



FDA Pesticide Monitoring Program

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Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

ACS Symposium:

Who Should Regulate Pesticides in Our Food?

August 25th, 2016



U.S. Food and Drug Administration

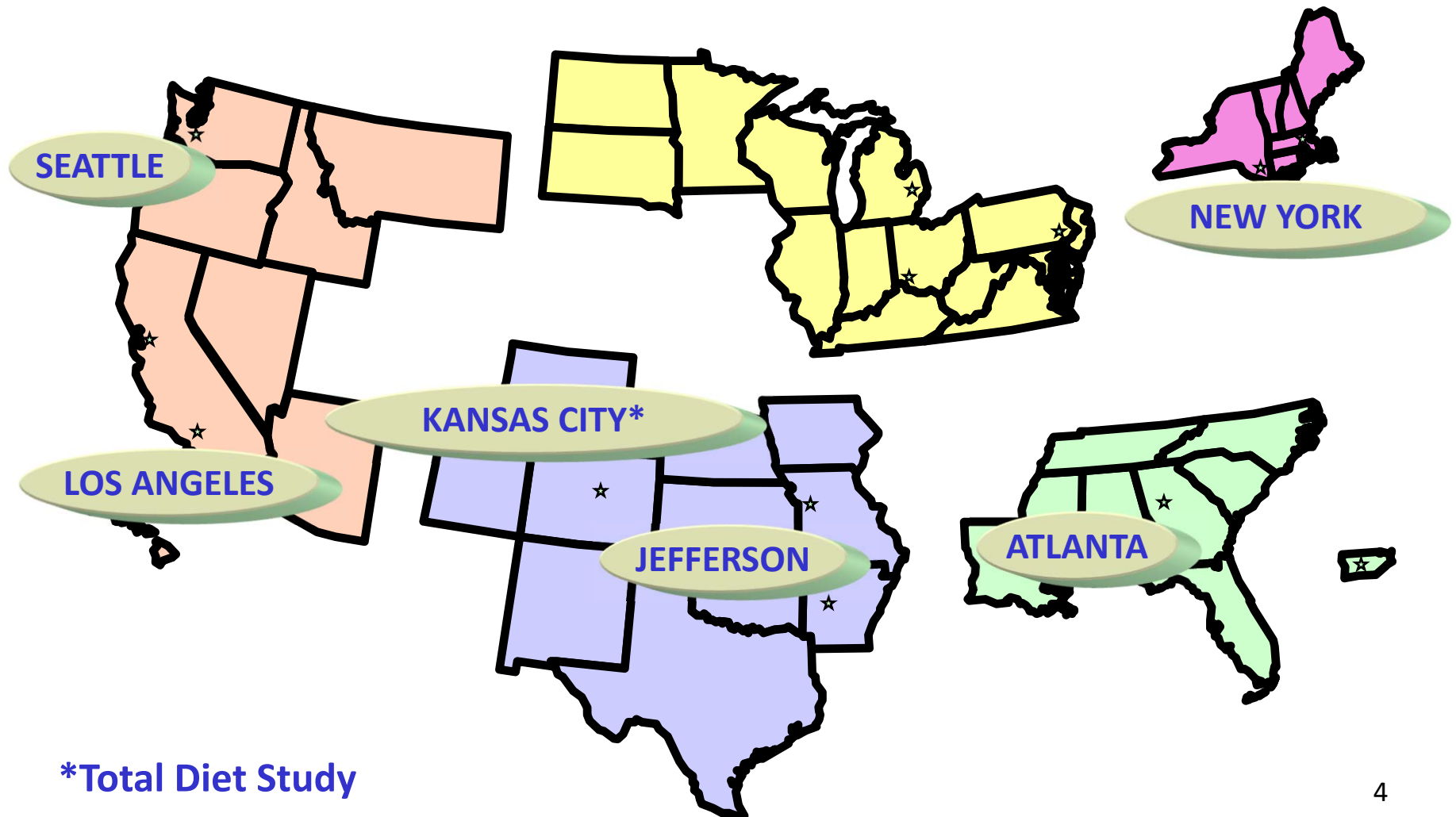
- Many responsibilities
 - Food
 - Drugs (prescription and over-the-counter)
 - Veterinary Products (animal drugs and feed)
 - Biologics (vaccine, blood, tissue)
 - Devices (medical, electronic products that give off radiation)
 - Tobacco
 - Cosmetics



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

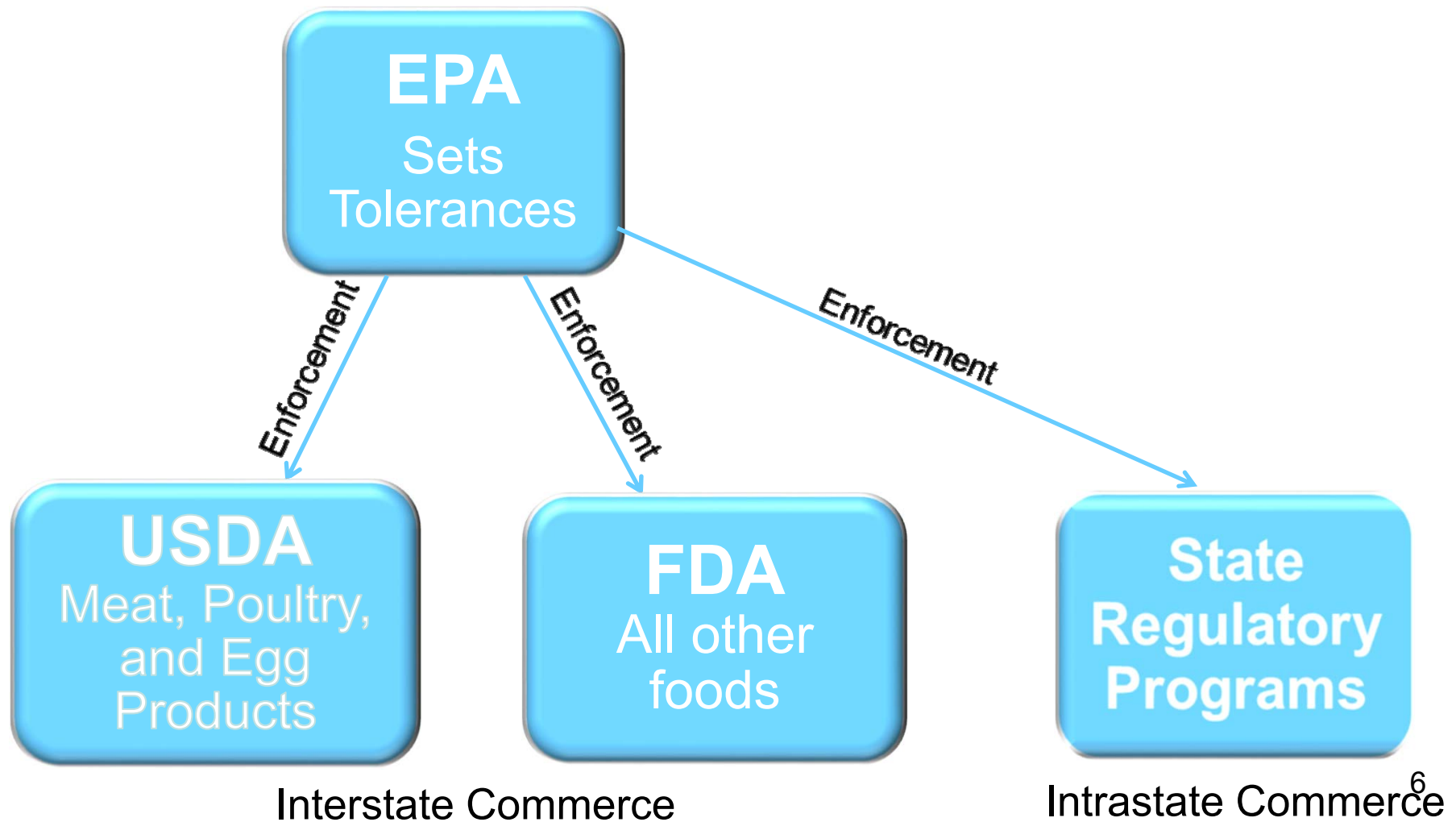


Pesticide Laws

- 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

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

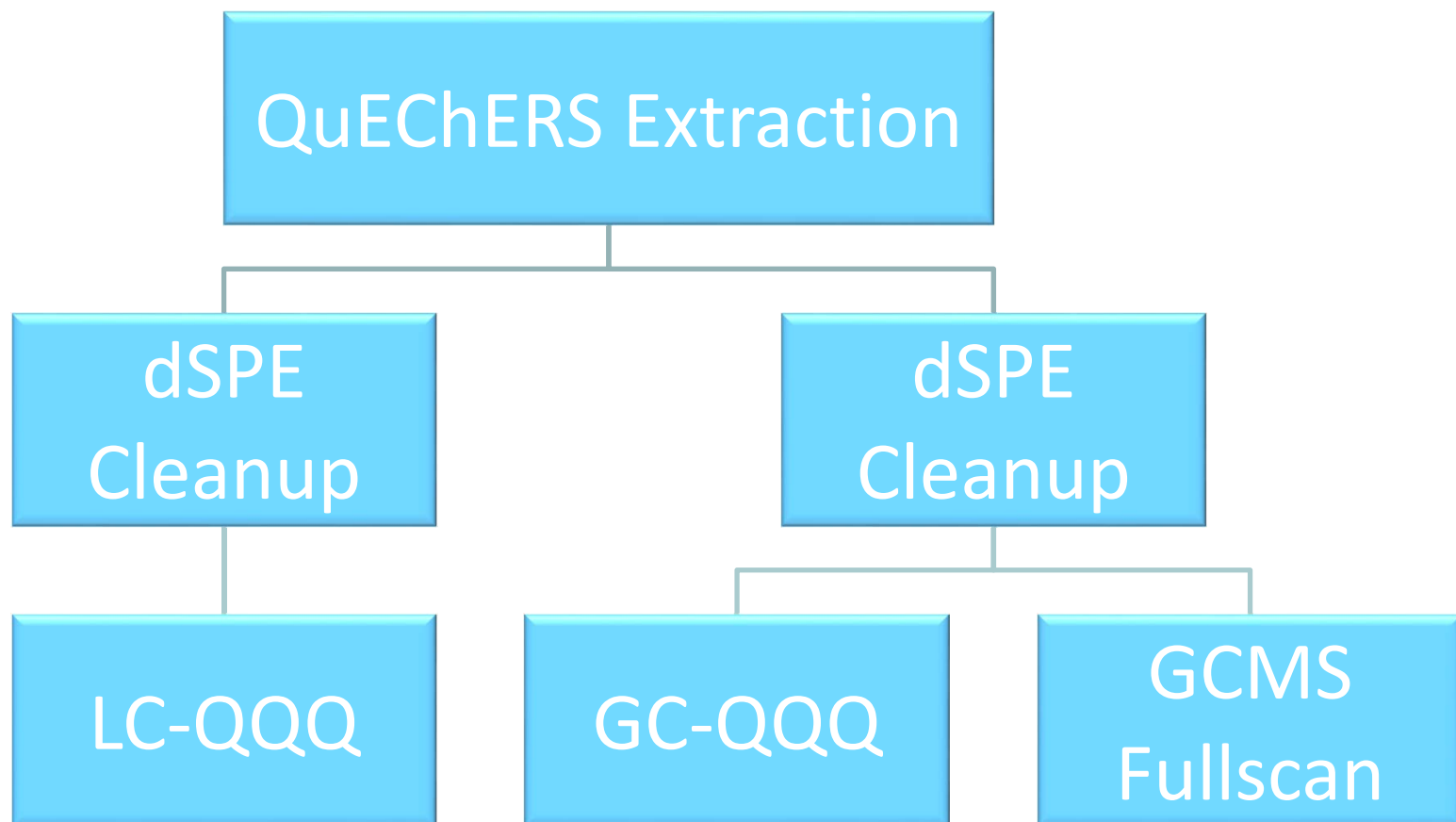




Regulatory Monitoring

- 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

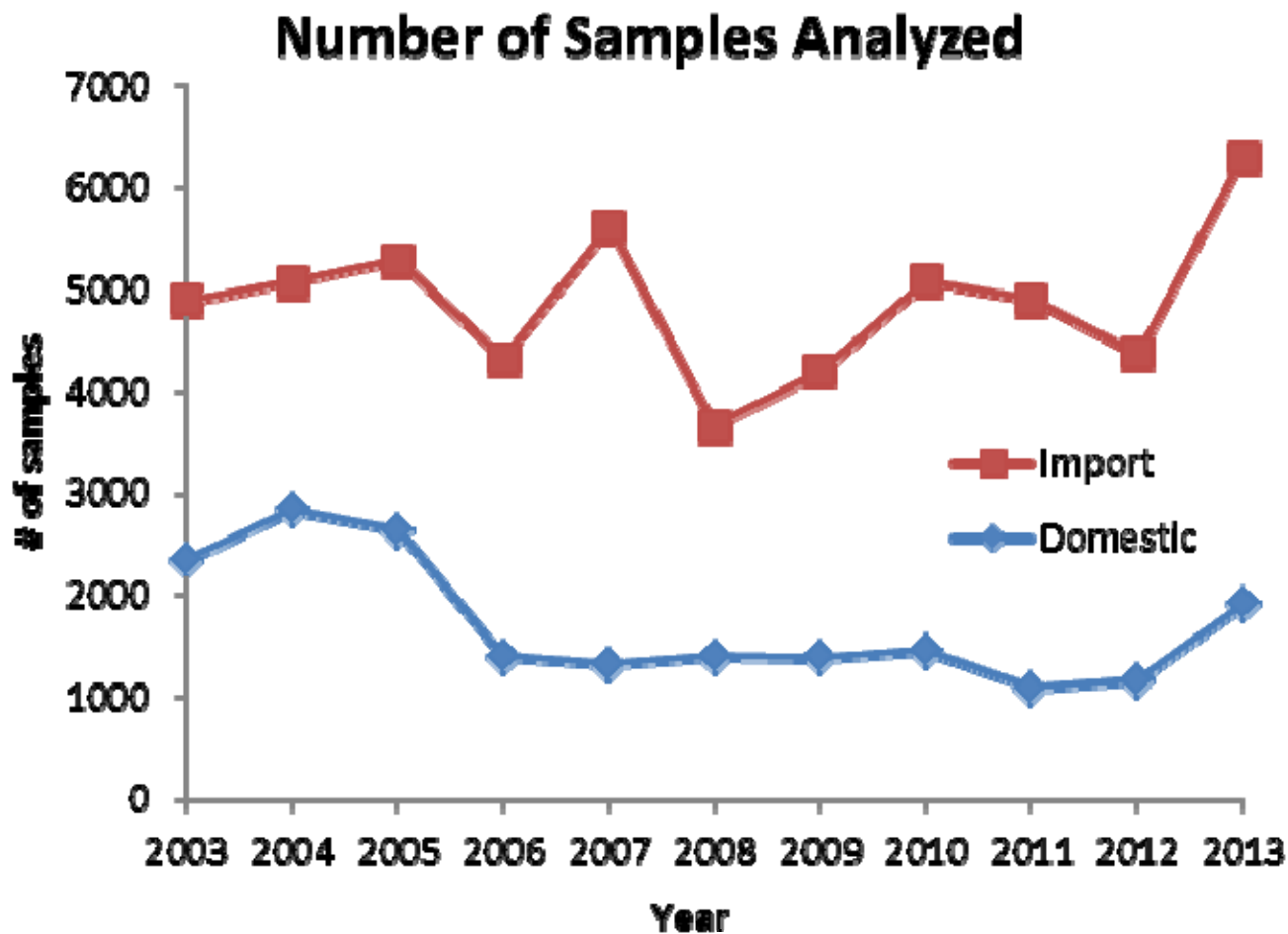




Data from Regulatory Monitoring Program

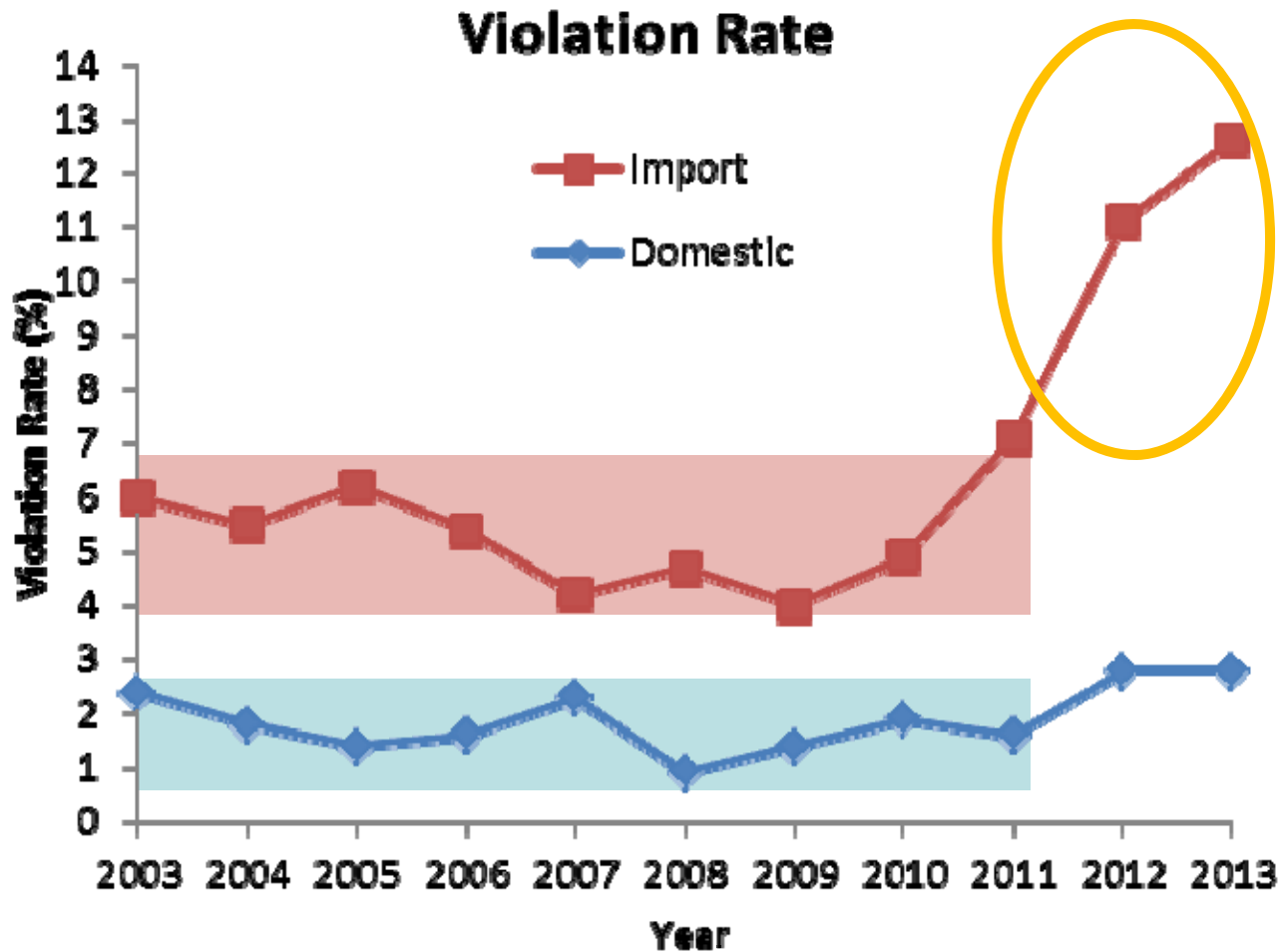


Regulatory Monitoring





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)





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



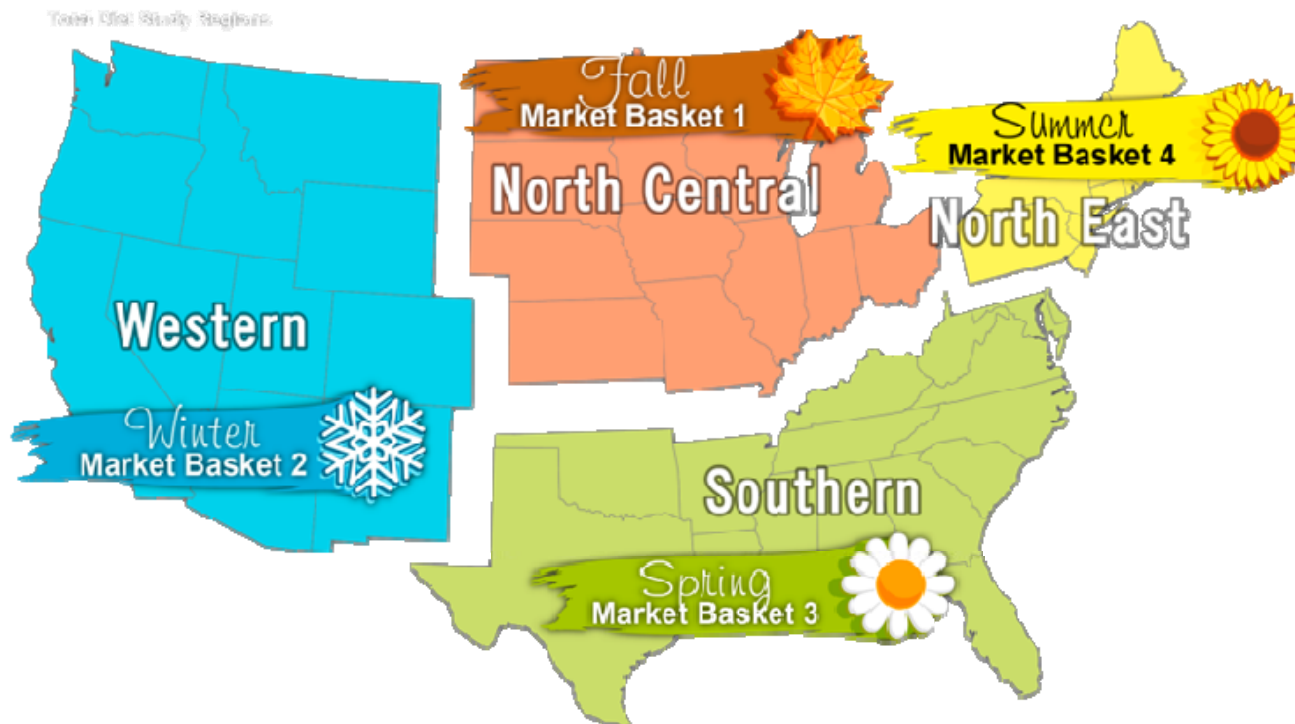


Total Diet Study (TDS)

- **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

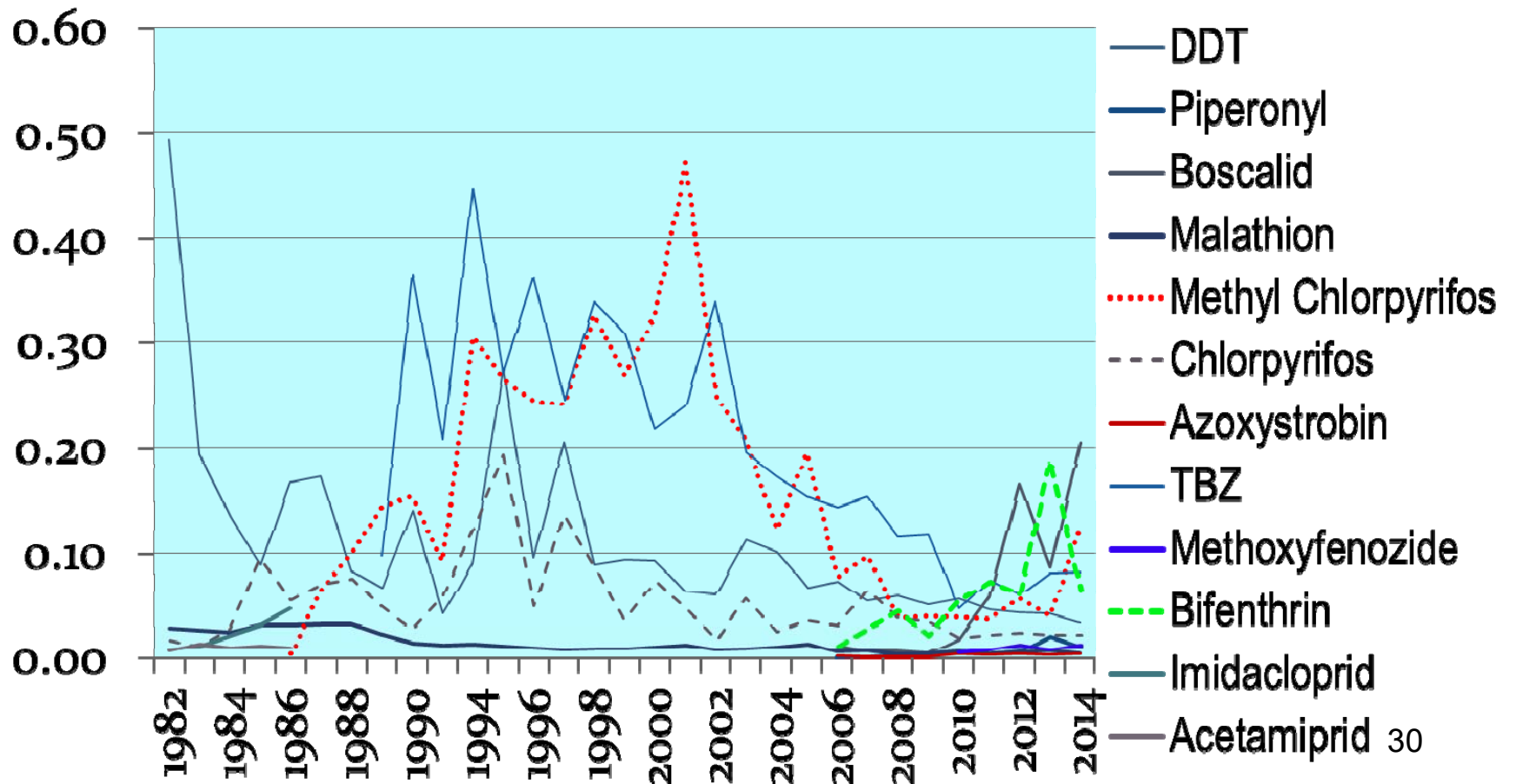
- ~2000 records
- 1200 - 1600 residues
- 80 % < 10 ppb
- 50 % \leq 1 ppb





TDS-Exposures

% ADI of Most Frequently Found Pesticides





Publications

- Annual Reports and Residue Monitoring Databases

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

- Glossary of Pesticide Chemicals

<http://www.fda.gov/Food/FoodbornellnessContaminants/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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