



FDA's Pesticide Program

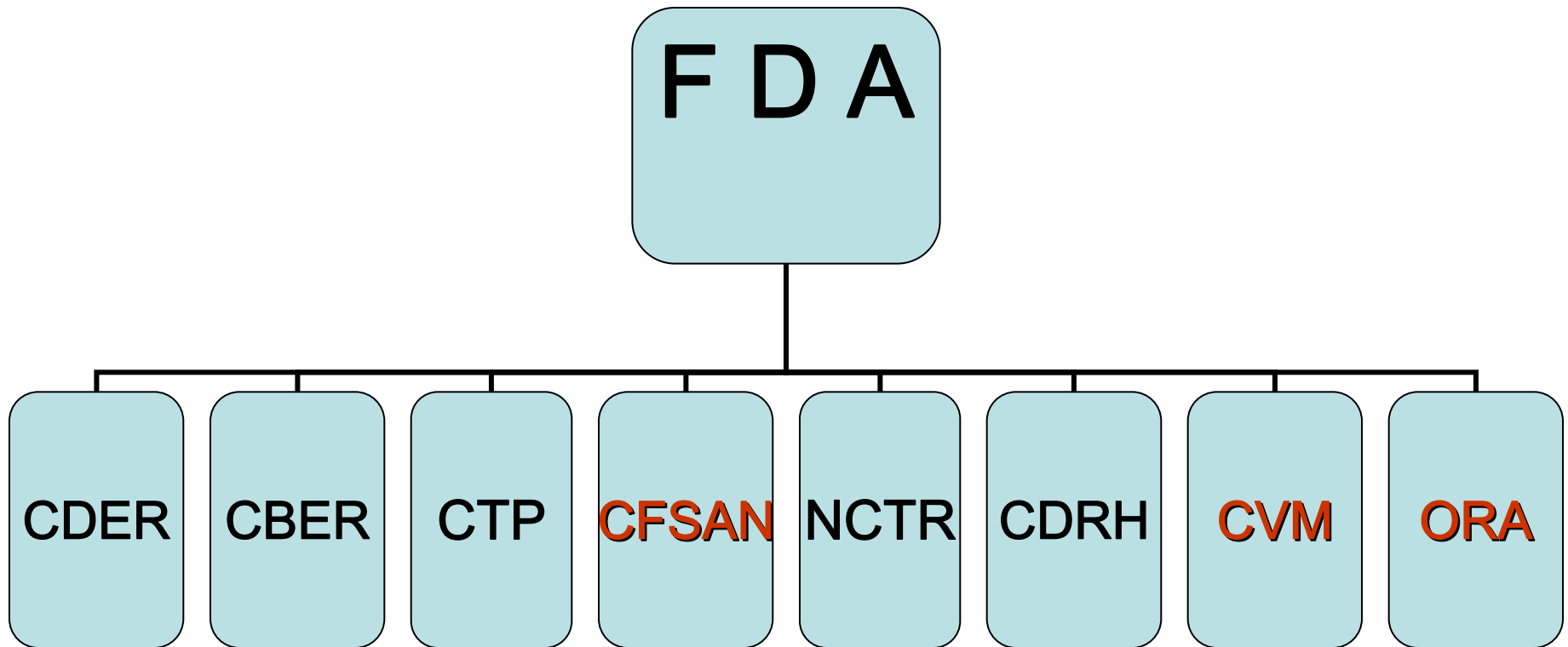
Young H. Lee, Ph.D.
Office of Food Safety
FDA/CFSAN

Regulation of Pesticides

- **EPA:** FIFRA - Registers Use of Pesticides
FFDCA - Establishes tolerances
- **FDA:** FFDCA - Compliance with Tolerance
(Foods & Feeds)
- **USDA:** FFDCA - Compliance with Tolerance
(Meat & Poultry)



FDA Organization





OFFICE OF REGULATORY AFFAIRS







PACIFIC

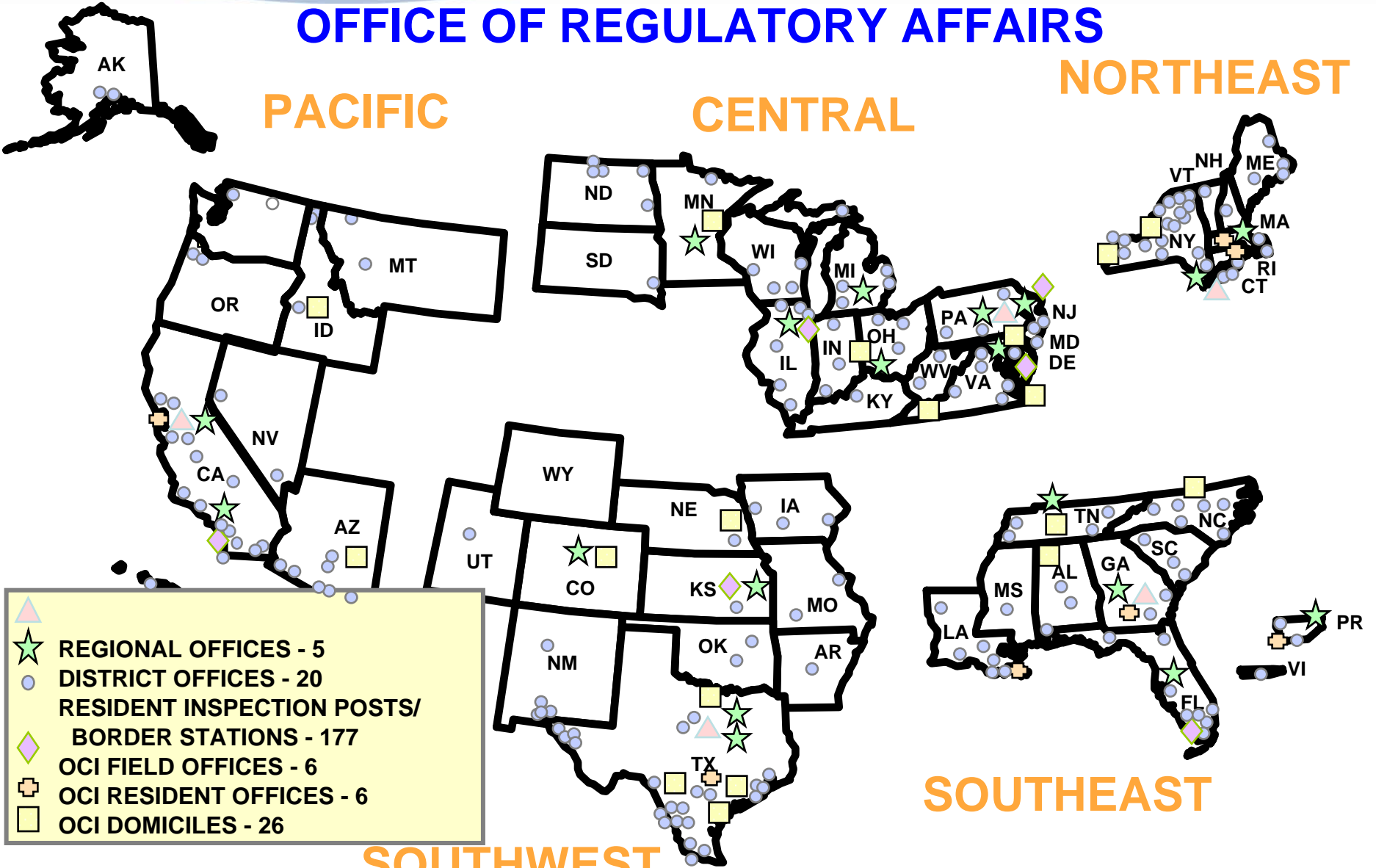
CENTRAL

NORTHEAST

SOUTHWEST

SOUTHEAST

-  REGIONAL OFFICES - 5
-  DISTRICT OFFICES - 20
-  RESIDENT INSPECTION POSTS/
BORDER STATIONS - 177
-  OCI FIELD OFFICES - 6
-  OCI RESIDENT OFFICES - 6
-  OCI DOMICILES - 26





FDA Residue Monitoring Program

- **Regulatory Monitoring: Enforce Tolerances**
- **Incidence/Level Monitoring
Specific Commodity/Pesticide**
- **Total Diet Study (Market Basket Survey)
Estimate Dietary Exposure**

Regulatory Monitoring Program

- **Domestic** – close to the point of production
- **Import** – point of entry
- **Emphasis**
 - Raw agricultural commodities
 - Foods consumed by infants & children
- ~ 450 pesticide chemicals

FDA Regulatory Monitoring Program - Violative Shipments

- **Illegal Residues**
 - > EPA Tolerances
 - No EPA Tolerances
- **Domestic – Invoke Sanctions**
seizure, injunction
- **Import – Refuse admission**
DWPE



DWPE - Imports

(Automatic Detention) Sec 801 of the FFDCA

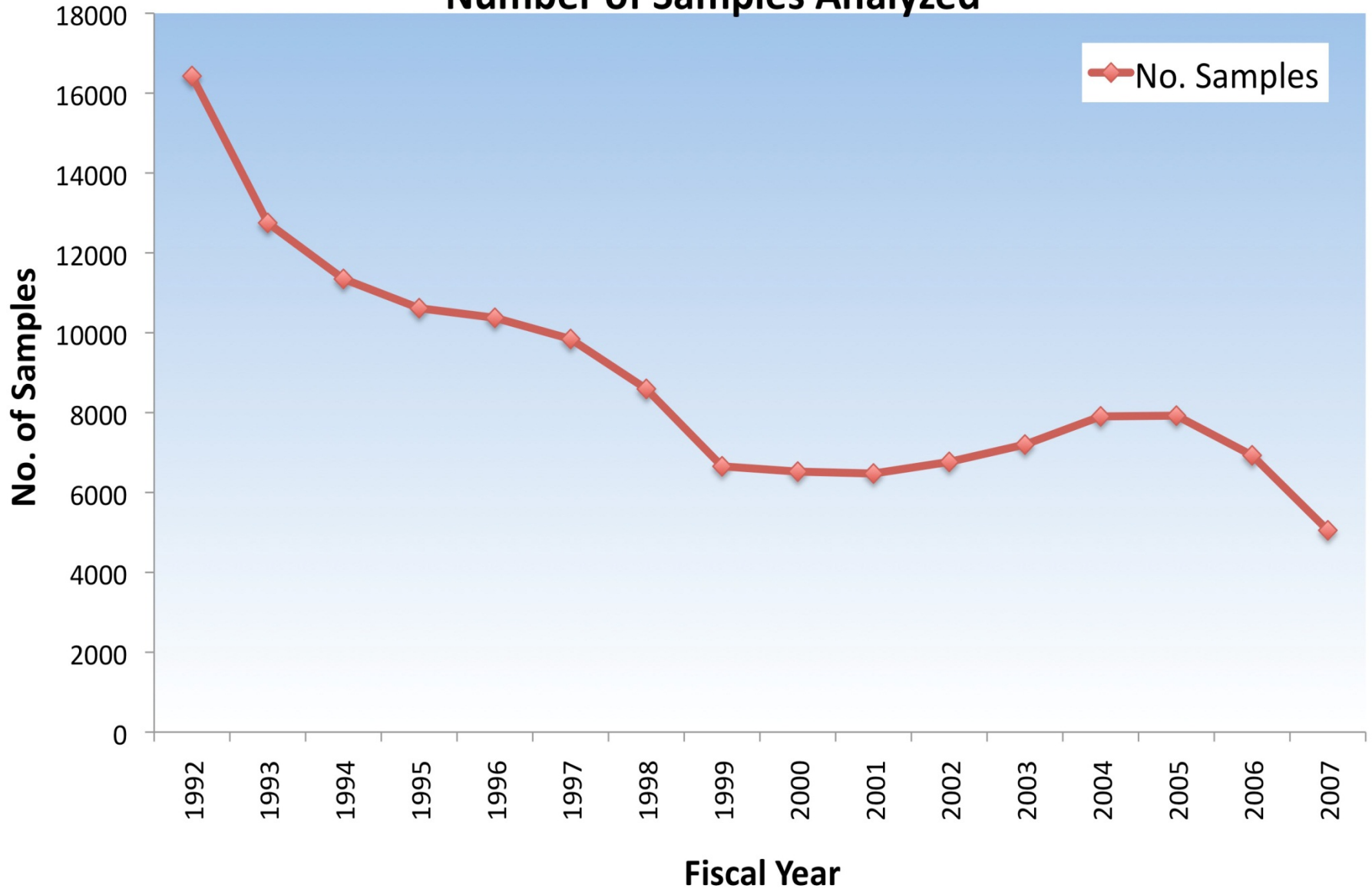
The recommendation may be based on the finding of ONE violative shipment if there is reason to believe that the same situation will exist in future lots during the same shipping season for a specific shipper, grower, geographic area, or country.

FDA Regulatory Monitoring Program Factors in planning samples

- **Review of residue data**
- **Pesticide use**
- **Dietary importance of food**
- **Foods consumed by infants & children**
- **Volume in commerce**
- **Toxicity & characteristics of pesticides**

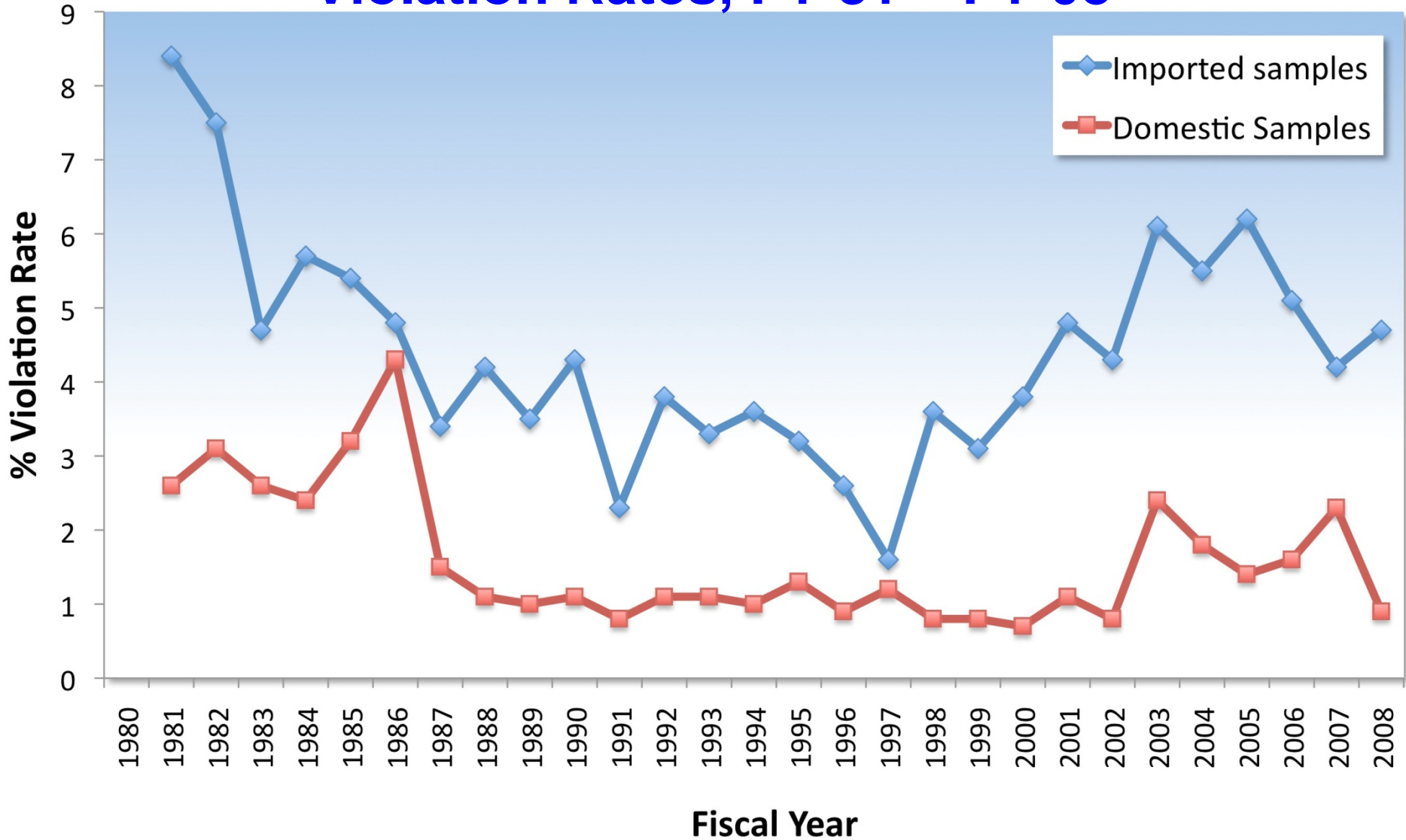


Number of Samples Analyzed





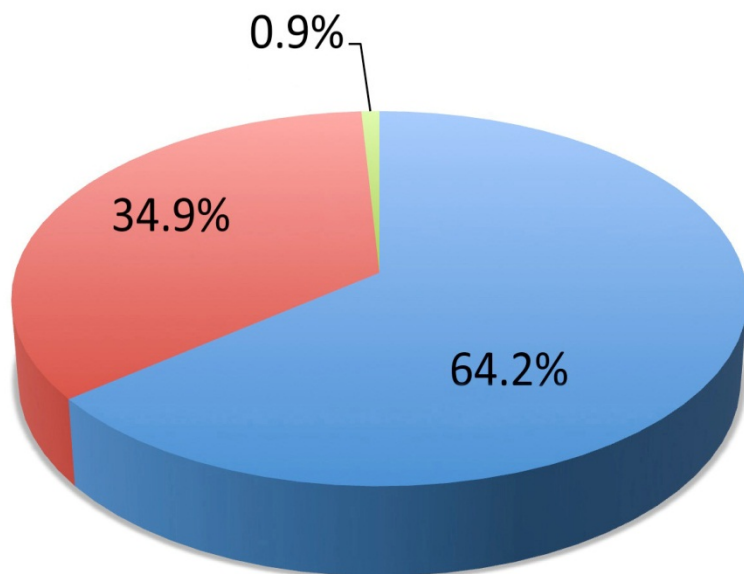
Violation Rates, FY 81 – FY 08



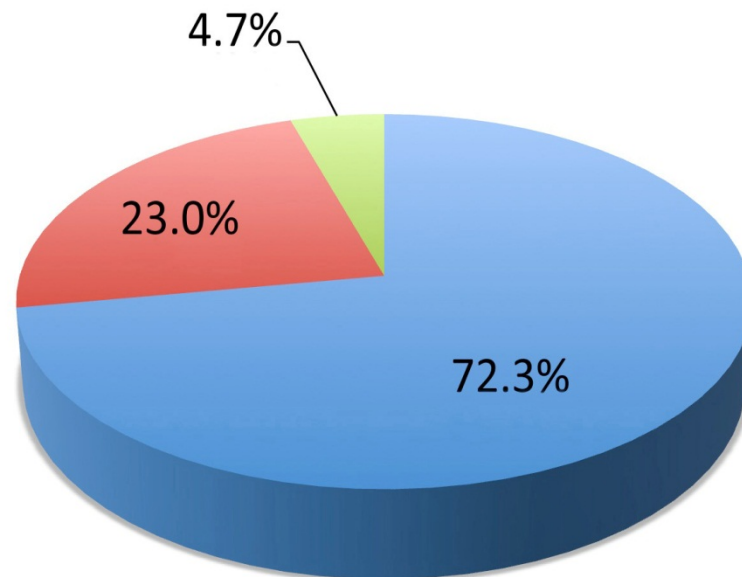
Summary of Results

Domestic vs. Import - FY 08

Domestic
1398 Samples



Import
3655 Samples



■ Spls w No Residues

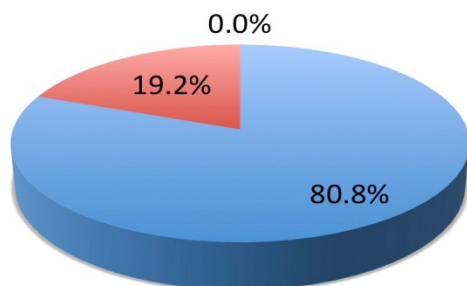
■ Spls w Residue(s); No Violation

■ Spls Violative

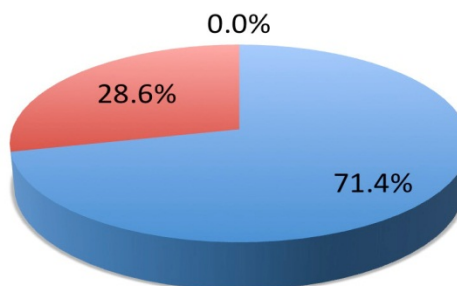


Results of Domestic Samples by Commodity Group – FY 08

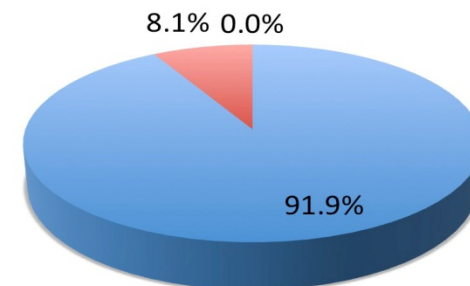
Grains & Grain Products



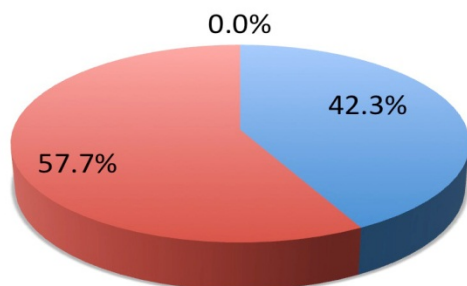
Milk/Dairy/Eggs



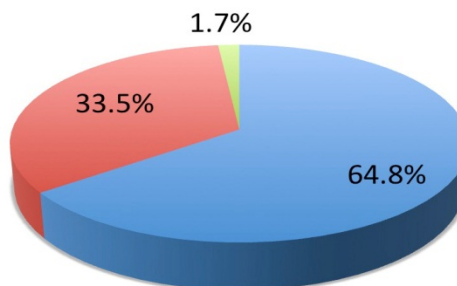
Fish/Shellfish



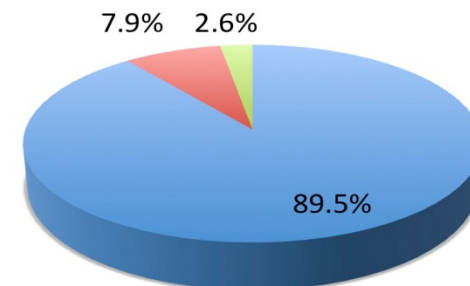
Fruit



Vegetables



Other



■ Spls w No Residues

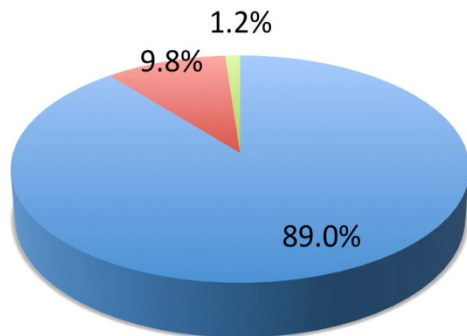
■ Spls w Residue(s); No Violation

■ Spls Violative

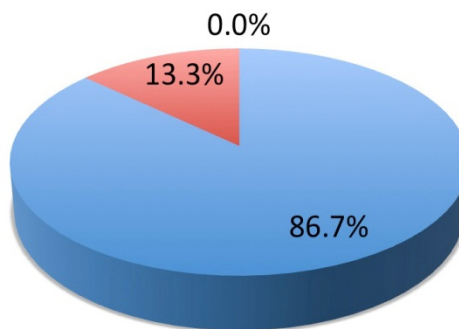


Results of Imported Samples by Commodity Group – FY 08

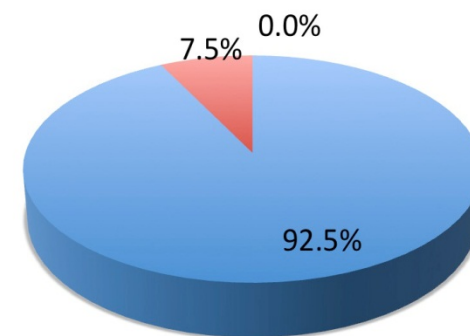
Grains & Grain Products



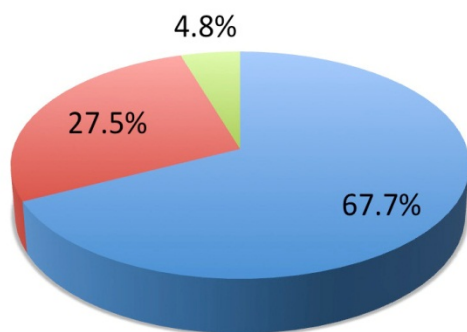
Milk/Dairy/Eggs



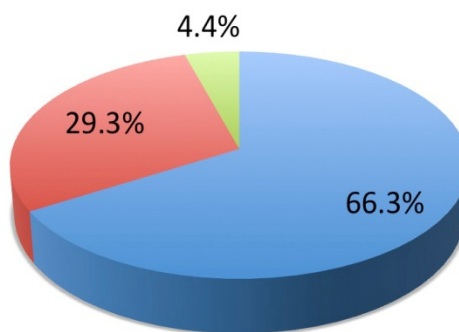
Fish/Shellfish



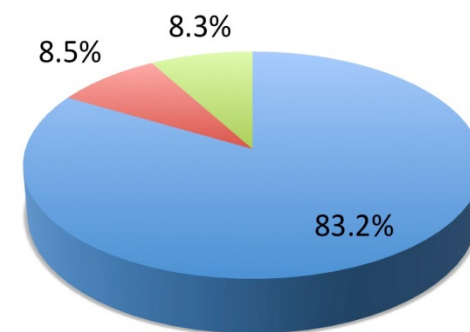
Fruit



Vegetables



Other



■ Spls w No Residues

■ Spls w Residue(s); No Violation

■ Spls Violative



Import Alerts of Pesticide Violations

<http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm>

View Import Alerts by

- **Option 1: Introduction**
- **Option 2: Country**
- **Option 3: Industry**
- **Option 4: Import alerts by number**

Import Alerts for Pesticide Residues

- **# 99-05: DWPE of RAC**
- **# 99-08: DWPE of Processed Foods**
- **# 99-14: Countrywide DWPE of RAC**
- **# 99-15: Countrywide DWPE of Processed Foods**



Incidence/Level Monitoring Program

- **In-depth coverage**
- **Specific commodity or group**
- **Raw or processed**



Incidence/Level Monitoring Program

- **Aquaculture Survey, FY 90 - 94**
- **Milk Survey, FY 90 - 93**
- **US Manufactured Pesticides (Circle of Poisons), FY 94**
- **Foods Eaten by Infants & Children, FY 94 -**
- **Statistically Based Surveys, FY 92 - 95**
- **Triazine Herbicides, FY 95**
- **Wheat Imported from Canada, FY 99**
- **Forchlorfenuron on Mexican Grapes, FY 99**
- **Canola – Dom & Imp from Canada, FY 00**
- **Dietary supplements, FY 02 - present**



Statistically Based Surveys FY 92 - 95

Objective

To determine how violation rates, frequency of occurrence of residues, residue levels obtained differ from those obtained through FDA's traditional surveillance approach.

Statistically Based Surveys FY 92 - 95

- **4 commodities:**
 - Tomatoes, pears, apples, rice
 - Widely consumed year round
 - Have a significant domestic & import component
- **Cost: ~ \$ 1 mil / commodity**



Statistically Based Surveys FY 92 - 95

Conclusion:

- **Corroborate the low levels of pesticide residues found in FDA's regulatory monitoring.**
- **Demonstrate that FDA's regulatory monitoring provides a reasonably reliable estimate of pesticide residues in the U.S. food supply.**



Total Diet Study Objectives

- **To determine levels**
- **To estimate dietary intakes**
- **To identify trends and changes in the levels**

Total Diet Study Revised 2003

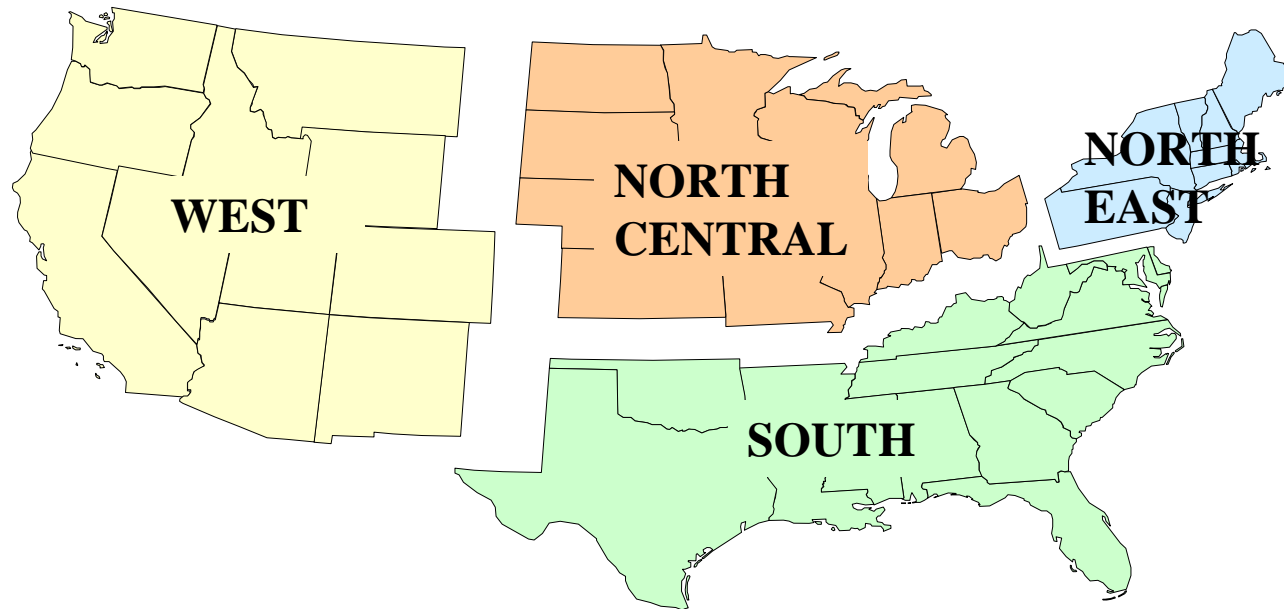
- **USDA's Nat'l Food Consumption Surveys**
>3,500 Foods Identified
- **280 Foods Selected**
- **Analysis of individual foods as eaten**
- **Modified analytical methods**
(1 – 2 ppb range for many)

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**

TDS - Sample Collections

- 4 regional market baskets each year
- 280 foods collected in 3 cities per region
- 3 samples per food are composited for analysis



TDS - Analytes

- **Pesticide residues**
- **Industrial chemicals (PCBs, Perchlorate)**
- **Radionuclides**
- **Toxic elements**
- **Nutrient elements**
- **Dioxin (1999 -); acrylamide (2003-06); furan (2004 -)**

Total Diet Study Summary of Findings

- **~ 300 Pesticide chemicals**
- **~ 100 chemicals found**
- **Estimated Intakes**
 - < FAO/WHO's ADIs**
- **Rarely exceed 1% of ADIs**



Channels of Trade Provision FFDCA

- **How long residues of a pesticide are expected to remain in various foods**
- **How long fresh/processed foods may remain in channels of trade**
- **Whether the presence of the residue is a result of lawful application of a pesticide**



CFSAN – Pesticide Program

<http://www.fda.gov>

- **Annual reports**
- **Residue monitoring databases**
- **Glossary of pesticide chemicals**
- **Pesticide analytical manuals**
- **Total Diet Study Data**



Questions?

Outreach and Information Center

1 - 888 - SAFEFOOD

1 - 888 - 723 - 3366

Consumers: consumer@fda.gov

Industry: industry@fda.gov

Center for Food Safety and Applied Nutrition

Food and Drug Administration

5100 Paint Branch Parkway

College Park, MD 20740