DRAFT FY17/18 FDA Surveillance Sampling Program: Processed Avocados/Guacamole Assignment

(Information in this document is draft and subject to change)

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) and 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 undergone pathogen kill step will NOT be collected.

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.

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. 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 positive, CRO, and pending CRO results (confirmed positives and negatives).

How many samples should be collected?

Type of Sample	# of sample units (subs)	Subsamples Sample Size
Processed avocado & guacamole	**20 (10 *Salmonella*, 10 *L. monocytogenes*)**	***Salmonella*: 75 g/sub *L. monocytogenes*: 25 g/per sub**

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.
- ✓ 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.

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.