



# **FDA Pesticide Monitoring Program**

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**U.S. Food and Drug Administration**

ACS Symposium:

Who Should Regulate Pesticides in Our Food?

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# U.S. Food and Drug Administration

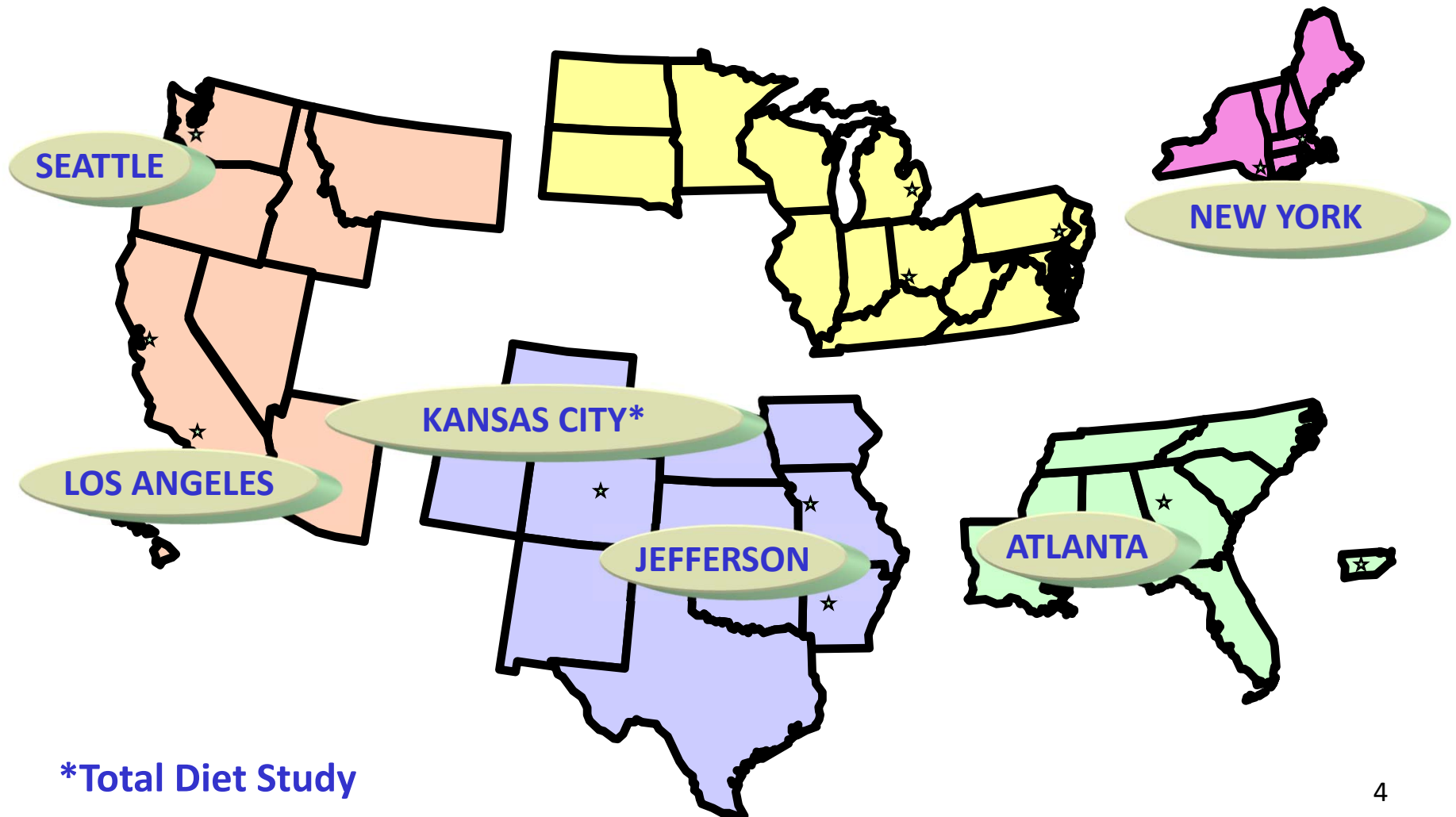
- Many responsibilities
  - Food
  - Drugs (prescription and over-the-counter)
  - Veterinary Products (animal drugs and feed)
  - Biologics (vaccine, blood, tissue)
  - Devices (medical, electronic products that give off radiation)
  - Tobacco
  - Cosmetics



# 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)**
  - Feed Safety (focus on feeds 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)

# Six Pesticide Laboratories



\*Total Diet Study

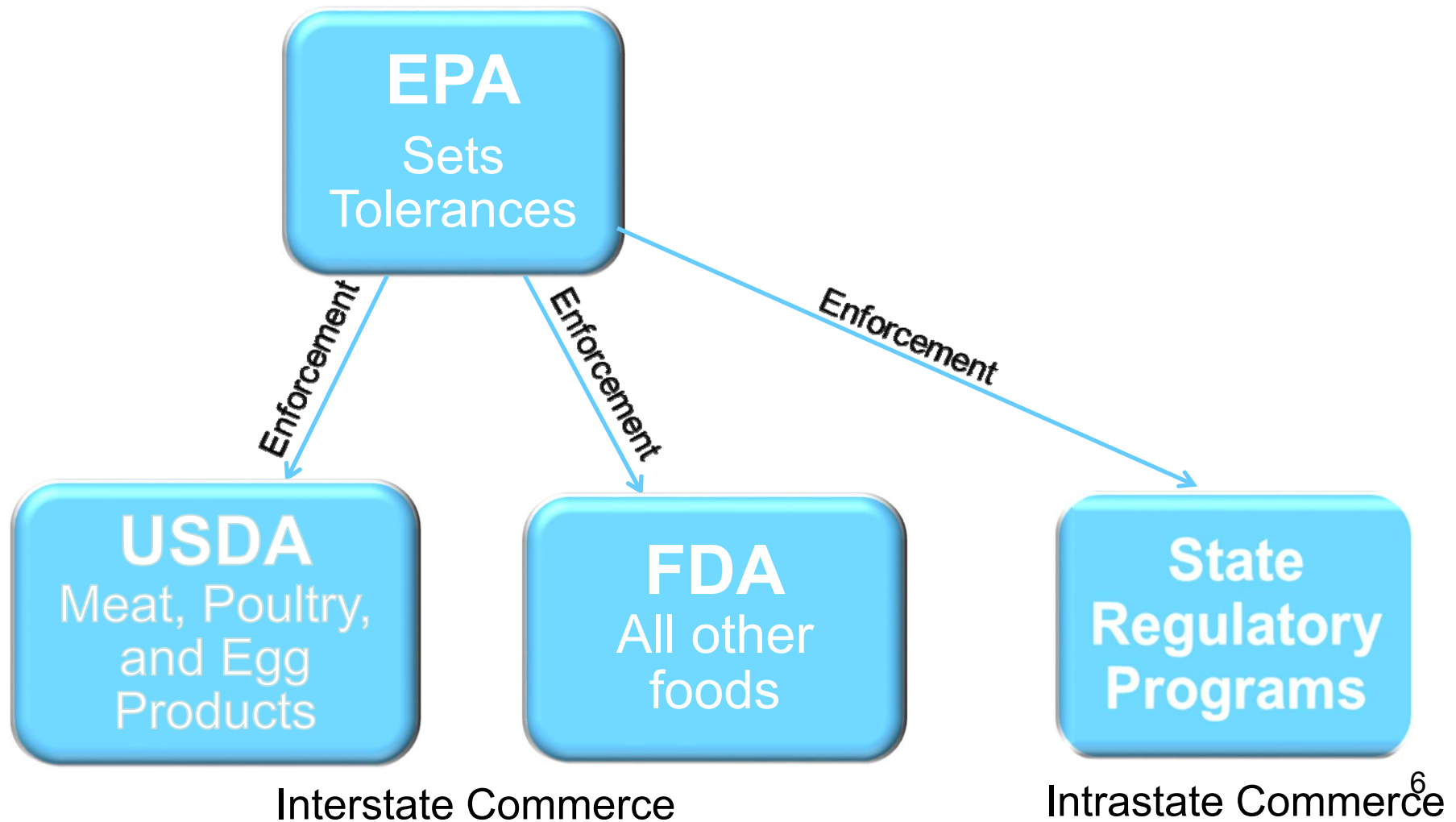


## Pesticide Laws

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



# Regulatory Agencies





**U.S. Food and Drug Administration**  
Protecting and Promoting Public Health

[www.fda.gov](http://www.fda.gov)

# **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 Feeds
- **Samples per year:** 4000-8000
- **Analytes:** ~800 pesticide per sample

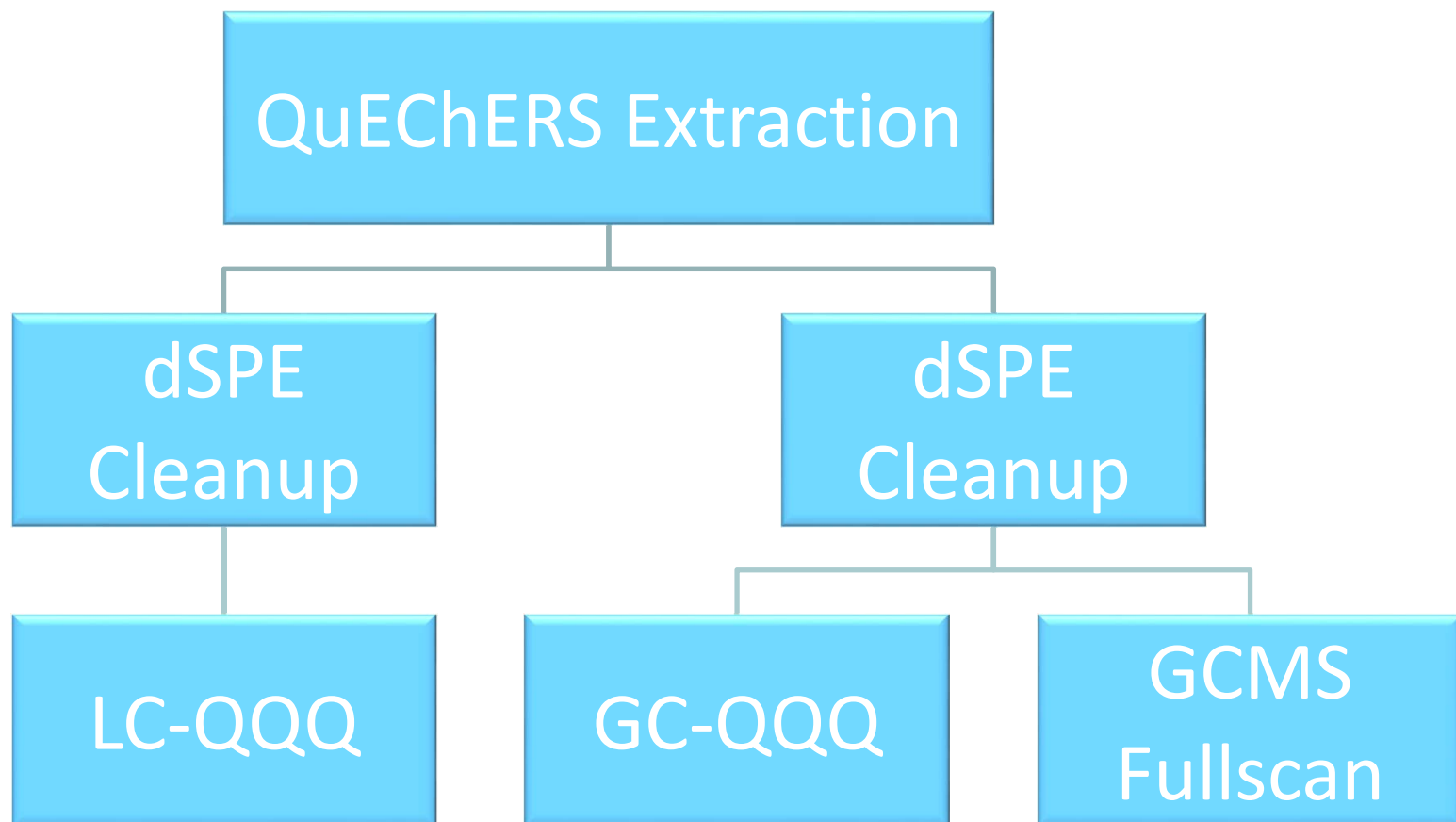




# Regulatory Monitoring

- 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)



# Violative Shipments

- **Illegal Residues**
  - Greater than the EPA tolerances
  - Pesticides with no EPA tolerances
- **Domestic – Invoke Sanctions**
  - Warning Letter, 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 during the same shipping season 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.



## Exports from the United States

- Must comply with U.S. standards while being grown here-some exceptions
- The responsibility of the grower to comply with destination country standards



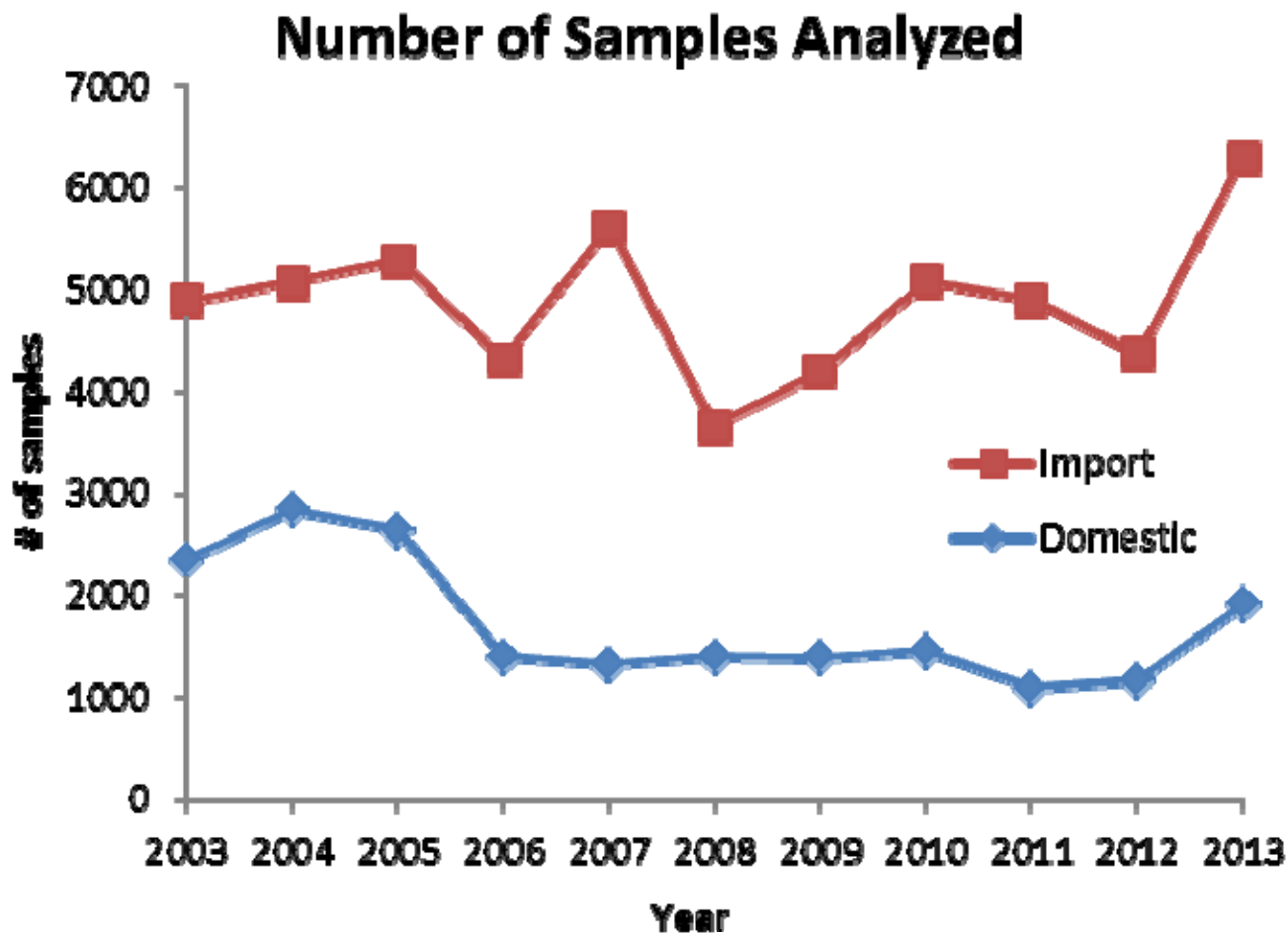




# Data from Regulatory Monitoring Program

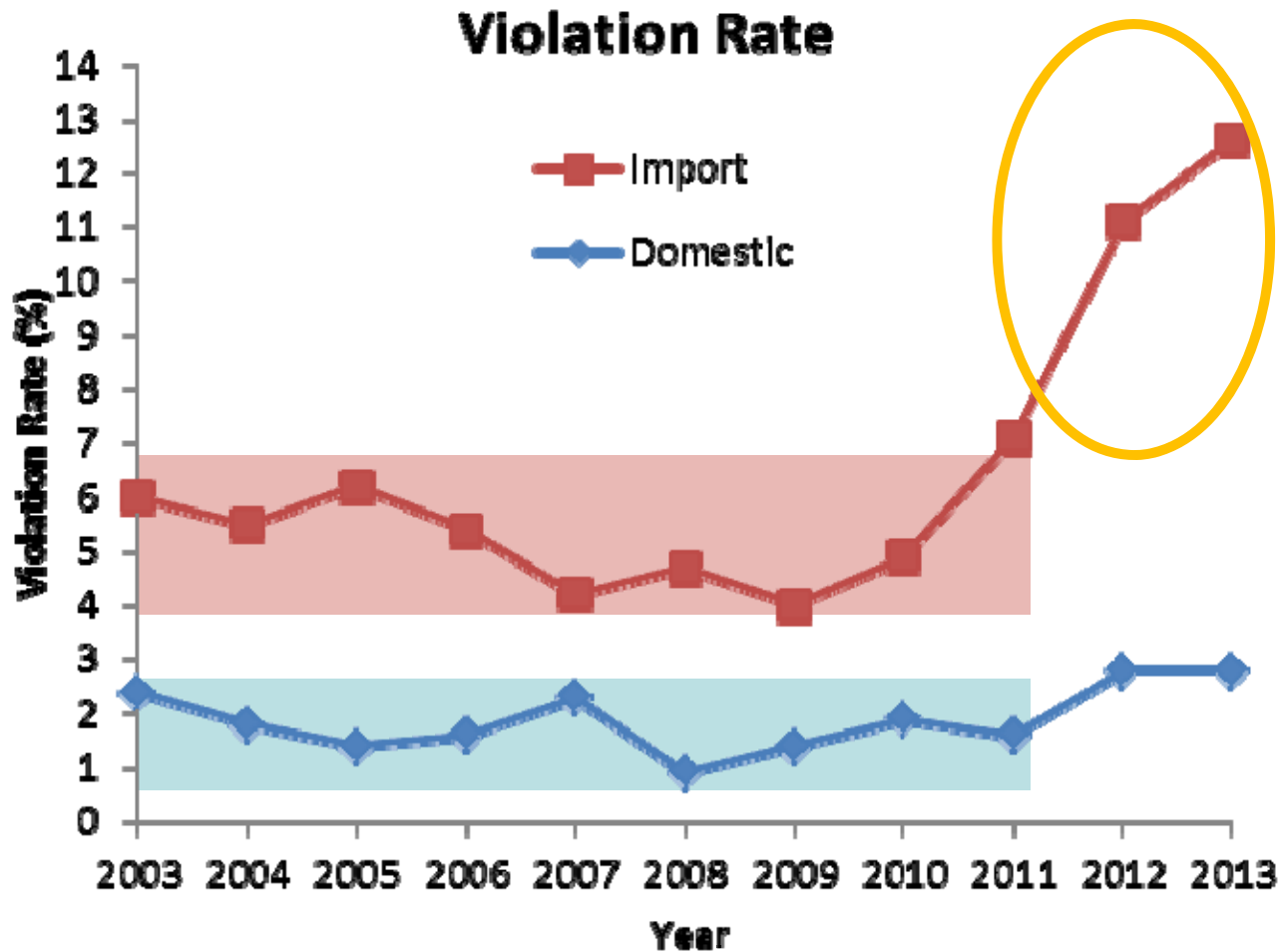


# Regulatory Monitoring





# Regulatory Monitoring





## Regulatory Monitoring

Year	# of Violative Residues	Violation Type (%)	
		No MRL	Exceeds MRL
2009	603	96.8	3.2
2010	686	94.5	5.5
2011	996	96.0	4.0
2012	1189	96.8	3.2
2013	1801	97.3	2.7



# Regulatory Monitoring

## Top violative import products (2013)\*\*

Product	Vio (%)
Capsicums, cayenne chili, hot peppers*	56.6
Rice, Basmati *	49.7
Rice, white*	24.2
Papaya*	21.8
Pepper, hot, dried/paste	21.2
Spinach, raw/dried/paste*	21.2

Product	Vio (%)
Serrano Pepper	20
Pepper, hot	14.2
Olive oil, crude	10.9
Husk Tomato	10.4
Mango	10.1



\*Commodity was on the FY 2012 table of import commodities warranting special attention.

\*\* commodities with > 50 samples analyzed





# Special Assignments

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



# Special Assignments

Assignment	Year	Spls	Vio%
EU (milk, eggs, honey)	2013	253	2
Tea (black, green, white)	2013	22	10
Dietary supplements	2013	183	35
Dietary supplements	2011	68	15
Orange juice	2012	184	17
Baby food	2012	27	0







# Total Diet Study (TDS)-Objectives:

- Monitor contaminants and nutrients in the food supply
- Estimate exposures:
  - Acceptable Daily Intakes (ADIs)
  - Provisional Tolerable Daily/Weekly/Monthly Intakes
  - Tolerable Upper Intake Levels (ULs)
- Assess contaminant/nutrient trends and risk



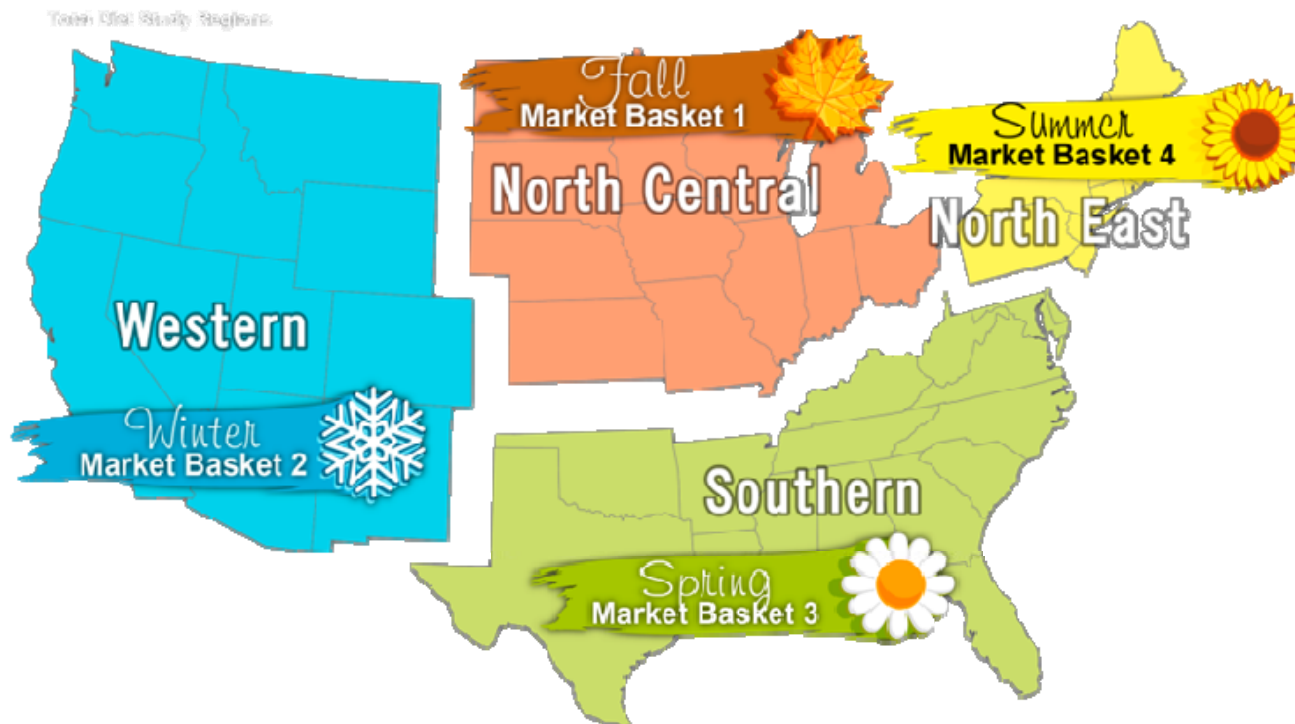


# Total Diet Study (TDS)

- **Analytes:**
  - **Pesticide Residues**
  - Industrial Chemicals (PCBs, Perchlorate)
  - Radionuclides
  - Toxic & Nutrient Elements
  - Volatile Organic Compounds
- **Serves as an early warning system:**
  - Has much greater sensitivity when compared to FDA's regulatory program (10-100 times more sensitive)
  - Capable of detecting many more pesticide residues

# TDS - Sample Collections

- 4 regional market baskets each year
- 280 foods collected in 3 cities per region
- Make “table-ready”, i.e. cook, peel, fry, etc.
- 3 samples per food are composited for analysis



# TDS – Estimate Dietary Intakes

- 6 – 11-month-old infants
- 2-year-old children
- 6-year-old children
- 10-year-old children
- 14 – 16-year-old females & males
- 25 – 30-year-old females & males
- 40 – 45-year-old females & males
- 60 – 65-year-old females & males
- 70+ -year-old females & males
- Total population





## TDS - Findings

### Residues Per Market Basket

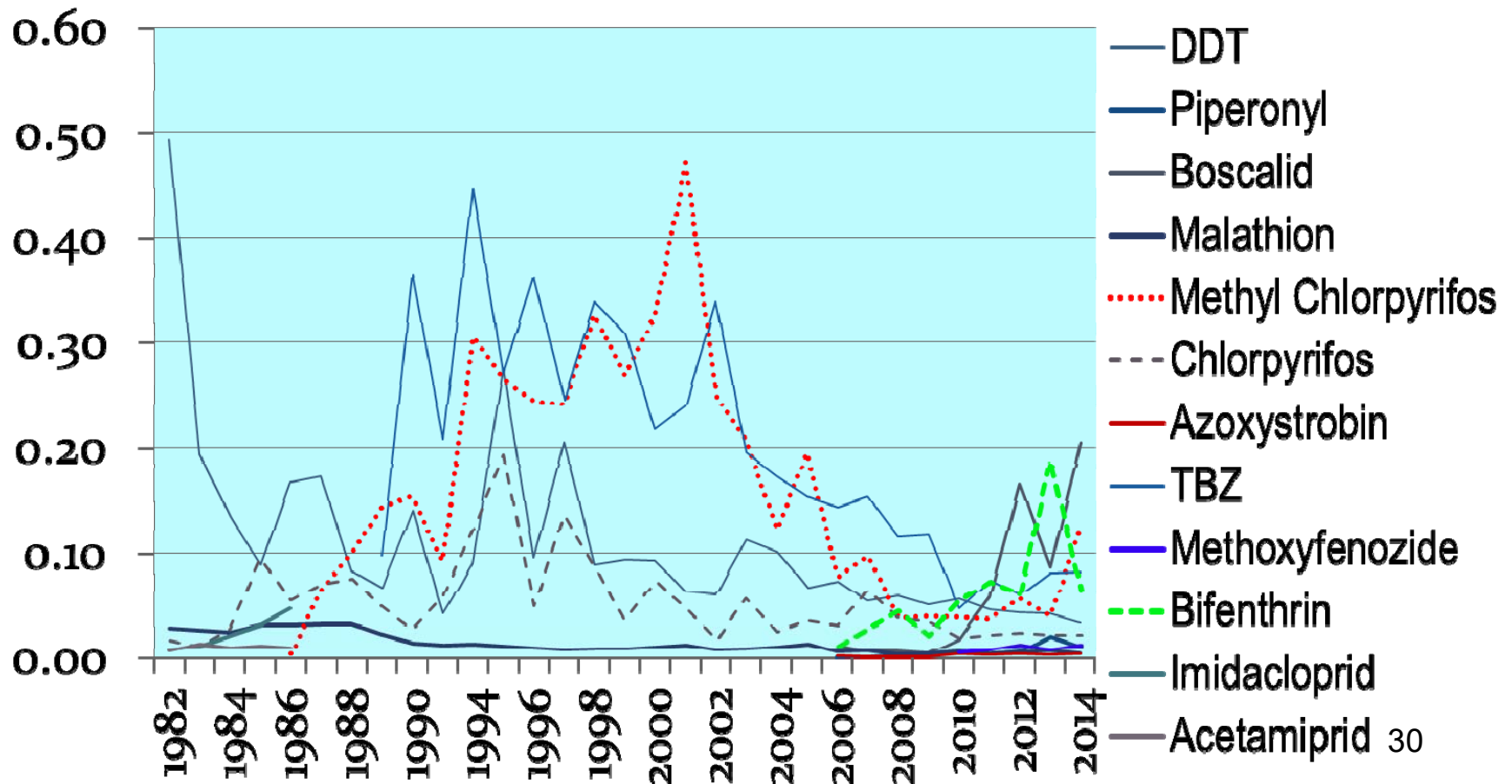
- ~2000 records
- 1200 - 1600 residues
- 80 % < 10 ppb
- 50 %  $\leq$  1 ppb





# TDS-Exposures

## % ADI of Most Frequently Found Pesticides





# Publications

- Annual Reports and Residue Monitoring Databases

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

- Glossary of Pesticide Chemicals

<http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm113891.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>



## **Regulatory Monitoring and Special Assignments:**

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## **Total Diet Study:**

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