FDA Large Scale Produce Assignment – Improving Risk Assessments

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Background of the Assignment

• The Food Safety Modernization Act (FSMA) outlines a new approach to food safety that is risk-informed and preventive in focus

• Not just traditional surveillance and compliance-based, but also a mechanism to actively identify risks and – when possible – identify areas where preventive controls can be put into place to better protect public health

• More effectively allocate resources to address public health risks through compliance sampling, targeted sampling or other risk mitigation strategies.
What Products?

- CFSAN working group was established to perform a five year review of microbiological sampling data.
- Development of a new analytical tool which calculated risk scores of each commodity collected and analyzed over the past five years based on the risk criteria
- Based on the ranking results from the analytical tool, the following commodities were selected for FY 2014: sprouts (seeds, spent irrigation water, and finished product), raw milk cheese (aged 60 days), and avocados (whole pit fruit and pulp)
FDA ranked foods based on a variety of criteria and identify three foods to serve as surveillance sampling pilot programs.

- Food consistently causing illnesses or linked to outbreaks
- High consumption level; and/or consumed by a high risk population
- Ready-to-eat (RTE) food
- Ingredient in ready-to-eat (RTE) products
- Food regularly comes in contact with contaminated sources (water, soil, or equipment) during growing, harvesting, processing, or at retail
- Food is intended to be cooked by consumer
- Processed or manufactured in a manner without a "kill step"
Avocado Associated Risk

- FDA’s limited sampling of avocado (429 avocado samples collected from 2001-2013) indicates the potential for a high incidence of contamination in this commodity (18% violative).
- Avocado products have been associated with six (6) recalls due to the presence of foodborne pathogens from 2004-2011: *Salmonella* in fresh avocado (n=1) and *L. monocytogenes* in frozen/processed products (n=5)
- CDC reported the rise of guacamole and salsa as common vehicles in foodborne outbreaks
Avocado Assignment Overview

“Over the course of 12 months, during Fiscal Years 2014-2015, 1,600 whole avocado samples will be collected of which 480 will be Domestic whole avocado samples and 1,120 will be imported whole avocado samples.”

-FY 14 and FY 15 CFSAN Surveillance Sampling Program Pilot
Objectives for Avocado Assignment

• To explore new processes and parameters for sample collections and analysis that will enhance our current system - usage of the FERN labs

• To determine the prevalence of selected microbiological hazards (*Salmonella*) in whole pit fresh avocados and *L. monocytogenes* in avocado pulp

• To determine if *Salmonella* or *L. monocytogenes* is present on avocado skin, and/or in the avocado fruit

• To determine if there are common factors among positive findings (region, country of origin, variety, seasonality, domestic vs. import, growing/harvesting practices etc.)
Avocado Assignment Preparation

• FERN MCAP began preparing for this assignment in November, 2013
• Weekly Conference calls to discuss logistics/methods
• Worksheet/Flowchart workgroups
• Reagents/supplies preparation
• Method validation – NMSU, VA, MN, NC and MI
• Set up servicing table based on laboratory capacity
• Assignment issued on May 7th 2014
• First sample arrived to the duty labs on May 14th
• **ORS Avocado Team responsible for overall coordination of FERN labs**
Assignment Preparation - 2014 MCAP Face-to-Face Meeting

• Addressed almost all aspects of the assignment
  – Worksheets
  – Data package
  – Method/Protocol
  – Preparation of the new method for pulp analysis
  – Data reporting procedures
When Sample is Confirmed Positive

Isolate is sent for:

- **Serology**
  - *Salmonella* - State CAP FERN Labs
- **Subtyping**
  - Pulsed Field Gel Electrophoresis (PFGE)
  - *Salmonella* - State CAP FERN Labs
  - *L. monocytogenes* – FL Ag lab
  - Whole Genome Sequencing
  - State CAP FERN Labs or FDA labs
Reporting

• eLEXNET project folder housing all documents related to the assignment

• Data reporting:
  – FERN website – activation module
  – Emails
  – FDA FACTS data entry by ORS team
    • Weekly trackers
  – Communication from ORS to CFSAN and District Offices (both import and domestics)
## Sample Collection Overview

<table>
<thead>
<tr>
<th>Source of Sample</th>
<th>Samples Collected No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic Samples</td>
<td>478 (29.6%)</td>
</tr>
<tr>
<td>Import Samples</td>
<td>360 (22.3%)</td>
</tr>
<tr>
<td>Domestic-Import Samples</td>
<td>777 (48.1%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Point of Sample Collection</th>
<th>Samples Collected No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distributor/Warehouse</td>
<td>198 (12.3%)</td>
</tr>
<tr>
<td>Grower</td>
<td>30 (1.9%)</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>3 (0.2%)</td>
</tr>
<tr>
<td>Packinghouse</td>
<td>28 (1.7%)</td>
</tr>
<tr>
<td>Retail</td>
<td>219 (13.6%)</td>
</tr>
<tr>
<td>Domestic-Import</td>
<td>777 (48.1%)</td>
</tr>
<tr>
<td>Import</td>
<td>360 (22.3%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variety</th>
<th>Samples Collected No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hass</td>
<td>1120 (69.3%)</td>
</tr>
<tr>
<td>Green Skin</td>
<td>495 (30.7%)</td>
</tr>
</tbody>
</table>

| Total Samples Collected        | 1615 (100%)               |
Total 1,615 avocado samples were collected (20 subs per sample)

478 domestic samples (56% green-skin and 44% Hass variety)

1,137 import samples (20% green-skin and 80% Hass variety)

- 3% violated for *Salmonella* - 12 samples from 9 different firms
- 0% violated for *L. mono*

- 0.3% violated for *L. mono* (pulp analysis) - 3 samples from 3 different firms
- 0% violated for *Salmonella*

**FDA Enforcement Actions:**
- Class I recall
- Follow up inspection
- Product voluntarily destroyed
- Pending action
Salmonella Findings:
• 0.74% of 1615 avocado samples collected – all samples

<table>
<thead>
<tr>
<th>Variety</th>
<th>Positives - Salmonella</th>
<th>Total Collected for Each Row</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hass - Domestic</td>
<td>1 (0.47%)</td>
<td>212</td>
</tr>
<tr>
<td>Hass - Import</td>
<td>0 (0%)</td>
<td>908</td>
</tr>
<tr>
<td>Green Skin - Domestic</td>
<td>11 (4.14%)</td>
<td>266</td>
</tr>
<tr>
<td>Green Skin - Import</td>
<td>0 (0%)</td>
<td>299</td>
</tr>
<tr>
<td>Total</td>
<td>12 (0.74%)</td>
<td>1615</td>
</tr>
</tbody>
</table>

• One category of samples that stand out as having particularly high rates of *Salmonella* contamination are domestic, green-skin avocados
• Further sampling and testing suggested
Listeria monocytogenes Findings:

- 0.24% of 1254 avocado samples collected for pulp analysis

<table>
<thead>
<tr>
<th>Variety</th>
<th>Positives - LM</th>
<th>Total Collected for Each Row</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hass - Domestic</td>
<td>0 (0%)</td>
<td>142</td>
</tr>
<tr>
<td>Hass - Import</td>
<td>2 (0.27%)</td>
<td>739</td>
</tr>
<tr>
<td>Green Skin - Domestic</td>
<td>0 (0%)</td>
<td>222</td>
</tr>
<tr>
<td>Green Skin - Import</td>
<td>1 (0.66%)</td>
<td>151</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3 (0.24%)</strong></td>
<td><strong>1254</strong></td>
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- For avocados collected from 5/13/2014 to 8/26/2014 and tested using the whole soak (skin) method, FDA observed 17.70% of the 361 samples collected were positive for *L. monocytogenes* on the skin
- No action were taken on these samples (Class 4)
Impact

• Demonstrated the ability of the FERN cooperative agreement program to participate in FDA surveillance program in a unified and coordinated manner

• Exercised all aspects of FDA use of state data from methodology to communication, data reporting, analytical worksheet package submittal, analytical review, ORS and CFSAN communication and district follow-up on positive samples.

• Exemplify on how to utilize the expertise of our national food testing laboratories and could be modeled as a basis for a comprehensive national surveillance system
Future Assignments

• Long list of potential foods
• More complex of an undertaking:
  – Involvement of countries, industry, states, trade associations
• FY 16 currently testing cucumbers and hot peppers
Acknowledgments

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Minnesota Department of Agriculture
New Hampshire Department of Public Health
New Mexico State University
North Carolina Department of Agriculture
Ohio Department of Agriculture
Pennsylvania Department of Health
Rhode Island Department of Health
Texas Department of State Health Services
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Washington Department of Agriculture