FDA Pesticide Monitoring Program

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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

EPA
Sets Tolerances

USDA
Meat, Poultry, and Egg Products

FDA
All other foods

State Regulatory Programs

Interstate Commerce

Intrastate Commerce
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)

QuEChERS Extraction

- dSPE Cleanup
  - LC-QQQ
  - GC-QQQ
  - GCMS Fullscan
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)

FDA Compliance Policy Guide 575.100 “Pesticide Residues in Food and Feed Enforcement Criteria”
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

Number of Samples Analyzed

- Import
- Domestic

Year

http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm2006797.htm
Regulatory Monitoring

Violation Rate

- Import
- Domestic

Year


Violation Rate (%)

http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm2006797.htm
### Regulatory Monitoring

<table>
<thead>
<tr>
<th>Year</th>
<th># of Violative Residues</th>
<th>Violation Type (%)</th>
<th>No MRL</th>
<th>Exceeds MRL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>603</td>
<td>96.8</td>
<td>3.2</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>686</td>
<td>94.5</td>
<td>5.5</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>996</td>
<td>96.0</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>1189</td>
<td>96.8</td>
<td>3.2</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>1801</td>
<td>97.3</td>
<td>2.7</td>
<td></td>
</tr>
</tbody>
</table>
## Regulatory Monitoring

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Vio (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsicums, cayenne chili, hot peppers*</td>
<td>56.6</td>
</tr>
<tr>
<td>Rice, Basmati *</td>
<td>49.7</td>
</tr>
<tr>
<td>Rice, white*</td>
<td>24.2</td>
</tr>
<tr>
<td>Papaya*</td>
<td>21.8</td>
</tr>
<tr>
<td>Pepper, hot, dried/paste</td>
<td>21.2</td>
</tr>
<tr>
<td>Spinach, raw/dried/paste*</td>
<td>21.2</td>
</tr>
<tr>
<td>Serrano Pepper</td>
<td>20</td>
</tr>
<tr>
<td>Pepper, hot</td>
<td>14.2</td>
</tr>
<tr>
<td>Olive oil, crude</td>
<td>10.9</td>
</tr>
<tr>
<td>Husk Tomato</td>
<td>10.4</td>
</tr>
<tr>
<td>Mango</td>
<td>10.1</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Assignment</th>
<th>Year</th>
<th>Spls</th>
<th>Vio%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU (milk, eggs, honey)</td>
<td>2013</td>
<td>253</td>
<td>2</td>
</tr>
<tr>
<td>Tea (black, green, white)</td>
<td>2013</td>
<td>22</td>
<td>10</td>
</tr>
<tr>
<td>Dietary supplements</td>
<td>2013</td>
<td>183</td>
<td>35</td>
</tr>
<tr>
<td>Dietary supplements</td>
<td>2011</td>
<td>68</td>
<td>15</td>
</tr>
<tr>
<td>Orange juice</td>
<td>2012</td>
<td>184</td>
<td>17</td>
</tr>
<tr>
<td>Baby food</td>
<td>2012</td>
<td>27</td>
<td>0</td>
</tr>
</tbody>
</table>
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 % ≤ 1 ppb

http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/default.htm
TDS-Exposures

% ADI of Most Frequently Found Pesticides

- DDT
- Piperonyl
- Boscalid
- Malathion
- Methyl Chlorpyrifos
- Chlorpyrifos
- Azoxystrobin
- TBZ
- Methoxyfenozide
- Bifenthrin
- Imidacloprid
- Acetamiprid
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
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