# FDA Large Scale Produce Assignment – Improving Risk Assessments

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FERN
Uniting Federal, State and Local Laboratories for Food Emergency Response

FOOD EMERGENCY RESPONSE NETWORK

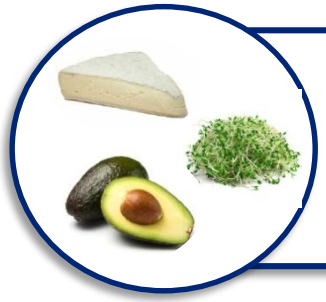
ORA
OFFICE OF REGULATORY AFFAIRS

# 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, or 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 form 2001-2013) indicates the potential for a high incidence of contamination in this commodity (18% violatiive).
- 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, 1600 whole avocado samples will be collected of which 480 will be Domestic whole avocado samples and 1120 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; *L. monocytogenes* – FL Ag lab
- 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

| Source of Sample | Samples Collected No. (%) |
|---|---|
| Domestic Samples | 478 (29.6%) |
| Import Samples | 360 (22.3%) |
| Domestic-Import Samples | 777 (48.1%) |
| **Point of Sample Collection** | **Samples Collected No. (%)** |
| Distributor/Warehouse | 198 (12.3%) |
| Grower | 30 (1.9%) |
| Manufacturer | 3 (0.2%) |
| Packinghouse | 28 (1.7%) |
| Retail | 219 (13.6%) |
| Domestic-Import | 777 (48.1%) |
| Import | 360 (22.3%) |
| **Variety** | **Samples Collected No. (%)** |
| Hass | 1120 (69.3%) |
| Green Skin | 495 (30.7%) |
| **Total Samples Collected** | **1615 (100%)** |

# Summary

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

Analyzed for *Salmonella* and *L. monocytogenes*

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

**FDA Enforcement Actions:**

- Class I recall
- Follow up inspection
- Product voluntarily destroyed
- Pending action

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

**FDA Enforcement Actions:**

- 3 firms on Import Alert

## Salmonella Findings:

- 0.74% of 1615 avocado samples collected – all samples

| Variety | Positives - Salmonella | Total Collected for Each Row |
|---|---|---|
| Hass - Domestic | 1 (0.47%) | 212 |
| Hass - Import | 0 (0%) | 908 |
| Green Skin - Domestic | 11 (4.14%) | 266 |
| Green Skin - Import | 0 (0%) | 299 |
| Total | 12 (0.74%) | 1615 |

- 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

| Variety | Positives - LM | Total Collected for Each Row |
|---|---|---|
| Hass - Domestic | 0 (0%) | 142 |
| Hass - Import | 2 (0.27%) | 739 |
| Green Skin - Domestic | 0 (0%) | 222 |
| Green Skin - Import | 1 (0.66%) | 151 |
| Total | 3 (0.24%) | 1254 |

- 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

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