASTA met with FDA on Nov 19 along with a group of food and beverage organizations to ask FDA to exercise enforcement discretion on this ban
- FDA has published guidance regarding plans to exercise enforcement discretion for a period of time
- In the meantime, several farm and ag organizations have sued the U.S. government in an effort to reverse the ban

### Chlorpyrifos Ban - Impact to Black Pepper

- There was never a U.S. chlorpyrifos tolerance for black pepper, so the tolerance is already zero – the ban does not change this situation.
- Questions related to if U.S. will increase enforcement
  - In general, FDA screening of pesticide residues on spices is infrequent
  - FDA has told ASTA residues on spices are "not a priority"
  - FDA guidance signals FDA enforcement discretion
  - Although technically zero tolerance, FDA guidance indicates that the agency will not take action on very low levels
- Other considerations: What will customers demand?
   Potential litigation risk?





#### **Current U.S. Tolerances for Black Pepper**

- §180.364 Glyphosate, 7.0ppm
- §180.516 Fludioxonil, 0.02ppm
- §180.544 Methoxyfenozide (indirect or inadvertent residue), 4.5ppm
- §180.628 Chlorantraniliprole, 90ppm
- §180.408 Metalaxyl, 0.3 ppm
- §180.475 Difenoconazole, 0.1 ppm



Recently granted based on ASTA petitions!

#### **EPA Establishment of Tolerances**



- EPA requires extensive data for each pesticide/commodity
  - Ingredients; site of crop; amount, frequency, manner, timing of use; storage/disposal
- Import Tolerance
  - Petition must be submitted to EPA with the information required in 40 CFR 180.7
  - Typically, the petition must include residue field trial data. However, for spices, monitoring data is accepted
- Petitions must include this data and information plus applicable PRIA fees – typically requires the cooperation with the chemical registrants



#### Potential Future Petitions

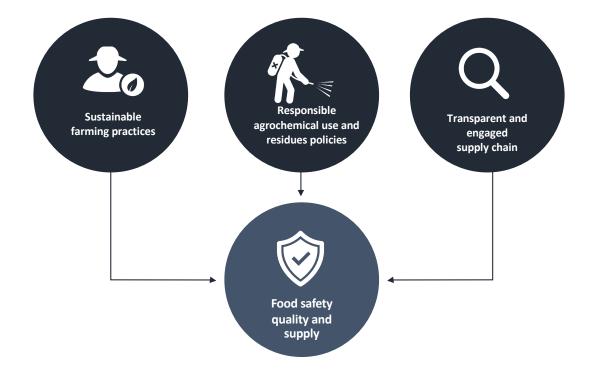


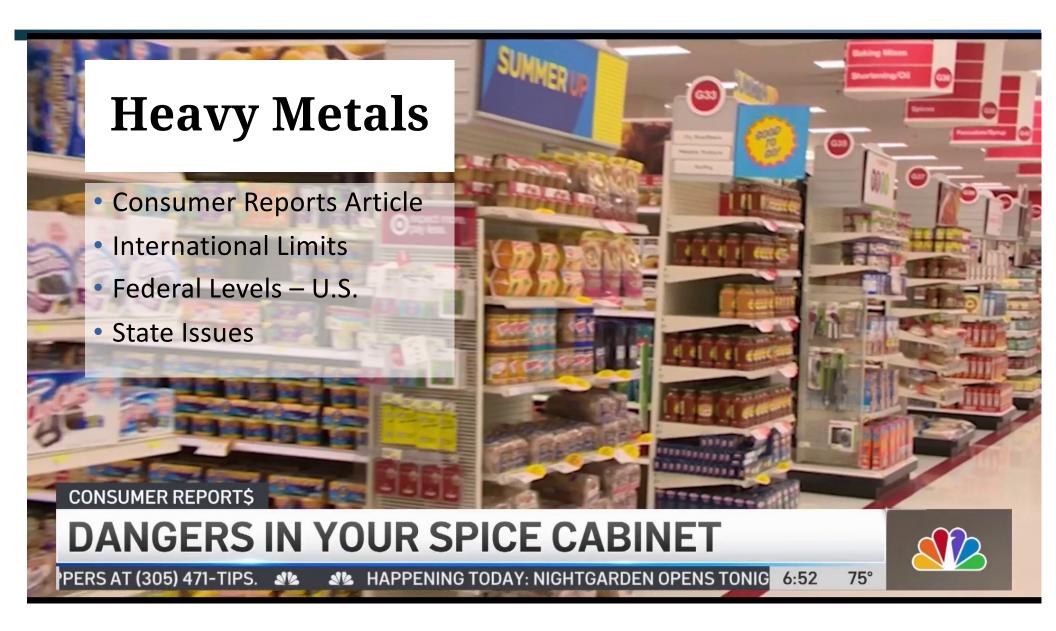
- ASTA has several petitions underway
  - Cypermethrin for two Codex crop subgroups:
    - Spices, fruits and berries: 0.5 ppm (2011)
    - Spices, roots and rhizomes: 0.2 ppm (2005)
  - Azoxystrobin 38ppm
- Additional petitions possible
  - Some chemicals may not be likely/possible to obtain new tolerances for black pepper or other spices due to political environment (e.g. chlorpyrifos, carbendazim)
  - Other chemicals may be possible. To develop a petition, we need a minimum of 70 datapoint for each pesticide.



### Ongoing Partnership in Vietnam on Pesticide Compliance











<b>Herb/Spice Commodity</b>	Proposal of ML (mg/kg)
Culinary herbs (fresh)	0.2
Culinary herbs (dried)	2.5
Aril	1
Bark	2.5
Buds	2.5
Floral parts	1
Fruits and berries spices	0.8
Rhizomes, bulbs and roots spices, excluding garlic and ginger	3
Ginger	5
Garlic	0.4
Seeds spices	1

#### U.S. Federal Government

ESTAN SPICE

- Congressional Report on Heavy Metals in Baby Food
- FDA Closer to Zero Initiative
  - Focus on foods for infants and young children
  - No plans to target spices at this time





#### U.S. States: New York State Action Levels for Heavy Metals in Spices



Analyte	Class II Recall Action
	Level
	(ppm)
Lead (Pb)	>0.21
Cadmium (Cd)	>0.26
Inorganic Arsenic (As)	>0.21

Implementation of these levels now on hold based on ASTA request for state to use a different approach

New York State *Updated* Recall Policy for Heavy Metals in Spices (effective <u>TBD</u>)

#### Salmonella Resources



- U.S. FDA requires validated kill step for *Salmonella* be applied to spices
- Problem FDA is cracking down on enforcement at import with scrutiny of spice company food safety plans and validation studies
- New ASTA Resources
  - Salmonella detection methods paper
  - Irradiation literature review
  - Updated validation guidance for spice groupings coming soon!

#### General Import Requirements



#### **Procedures and Requirements for Importing Food Products**

In addition to meeting the requirements of U.S. food regulations including <u>food facility</u> <u>registration</u>, importers must follow U.S. import procedures as well as the requirements of Prior Notice.

- Manual of Compliance Policy Guides Chapter 5 Food, Colors, and Cosmetics
- Prior Notice of Imported Food
- Imported Seafood Safety Program
- Hazard Analysis Critical Control Point (HACCP)
- Accredited Third-party Certification Program
- <u>Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals</u>
- Voluntary Qualified Importer Program (VQIP)

#### <u>Additional Guidance on Import</u> Documentation

- Consider consulting with a U.S.
   Customs and Border Protection (CBP)
   Import Specialist (cee-agriculture@cbp.dhs.gov)
- May wish to hire licensed customs broker to help assist with import requirements

https://www.fda.gov/food/food-imports-exports/importing-food-products-united-states

#### Other Regulatory Issues in the U.S.



- FDA Inspection Update & New Era of Food Safety
  - Focus on tech-enabled traceability
- FASTER Act Adds sesame as a major allergen
- Customs & Border Protection detention of goods suspected to be produced with forced labor

## Please join us in Miami





2022 ASTA Annual Meeting and Exhibits April 10-12, 2022 InterContinental Miami - Miami, FL

















## Additional Slides for Reference

# Relevant Laws & Regulations Pertaining to Pesticides

- <u>Federal Insecticide</u>, <u>Fungicide</u>, <u>and Rodenticide Act (FIFRA)</u> Requires all pesticides in the U.S. (including imported pesticides) to be registered by EPA.
- Federal Food, Drug and Cosmetic Act (FFDCA) Requires tolerance (max permissible level) for all pesticides used in/on food.
- The <u>Food Quality Protection Act</u>, of <u>1996</u> requires re-registration and establishes more conservative risk assessment requirements.
- The <u>Pesticide Registration Improvement Act of 2003 (PRIA)</u> requires companies to pay fees for pesticide registration and establishes timelines for EPA review.
- Regulations implementing the pesticide statues are available at <u>40 CFR Part</u> <u>150-189</u>