Memorandum

To: FDA Industry & Regulatory Stakeholders

From: Amy Barringer, FDA, Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Field Programs and Guidance

Date: October 11, 2017

Subject: Summary of External Feedback and FDA Responses to the FY17-19 Surveillance Sampling Program Assignments

Background

As you are aware, in August 2017, FDA conducted outreach to our External Stakeholder groups on the FY17 – 19 surveillance sampling assignments for Fresh Herbs (parsley, basil, and cilantro) and Processed Avocado and Guacamole. We solicited feedback to ensure that sample collection is done as effectively and efficiently as possible under these two assignments. We would like to thank our External Stakeholders for providing very constructive, informative feedback that will aid us in implementing these assignments. While FDA determined that no major changes to the assignments were needed, additional clarifications and additional instructions to investigators were included to increase assignment efficiency and decrease impact on trade, as noted in the responses below. In addition, the external feedback highlighted topics that we will provide greater clarity on in the External Feedback Summary provided below.

Sampling Allocations

1. FDA received feedback requesting greater clarification on minimizing the impact of multiple sample collections for a given firm or importer throughout the duration of this sampling assignment as well as how the sampling allocations were determined.

Under these assignments, a variety of sampling strategies will be implemented which includes collections from a diversity of locations, establishment types, seasonality and product varieties. The concerns of external stakeholders regarding oversampling will be shared with Field personnel to highlight the importance of completing the assignment while working to minimize impact on trade. In addition, the assignments were updated to request investigators not collect from the same establishment more than 3 times every 6 months. In the instance in which multiple samples are obtained from the same establishment during this assignment, 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 be closely monitoring sampling allocations throughout the entirety of the assignment to ensure that the sampling model reflects current market production and to ensure, to the extent possible, that oversampling does not occur. However, samples might be collected from the same establishment or the same importer multiple times in one year.

Domestic and Import allocations in the assignments reflect current market production. For import allocations, FDA internal imports data was evaluated to generate the Division import sample allocations. Data such as import line volume, port of entry, and import country of origin were used to create the import allocations. FDA also evaluated external data, using USDA's AMS data, to generate a market share outlook for the commodities of concern.

If our external partners have additional historical information on incidence of contamination that they would like to share with FDA, we would likely take that into consideration in determining follow-up activities to these assignments, and in prioritizing commodities for future assignments.

Sample Collection

2. FDA received feedback requesting further clarification on the types of products that could be collected under the Processed Avocado and Guacamole assignment as well as how investigators will determine which products to collect.

Investigators are instructed to ascertain, to the extent possible, if the product has undergone a pathogen kill step or is intended to undergo a pathogen kill step, including if the product is intended for a 5-log reduction as required by Juice HACCP, by asking the processor where feasible and reviewing the product labeling. Product collected at a processor that has gone through a kill step should be supplemented by documentation. If product is collected at retail, the investigator will review product labeling to determine if product is treated with a kill step. However, FDA is aware that some avocado products may go through a kill step but the label may not identify this characteristic. In this situation, 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.

Regarding imported products, inclusion of any pathogen kill step information in the entry documents will assist field staff in reviewing eligibility of entries for the assignment. Additionally, the importers can work with the entry filers to have that information provided electronically during the entry filing, for example, by including it with the importers product description. Importers and entry filers should communicate with the import staff at the port of entry.

3. FDA received feedback regarding guidelines for collecting and shipping samples to increase result turn - around time and decrease impact on trade.

The assignment emphasizes that these samples are high priority and should be analyzed and reported out as soon as possible. Specifically, samples will be collected Monday through Thursday and shipped via expediting shipment so that the laboratories receive the sample within 24 hours of collection. Investigators are instructed to ship refrigerated samples overnight via UPS Next Day Air Early A.M. shipping for earliest arrival to servicing laboratories. This approach provides flexibility for sample collections while meeting critical shipment deadlines.

Negative and cannot rule out (CRO) results should typically be available within 3-4 business days from receipt by the lab. Final confirmation of results should be made available within an additional 6-8 days for *Salmonella* (processed avocados, guacamole and fresh herbs)*, Listeria monocytogenes* (processed avocados and guacamole only) and STEC (fresh herbs only). The collecting Division, in coordination with the servicing laboratories, should notify the firm of negative, CRO, and confirmed positive results within the mentioned timeframes. The State regulatory agency official shall also be notified of negative, CRO, and confirmed positive results.

4. FDA received feedback regarding industry's domestic voluntary holding practices and the timely release and notification of all test results, both in the domestic and import arena, to minimize impact on trade, minimize economic losses, as well as to enhance a firm's ability to quickly act if positive product is identified.

FDA has deployed the Import Trade Auxiliary Communication System (ITACS) for use by the import trade community. This system was implemented to improve communication between FDA and the import trade community. ITACS basic functionality provides the import trade community with four functions: the ability to check the status of FDA-regulated entries and lines, the ability to submit entry documentation electronically, the ability to electronically submit the location of goods availability for those lines targeted for FDA exam and the ability to check the estimated laboratory analysis completion dates for lines which have been sampled. When an import sample is collected, the import community is notified when their product is released through ITACS or the broker seeing the release of the entry in their system and notifying the appropriate individuals. FDA also sends a Notice of FDA action to the importer, filer, and consignee when a product is released.

Further, to address industry's concerns regarding voluntarily holding domestic product pending FDA results, investigators have been requested to inquire if dealer is holding products pending FDA analytical results.
Per Field Management Directive 147, Procedure for Release of Analytical Results Pursuant to Section 704(d) and Situations When Dealer is Voluntarily Holding Product, if the sample is found to be contaminated with pathogens, the FDA collecting Divisions 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.

Sample Analysis

5. FDA received feedback regarding 'sample size' and 'subsample size' terminology and commenters requested clarity on sample sizes versus composite sizes.

For the fresh herbs assignment, one (1) sample will consist of 30 bunches of a given commodity (basil, parsley, or cilantro), with each bunch weighing a minimum of 2 oz. The thirty (30) bunches will be used for both *Salmonella* and STEC analysis.

- For *Salmonella* testing, a 25g analytical unit will be taken from each bunch. During analysis, two (2), 375g composites are formed by combining fifteen (15), 25g analytical units per composite. For more information please refer to Bacteriological Analytical Manual Chapter 1 Food Sampling and Preparation of Sample Homogenate.

- For STEC testing, a 25g analytical unit will be taken randomly from 10 bunches in each sample for analysis. For more information, please refer to Bacteriological Analytical Manual Chapter 4A: Diarrheagenic *Escherichia coli*.

For the processed avocado and guacamole assignment, the investigator will collect a sample that consists of ten (10), 8oz subsamples. The ten (10), 8oz subsamples will be used for both *Salmonella* and *Listeria monocytogenes* analysis.

- For *Salmonella* testing, a 75g analytical unit will be taken from each of the subsamples. During analysis, two (2), 375g composites are formed by combining five (5), 75g analytical units per composite. For more information on *Salmonella* lab methodology please refer to AOAC methods 2001.09, 2004.03 and 2011.03 and confirmation methods detailed in Bacteriological Analytical Manual Chapter 5 *Salmonella*.

- For *Listeria monocytogenes* testing, a 25g analytical unit will be taken from each of the subsamples. During analysis, two (2), 125g composites are formed by combining five (5), 25g analytical units per composite. For more information on the *Listeria monocytogenes* lab methodology, please refer to Bacteriological Analytical Manual Chapter 10 - Detection of *Listeria monocytogenes* in Foods and Environmental Samples, and Enumeration of *Listeria monocytogenes* in Foods.

6. FDA received comments requesting more information on the lab methods utilized in these assignments.

Fresh Herbs Assignment

- *Salmonella* Lab Methodology - Bacteriological Analytical Manual Chapter 5 *Salmonella*.

- Shiga toxin-producing *E. coli* (STEC) Lab methodology: Bacteriological Analytical Manual Chapter 4A: Diarrheagenic *Escherichia coli*.

Processed Avocado and Guacamole Assignment

- *Listeria monocytogenes* lab methodology: The following methods can be used following the sampling preparation procedures described in the instructions.
    1. AOAC OMA 2013.10, VIDAS LPT *Listeria* in foods and environmental surfaces
    2. AOAC PTM (No. 981202) VIDAS LIS, *Listeria* in environmental samples
    3. AOAC 999.06 VIDAS LIS Assay for *Listeria* in Foods

    If the package insert does not give specific instructions on sampling, laboratories will follow the BAM Chapter 10 Instructions for Environmental Sampling preparation. If AOAC methods are used, culture will be confirmed using the BAM Chapter 10. Enumeration should be done on positive samples following instructions in BAM Chapter 10.

- *Salmonella* Lab Methodology: Laboratories should use AOAC methods 2001.09, 2004.03 and 2011.03 and use confirmation methods detailed in Bacteriological Analytical Manual Chapter 5 *Salmonella*.

7. FDA received comments requesting further information on the addition of *Cyclospora cayetanenis* testing and analysis to the Fresh Herbs assignment.

Cyclospora cayetanenis testing and analysis is slated to coincide with the season (spring and summer in the USA) when human

illnesses have more commonly been seen for this organism involving herbs. This will also allow FDA to focus laboratory resources to carry out analysis under the new methods for the detection of this organism in foods.

At this time sample size and subsample size are not known. The Agency will provide additional outreach when this amendment is made.

8. FDA received comments regarding if enumeration will be performed on positive *Listeria monocytogenes* samples under the Processed Avocado and Guacamole assignment.

Enumeration should be performed on positive *Listeria monocytogenes* samples following instructions in Bacteriological Analytical Manual Chapter 10 - Detection of *Listeria monocytogenes* in Foods and Environmental Samples, and Enumeration of *Listeria monocytogenes* in Foods.

Industry Outreach

9. FDA received feedback regarding industry outreach prior and throughout assignment execution.

External engagement is a key component of the large-scale surveillance sampling assignment model, whereby FDA seeks to engage external stakeholders throughout the assignment prioritization, development, execution, and data evaluation processes. FDA will provide this outreach to our Federal, State, Foreign, Industry, and Academic partners, and work through these channels to request and provide outreach throughout the process.

FDA welcomes additional outreach that Industry wishes to provide to their partners, including additional guidance or counsel that they feel appropriate. We consider this a continuous improvement process and one that where we welcome constructive feedback.

In addition, FDA will be sharing information on the foods sampling program, specifically the surveillance sampling assignment program, as well as publically share outcomes from the assignments through FDA's website. Per external stakeholder request, the FDA website will contain more information on the purpose behind sampling, what happens in the event of a positive or negative sample, and what happens to the data collected from these assignments. The food program sampling website can be accessed by going to http://www.fda.gov/Food/ComplianceEnforcement/default.htm and clicking on "Sampling."