FY17-19 FDA Surveillance Sampling Program: Processed Avocados/Guacamole Assignment

SURVEILLANCE SAMPLING EXECUTON: ***800 Domestic*** samples and ***800 Import*** samples will be collected.

Sampling Guidelines

What samples will be collected?

- ✓ Processed avocado including fresh cut (cut, sliced, or diced) & frozen (cut, sliced, or diced)
- ✓ Puree (only avocado & not intended for beverage or further processed)
- ✓ Refrigerated or frozen pulp with additives
- ✓ Guacamole

Processed Avocado

What will NOT be collected?

- ✓ Whole avocados (in tact, with skin) will NOT be collected. Samples will NOT be collected from farms or growers.
- ✓ Avocado indicated as intended for beverage or product that has indicated that it has undergone pathogen kill step will NOT be collected.
- ✓ FDA subject matter experts will be available at headquarters to provide guidance to investigators to help determine if the product has undergone a pathogen kill step.

Whole Avocado, Avocado intended for juicing

Where and when will samples be collected?

Where:

- ✓ Domestic samples will be collected from a variety of establishments: Manufacturer/Processor, Distributor/Warehouse, and Retail. Import samples will be collected at ports of entry, importer's warehouses, or other storage facilities.

When:

- ✓ Samples will be collected Monday - Thursday.
- ✓ Throughout the year, **across all seasons.**
- ✓ Samples might be collected from the same establishment or the same importer multiple times throughout the assignment. Samples might be collected from the same establishment or the same importer multiple times in one year (not to exceed 3 collections every 6 months). FDA will closely monitor allocations at the country and firm level to minimize impact on trade.

How will States be involved?

- ✓ The Divisions, ORA/Office of Partnerships and Operational Policy , and ORA/Office of Regulatory Science will coordinate State involvement, which may be performed under contract, cooperative agreement, partnership agreement, or other collaborative efforts.
- ✓ FDA does not anticipate State participation in sample collection or analysis at this time.
- ✓ Upon request, FDA Divisions will share the assignment with Commissioned state regulatory counterparts.
- ✓ FDA Divisions will notify the State regulatory agency officials of negative, CRO, and confirmed positive results.

How many samples should be collected?

Type of Sample	Sample Size	Analytical Unit Size
Processed avocado & guacamole	**1 sample = 10, 8oz subsamples**	***Salmonella*[1]: 10 analytical units weighing 75 g each** ***L. monocytogenes*[2]: 10 analytical units weighing 25g each**

How will samples be collected?

- ✓ Samples will be collected aseptically per normal sample collection procedures found in IOM, Chapter 4. Section 4.5 Sampling: Preparation, Handling, Shipping
- ✓ Documentation will include variety, name and address of manufacturer, country of origin for imported product or origin for domestic product, or other supply chain information including food identification code (if available).
- ✓ Samples will be stored in cooler with adequate coolant.
- ✓ When feasible, photos might be taken of the product collected and retail box (including label, firm name, etc.).
- ✓ Per FDA Field Management Directive 147, if the sample is found to be contaminated with pathogens, the collecting FDA Districts will promptly furnish a copy of the results of such analysis to the owner, operator, or agent in charge of the product. In addition, if the firm indicates to the FDA investigator that the firm is voluntarily holding products pending FDA results, the FDA investigator will make a notation on the Collection Report and FDA will notify the firm of the results as soon as they are available. Investigators have been requested to inquire if dealer is holding domestic products pending FDA analytical results.

Who will analyze samples?

- ✓ FDA Servicing Laboratories will analyze samples under this assignment.
- ✓ FDA lab capacity will be closely monitored.
- ✓ FDA does not anticipate FERN lab participation at this time.

General Timeframes for Negative/CRO/Confirmation Results (after receipt by lab)

Microorganism	Negative or Cannot Rule Out	Final Confirmation
Salmonella	3-4 business days	Additional 6-8 days
Listeria monocytogenes	3-4 business days	Additional 6-8 days

Inspections

- There are no **initial** inspections required under this Surveillance Sampling Program Assignment for processed avocados.

Why Processed Avocados?

- Processed avocado products, including avocado that is fresh cut, refrigerated and frozen can be packaged and consumed without a "kill-step" applied prior to consumption. Processing fresh produce into fresh-cut products increases the risk of bacterial growth by breaking the natural exterior barrier of the produce and allowing for the spread and potential growth of any harmful pathogens that may be present. Avocados have high concentrations of lipids and moisture content, low carbohydrates, and non-acidic pH, providing an excellent growth medium for pathogens such as *Salmonella* and *L. monocytogenes*.
- According to CDC, from 2005-2015 there have been 12 foodborne outbreaks related to avocado, avocado products, or guacamole products; 9 of the outbreaks involved Salmonella and 3 involved E.coli (2 STEC [O157:H7] and 1 EHEC unknown) resulting in 525 illness, 23 hospitalizations. Though no *Listeria* outbreaks were reported from 2005 to 2015, a recent large-scale, FDA sampling assignment detected *L. monocytogenes* in samples collected from the exterior skins and internal pulp of avocados.
- There is a lack of prevalence data available for *Salmonella* and *L. monocytogenes* associated with processed avocado and processed avocado products.

Follow-Up & Enforcement

- A follow-up inspection and environmental sampling may be conducted at the domestic manufacturing site if multiple samples yield nearly identical pathogenic strains, based on WGS or one or more samples yielding a current outbreak strain of *Salmonella* or *L. monocytogenes*.
- If a positive product is found that has been distributed, FDA will consider its regulatory and enforcement options to address the public health impact, including possible follow-up inspections. Enforcement steps could include encouraging voluntary recall, ordering a mandatory recall, administrative detention, or issuing public warnings.
- FDA's response to positive analytical results relative to imported samples, collected in import status at the port of entry, will be as per standard operating procedure, i.e., current shipments may be detained and refused, future entries will be subject to Import Alert (detention without physical examination) when warranted.

[1]Bacteriological Analytical Manual Chapter 5 *Salmonella*; [2]Bacteriological Analytical Manual Chapter 10 - Detection of Listeria monocytogenes in Foods and Environmental Samples, and Enumeration of Listeria monocytogenes in Foods

FY17-19 FDA Surveillance Sampling Program: Fresh Herbs Assignment

SURVEILLANCE SAMPLING EXECUTON: ***761 Domestic fresh herb*** samples and ***839 Import fresh herb*** samples will be collected.

Sampling Guidelines

What samples will be collected?

✓ Fresh, raw parsley, cilantro, and basil samples will be collected. All varieties may be collected.

Parsley, Cilantro, & Basil

What will NOT be collected?

✓ Frozen, chopped, dried and/or fresh herbs known to be intended for further processing will NOT be collected

Frozen, chopped, or dried herbs

Where and when will samples be collected?

Where:

✓ Domestic samples will be collected from a variety of establishments: Packers (including post-harvest products in packing houses located on farms), Wholesalers, Distributer/Warehouse, and Retail (from dealers' storage and not from consumer areas). Import samples will be collected ports of entry, importer's warehouses, or other storage facilities.

When:

✓ Samples will be collected Monday – Thursday, throughout the year, **across all seasons.**

✓ Samples might be collected from the same establishment or the same importer multiple times in one year (not to exceed 3 collections every 6 months). Investigators are requested to obtain samples from different crop cycles/growing seasons at that location and documentation should reflect the crop cycle/growing season sampled, where appropriate. FDA will closely monitor allocations at the country and firm level to minimize impact on trade.

How will States be involved?

✓ The Divisions, ORA/Office of Partnerships and Operational Policy, and ORA/Office of Regulatory Science will coordinate results with the responsible party, and subsequent follow-up inspections.

✓ FDA does not anticipate State participation in sample collection or analysis at this time.

✓ Upon request, FDA Divisions will share the assignment with Commissioned State regulatory counterparts.

✓ FDA Divisions will notify the State regulatory agency officials of negative, CRO, and confirmed positive results.

How many samples should be collected?

Type of Sample	Sample Size	Analytical Unit Size
Fresh, raw parsley, cilantro, & basil	1 sample = 30 bunches (~2oz/bunch)	STEC[1]: 10 analytical units weighing 25g each *Salmonella*[2]: 30 analytical units weighing 25g each

How will samples be collected?

✓ Samples will be collected aseptically per normal sample collection procedures found in IOM, Chapter 4. Section 4.5 Sampling: Preparation, Handling, Shipping

✓ Sub samples will be collected at random to ensure that the sample is representative of the lot(s).

✓ Documentation including shipping records, name and address of product's origin/grower, lot numbers, or other supply chain information will be collected.

✓ Photos might be taken of the product collected and retail box (including label, firm name, etc.).

✓ Per FDA Field Management Directive 147, if the sample is found to be contaminated with pathogens, the FDA collecting Districts will promptly furnish a copy of the results of such analysis to the owner, operator, or agent in charge. In addition, if the firm indicates to the FDA investigator that the firm is voluntarily holding products pending FDA results, the FDA investigator will make a notation on the Collection Report and FDA will notify the firm of the results as soon as they are available. Investigators have been requested to inquire if dealer is holding domestic products pending FDA analytical results.

Who will analyze samples?

✓ FDA Servicing Laboratories will analyze samples under this assignment.

✓ FDA lab capacity will be closely monitored.

✓ FDA does not anticipate FERN lab participation at this time.

General Timeframes for Negative/CRO/Confirmation Results (after receipt by lab)

Microorganism	Negative or Cannot Rule Out	Final Confirmation
Salmonella	3-4 business days	Additional 6-8 days
Shiga toxin-producing *E.coli* (STEC)	3-4 business days	Additional 6-8 days

Please note: The Agency is considering amending the assignment in the Spring of FY18 to include the testing and analysis for *Cyclospora cayetanenis*, to focus resources on the months that *Cyclospora* related illnesses are typically observed.

Inspections

- There are no **initial** inspections required under this surveillance sampling assignment.

Why Fresh Herbs?

- Fresh herbs are typically consumed fresh, without a "kill-step" prior to consumption, and are often consumed as a 'stealth' component in in multi-ingredient foods. Fresh produce, including herbs, have relatively short shelf lives and present investigation hurdles since they are consumed quickly and there often are no remaining samples available in the event of any follow-up.
- From 1996-2015, FDA reported 9 total outbreaks related to basil, parsley, and cilantro: specifically 4 related to basil, 3 related to cilantro, and 2 related to parsley, resulting in 2699 illnesses and 84 hospitalizations. No deaths were reported. 7 of the 9 outbreaks were associated with *Cyclospora cayetanensis*; 1 was associated with *E. coli* O157:H7 and 1 was associated with *Shigella sonnei*. The most recent *Cyclospora* outbreaks in 2013, 2014, and 2015 resulted in 1080 illnesses and 74 hospitalizations.
- This sampling assignment would address knowledge gaps on prevalence of *Salmonella,* and Shiga toxin-producing *E.coli* (STEC) in cilantro, basil, and parsley.

Follow-Up & Enforcement

- If a positive product is found that has been distributed, FDA will consider its regulatory and enforcement options to address the public health impact, including possible follow-up inspections. Some enforcement steps could include encouraging voluntary recall, ordering a mandatory recall, administrative detention, or issuing public warnings.
- FDA's response to positive analytical results relative to imported samples, collected in import status at the port of entry, will be as per standard operating procedure, i.e., current shipments may be detained and refused, future entries will be subject to Import Alert (detention without physical examination) when warranted.

[1]Bacteriological Analytical Manual Chapter 4A: Diarrheagenic Escherichia coli; [2]Bacteriological Analytical Manual Chapter 5 *Salmonella*