

FDA's Pesticide Residue Monitoring and Enforcement

Charlotte Liang, Ph.D.

Office of Food Safety

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

2018 MRL Harmonization Workshop

May 30, 2018

Agenda

- Overview of FDA and pesticide laws
- FDA's enforcement policy for pesticide residues in food
- FDA's pesticide residue monitoring program

U.S. Food and Drug Administration



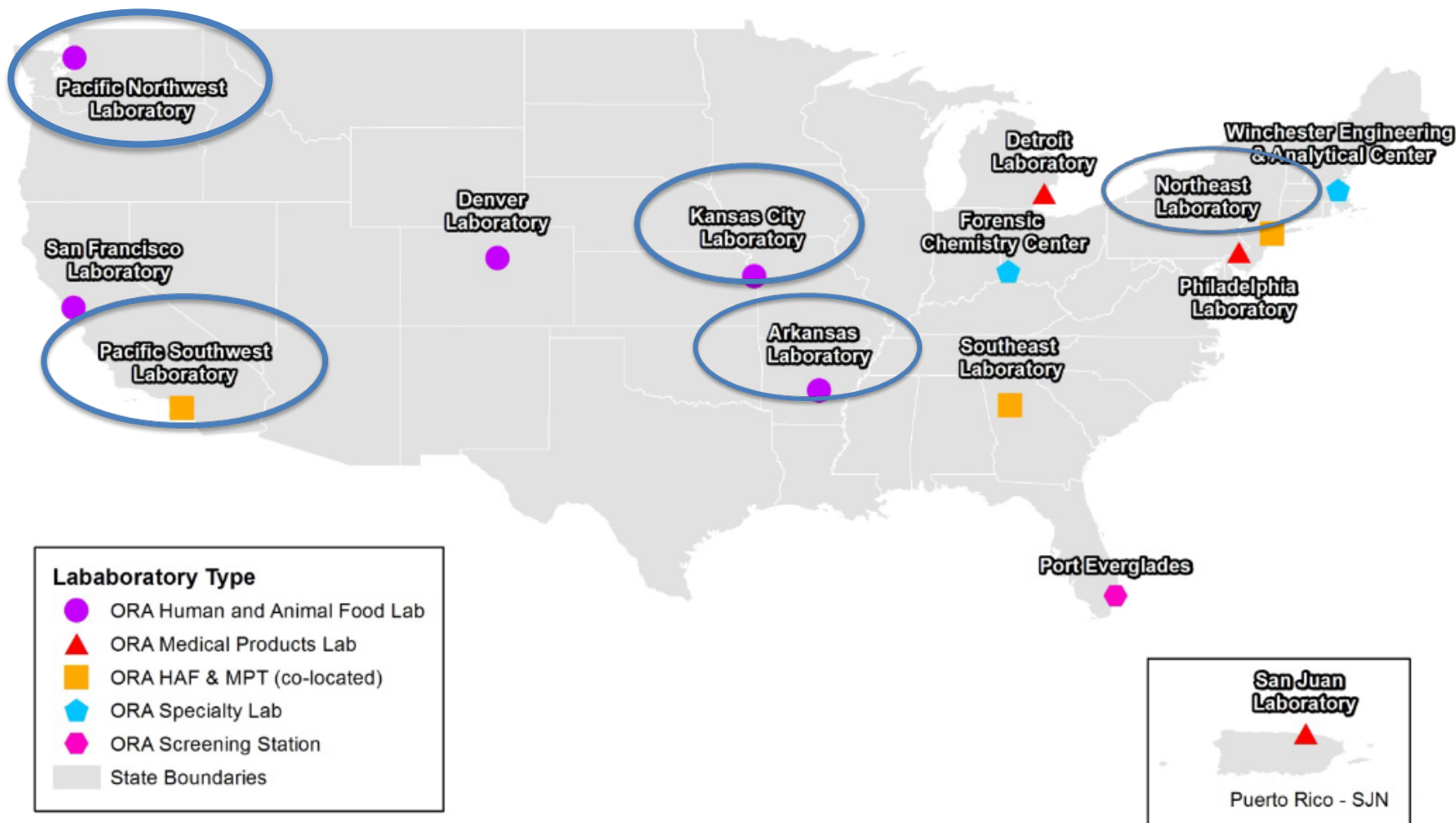
- Many responsibilities
 - Food
 - Drugs (prescription and over-the-counter)
 - Animal/Veterinary Products (animal food and drugs)
 - Biologics (vaccine, blood, tissue)
 - Devices (medical, electronic products that emit radiation)
 - Tobacco
 - Cosmetics

U.S. Food and Drug Administration



- **Center for Food Safety and Applied Nutrition (CFSAN)**
 - Food Safety (Pesticides, Radionuclides, Pathogens, Filth, Toxins, Heavy Metals)
- **Center for Veterinary Medicine (CVM)**
 - Animal Food Safety (focus on animal food for livestock and poultry animals that ultimately become or produce foods for human consumption)
- **Office of Regulatory Affairs (ORA)**
 - Inspections/Investigations
 - Laboratory Analysis (pesticide testing)

ORA Laboratory Locations



Pesticide Laws

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA):
 - Registers use of pesticides (EPA)
- Federal Food, Drug, and Cosmetic Act (FFDCA):
 - Establishes tolerances (EPA)
 - Compliance with tolerances (FDA)
- Food Quality Protection Act (FQPA):
 - More stringent safety standards
 - Protection of children
 - Periodic reviews of all registered pesticides

Enforcement of Tolerances: FD&C Act

- Section 402 (a)(2)(B):

A food shall be deemed to be adulterated if it bears or contains a pesticide chemical residue that is **unsafe** within the meaning of section 408 (a).

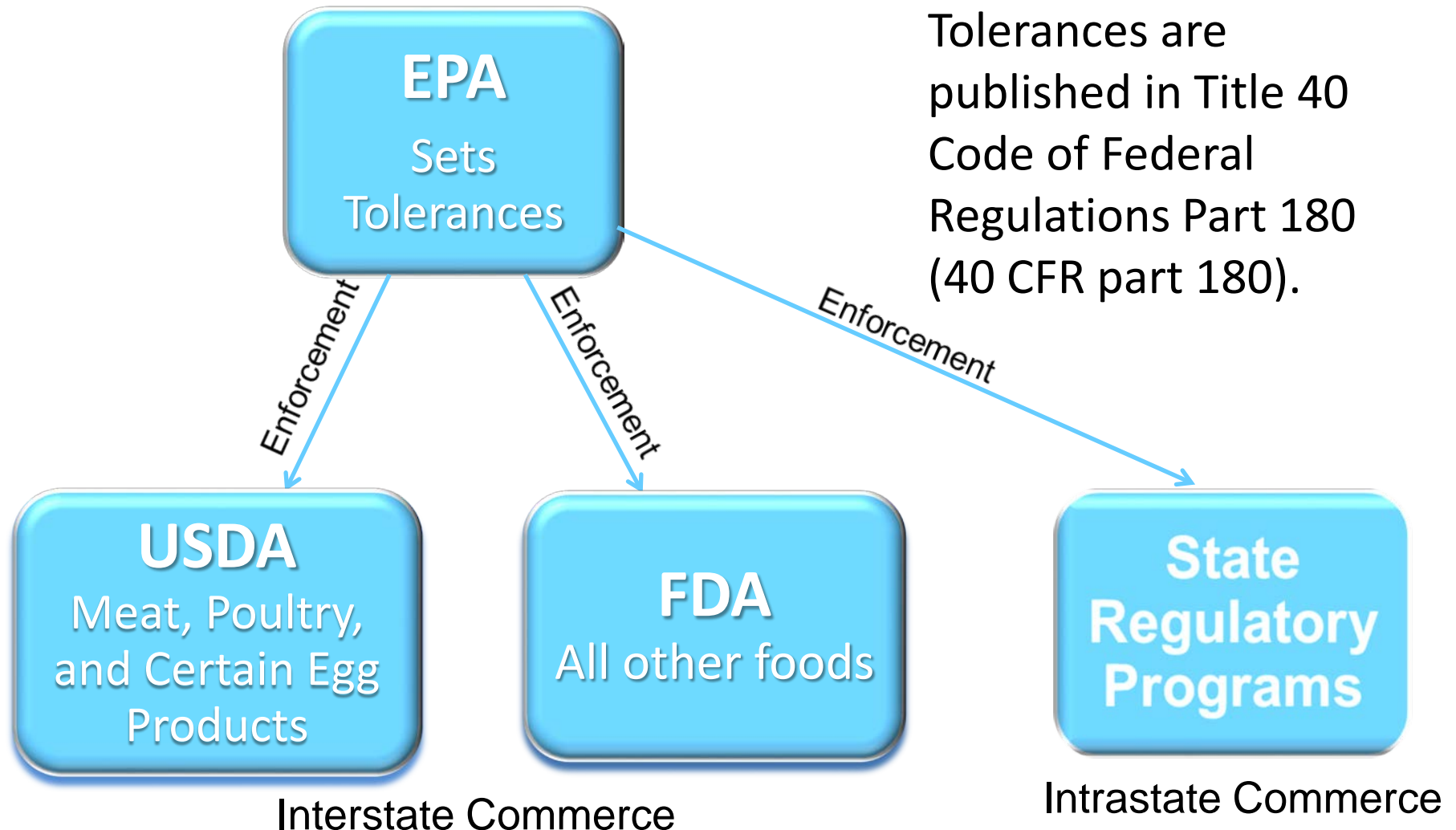
- Section 408 (a):

General rule: any pesticide chemical residue in or on a food shall be deemed unsafe unless-

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

U.S. Regulatory Agencies



Enforcement of 40 CFR Part 180

How does FDA enforce tolerances?

**Raw Agricultural Commodity (RAC)
VS.
Processed Food**



40 CFR §180.1 (h)(10)

- For processed foods consisting primarily of one ingredient and sold in a form requiring further preparation prior to consumption:
 - the processed food to be examined for residues shall be the whole processed commodity after compensating for or reconstituting to the commodity's normal moisture content, unless a tolerance for the concentrated or dehydrated food form is included in this part.

Enforcement policy for processed food sold in a form requiring further preparation prior to consumption

Examples:

- fruit juice concentrates
- dehydrated vegetables
- powdered potatoes

Does tolerance exist for the processed food?

yes

Examine the processed food as is, then apply the processed food tolerance.

Convert results for the pesticides to single strength values and then apply the crop tolerance.

yes

Does tolerance exist for RAC?

NO

NO

Examine the processed food “as is.” Product is violative if residue is present at or above LOQ.



Root Vegetables: Root vs. Leaves



40 CFR 180.1(h)(6)

Where a tolerance is established on a root vegetable including tops and/or with tops, and the tops and the roots are marketed together, they shall be analyzed separately and neither the pesticide residue on the roots nor the pesticide residue on the tops shall exceed the tolerance level. Exceptions:

- **Carrots, Parsnips, and Rutabagas:**
the tops shall be removed and discarded before analyzing roots for pesticide residues.



illustrations of.com #94365

**How about pesticide
chemicals with revoked
tolerances that persist in the
environment and that were
considered to be unavoidable
in food and feed?**



Action Levels for Poisonous or Deleterious substances

- Action levels are established by FDA (in consultation with EPA) based on the **unavoidability** of the poisonous or deleterious substances.
- Represent levels at which FDA will consider whether it should exercise enforcement discretion.
- Do not represent permissible levels of contamination where it is avoidable.
 - The blending of a food or feed containing a substance in excess of an action level or tolerance with another food or feed is not permitted, and the final product resulting from blending is unlawful, regardless of the level of the contaminant.

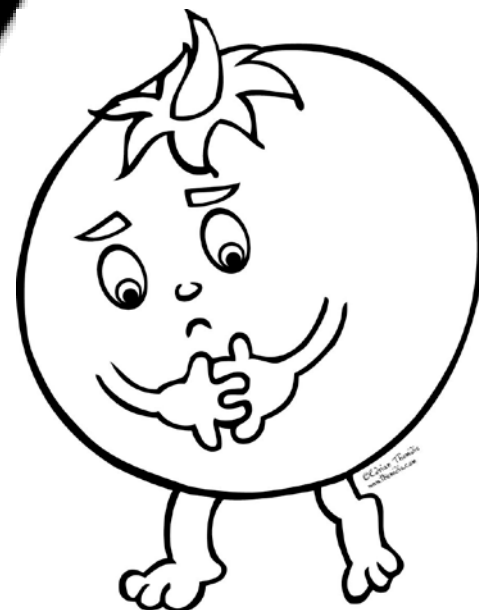
Action Levels for Poisonous or Deleterious substances



- Aldrin and Dieldrin
- Benzene Hexachloride (BHC)
- Chlordane
- Chlordecone (Kepone)
- Dicofol (Kelthane)
- DDT, DDE, TDE
- Ethylene Dibromide
- Heptachlor and heptachlor epoxide
- Lindane
- Mirex

Note: None of the action levels listed here are binding on the agency, the regulated industry, or the courts.

How about food containing pesticides that were lawfully applied or used under FIFRA and are still in commerce after the pesticide tolerance has been revoked?



Channels of Trade Provision



- Section 408(l)(5) of the FD&C Act:
 - addresses the situation where food, containing pesticide chemical residues from pesticide chemicals that were lawfully applied or used under FIFRA, is still in commerce after the pesticide chemical tolerance has been revoked, suspended, or modified.
- A firm needs to provide evidence showing that:
 - (A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful;
 - (B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food.

Channels of Trade (COT) Guidance



- Is used to addresses pesticides that are canceled due to **dietary risk considerations** where EPA must revoke tolerance in specified timeframe. Examples:
 - Vinclozolin: revoked tolerances in or on strawberries, stone fruits, cucumbers, and bell peppers on June 12, 2002 (67 FR 40185).
 - Methyl parathion: revoked tolerances on October 27, 1999 (64 FR 57877).
- Would not be used to cover pesticide tolerances revoked by the request of the registrant due to cessation of its production. EPA allows COT to clear out before revocation of tolerance.

Violative Shipments

- Illegal Residues
 - Greater than the EPA tolerances
 - Pesticides with no EPA tolerances
- Domestic
 - Warning Letter
 - Invoke Sanctions: Seizure, Injunction
- Import
 - Refuse admission
 - Import Alert: Detention Without Physical Examination (DWPE)



DWPE - Imports

(Automatic Detention) Sec 801 of the FFDCA

The recommendation may be based on the finding of **ONE** violative shipment **if there is reason to believe that the same situation will exist** in future lots for a specific shipper, grower, geographic area, or country.

Import Alerts for Pesticide Residues

- # 99-05: DWPE of Raw Agricultural Commodities
- # 99-08: DWPE of Processed Foods
- # 99-14: Countrywide DWPE of Raw Ag Commodities
 - Dominican Republic:
 - Squash (Problems: dimethoate, methamidophos, monocrotophos)
 - Peas, Snow Peas, Pea Pod, Sugar Snap Peas (Problems: methamidophos, dicrotophos, monocrotophos, profenofos, chlorpyrifos)
- # 99-15: Countrywide DWPE of Processed Foods
 - Hong Kong: Duck Eggs, in shell (Problems: BHC, DDT)
 - Turkey: Raisins (Problem: procymidone)

Removal from DWPE

- FDA decisions to remove a product, manufacturer, packer, shipper, grower, country, or importer from detention without physical examination should be based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and the agency has confidence that future entries will be in compliance with the Act.

<http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf>

Exports from the United States

- Must comply with U.S. standards (FIFRA) while being grown here-some exceptions.
- It is the responsibility of the grower to comply with destination country standards.



FDA Pesticide Monitoring Program

FDA Pesticide Monitoring Program



Three-fold Approach:

1. Regulatory Monitoring

- Enforce Tolerances

2. Special Assignments

- Specific Commodity/Pesticides/Countries

3. Total Diet Study (Market Basket Survey)

- Estimate Dietary Exposure to contaminants and nutrients

Regulatory Monitoring

- **Domestic** – Interstate Commerce
 - close to the point of production (at grower, packing sheds, major distribution centers)
- **Import** – Point of entry
- **Sample Types**
 - Raw agricultural commodities (unwashed, whole, unpeeled)
 - Processed foods (limited)
 - Animal food
- **Samples per year:** 4000-8000
- **Analytes:** ~800 pesticides per sample

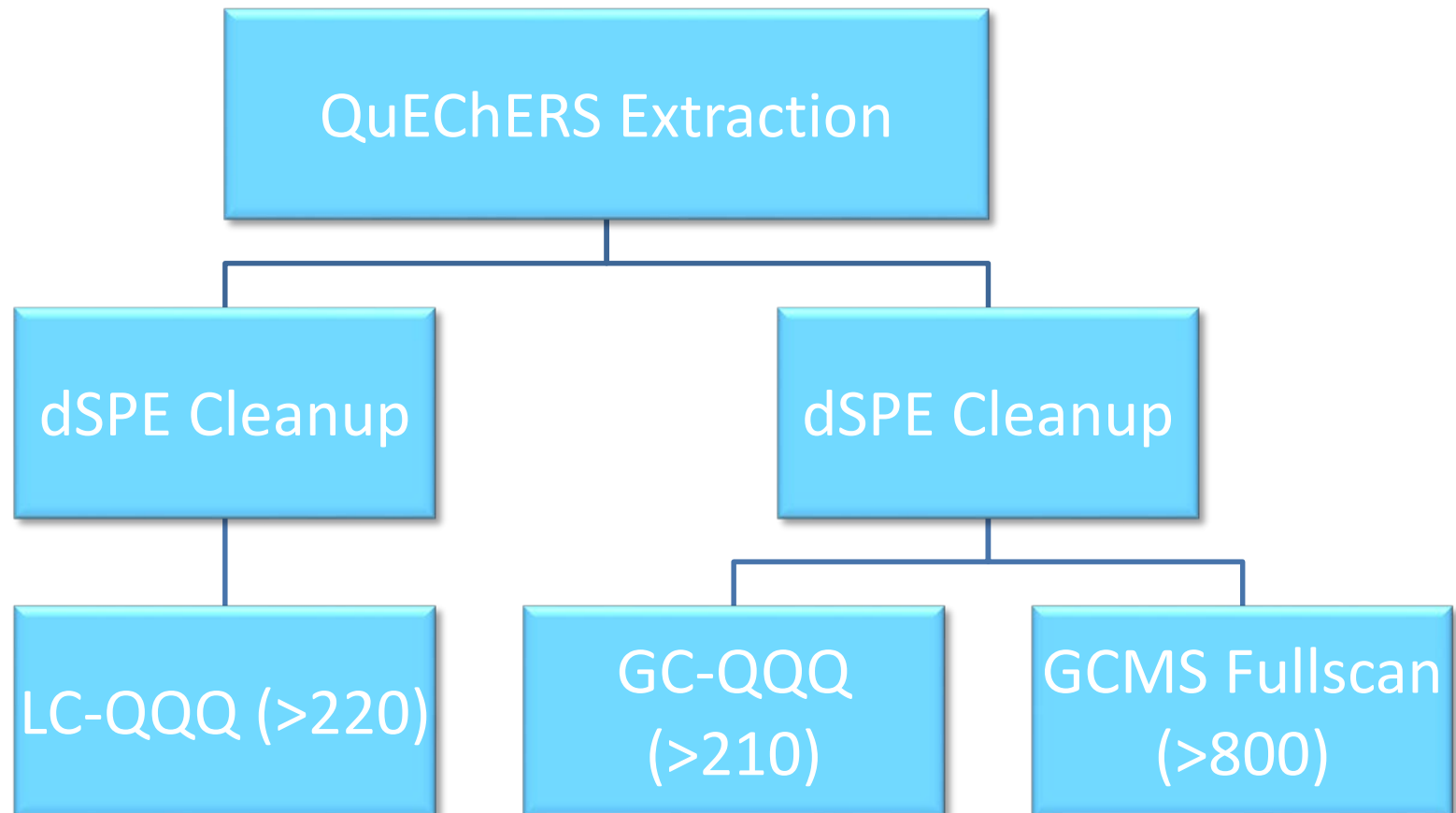


Regulatory Monitoring



- Targeted sampling:
 - Violation history
 - State/USDA monitoring reports
 - Pesticide usage reports
 - Dietary significance
 - Foods consumed by infants & children
 - Foreign office reports
 - Volume in commerce
 - Toxicity & characteristics of pesticides
- Coordination with other agencies

Pesticide Multi-residue Method (MRM)

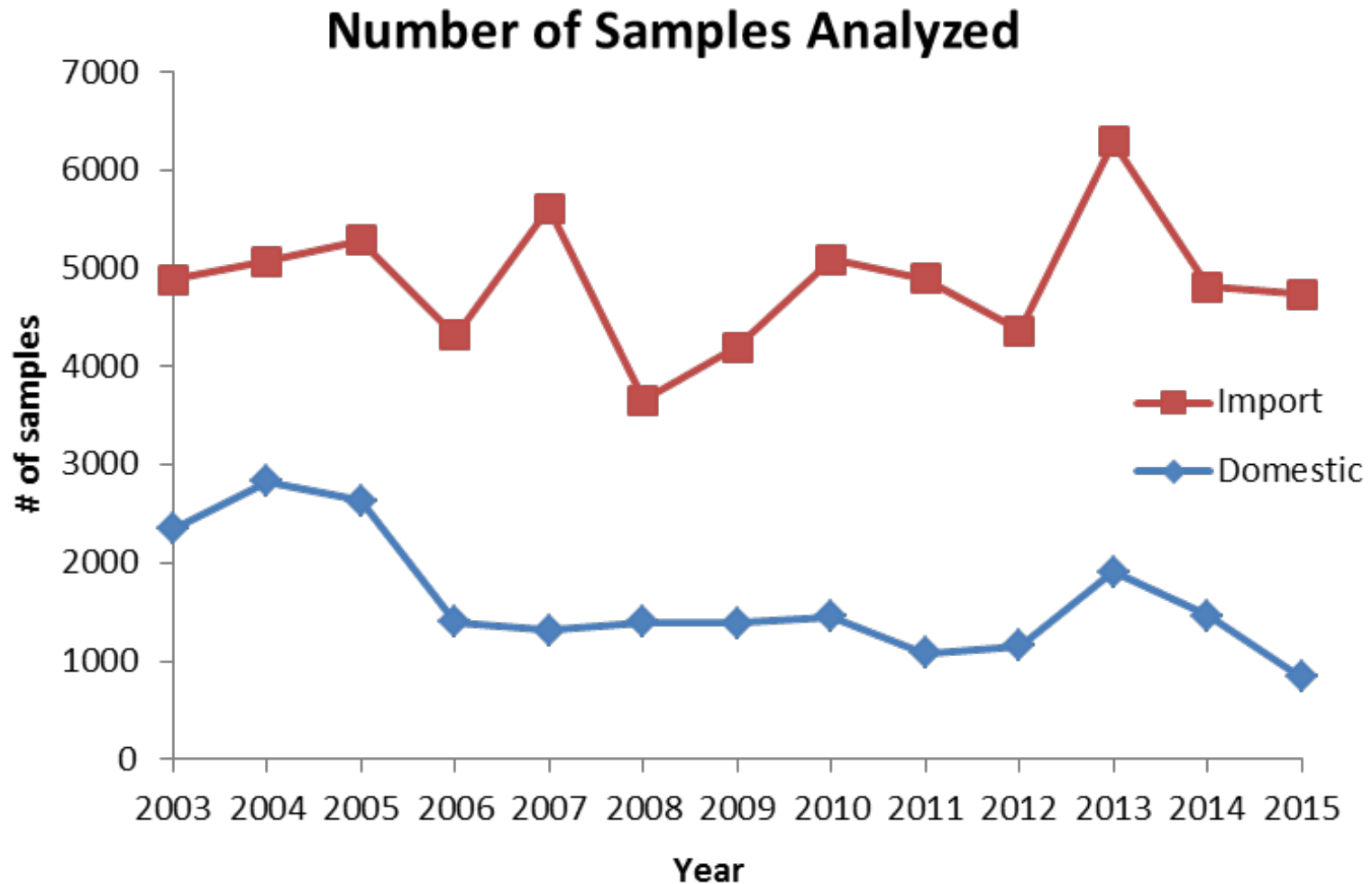


Data from Regulatory Monitoring Program

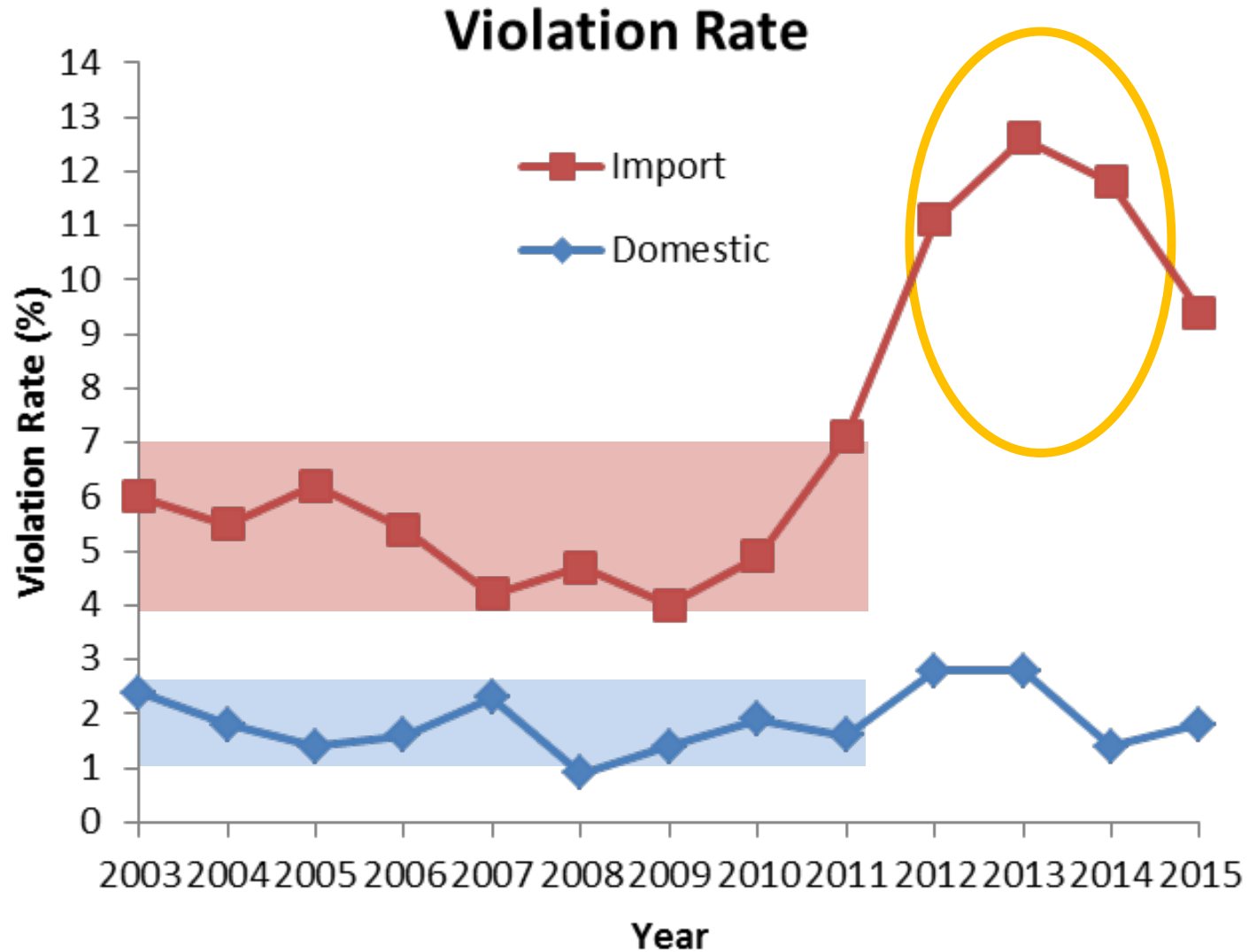
Reports available at

<http://www.fda.gov/Food/FoodbornIllnessContaminants/Pesticides/ucm2006797.htm>

Regulatory Monitoring

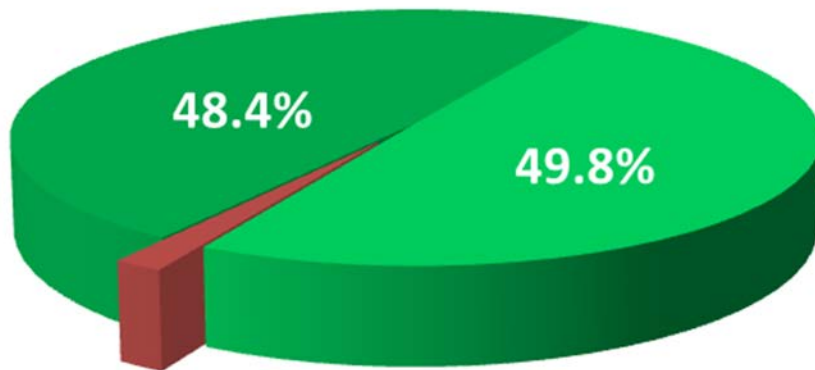


Regulatory Monitoring



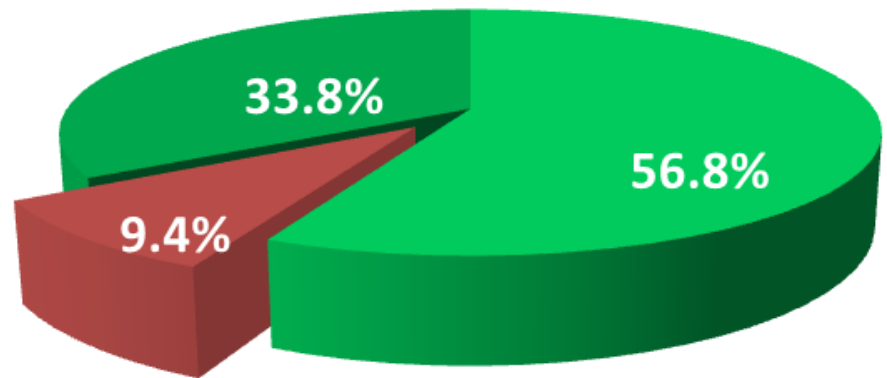
Regulatory Monitoring FY15

**Domestic
835 Samples**



1.8%

**Import
4737 Samples**



- Violative
- Nonviolative, No Residue
- Nonviolative, Residues Detected

Regulatory Monitoring FY15

	Sample s Analyzed	Violative Samples # (%)	Over Tolerance Violations (#)	No Tolerance Violations (#)
Domestic	835	15 (1.8)	2	15
Import	4737	444 (9.4)	19	436

Note: Total number of violative samples may not equal sum of samples with “Over Tolerance” and “No Tolerance” violations because one sample can have both violation types.

Regulatory Monitoring FY15

Commonly Found Pesticide Residues in Food



- In FY 2015, FDA pesticide methods could detect 696 pesticides and industrial chemicals.
- Of these chemicals, 207 different pesticides were actually found in the samples analyzed.

Imidacloprid (362)	Thiophanate-methyl (352)	Boscalid (319)
Chlorpyrifos (310)	Acetamiprid (240)	Azoxystrobin (231)
Tebuconazole (190)	Cypermethrin (176)	Fludioxonil (160)
Pyraclostrobin (158)	Metalaxyl (154)	Bifenthrin (142)

(): number of samples in which the pesticide was found

Regulatory Monitoring FY15



Top Violative Imported Commodities (more than 20 samples analyzed)

Commodity	Violation Rate (%)	Commodity	Violation Rate (%)
Jackfruit fruit/juice	29.2	Strawberries fruit/juice	15.7
Cilantro	27.3	Chia seeds	15.4
Prickly pear fruit/juice	27.3	Pineapple fruit/juice	15.4
Mushroom	26.7	Squash (Mexico)	15.1
Rice, processed	21.1	Raisins	15
Radish	19.1	Peas	13.2
Scallions and shallots	19.1	Olive oil	12.3



Commodity was on the FY 2014 table of imported commodities warranting special attention

Special Assignments

- Follow up on suspected area
- In-depth coverage
- Specific commodity or group
- Raw or processed

Special Assignments

Assignment	Year	Spls	Vio%
EU (game meat)	2015	17	0
EU (milk, eggs, honey)	2014	725	0.8
EU (milk, eggs, honey)	2013	253	2
Tea (black and green)	2014	21	57
Tea (black, green, white)	2013	22	10
Dietary supplements	2013	183	35
Dietary supplements	2011	68	15

Publications



- Annual Reports and Residue Monitoring Databases
<http://www.fda.gov/Food/FoodbornellnessContaminants/Pesticides/ucm2006797.htm>
- Pesticide Analytical Manuals (PAM)
<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006955.htm>
- Total Diet Study-Analytical Results
<http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm184293.htm>
- FDA Compliance Policy Guide 575.100 “Pesticide Residues in Food and Feed Enforcement Criteria”
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm123236.htm>



Regulatory Monitoring and Special Assignments:

Office of Food Safety: charlotte.liang@fda.hhs.gov

chris.sack@fda.hhs.gov

lauren.robin@fda.hhs.gov

Total Diet Study:

Office of Analytics and Outreach: terry.council@fda.hhs.gov

mark.wirtz@fda.hhs.gov