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Food and Drug Administration (FDA) Surveillance Sampling Assignment Salinas Valley, CA

DISCLAIMER

This document includes questions Western Growers has received from members impacted by the FDA assignment in the Salinas Valley, California. This guide does not constitute legal advice. The answers below are not necessarily exhaustive and may not apply in every situation but provide our best understanding of the assignment based on exchanges with the FDA. This document will continue to be updated as we learn new information and details.

1. **The announcement states the samples will be taken at commercial coolers - does this mean that processing facilities will not be visited for sampling?**

   The FDA assignment will direct sampling to be conducted at commercial cooling and cold storage facilities where field heat is removed from harvested lettuce and where product is cold-stored before processing.

   Thus, during the assignment the FDA may visit cold-storage facilities located on site with processing facilities.

   Sampling may include pre-cooled product (preferred) or post-cooled product. Sample collection at commercial coolers helps the FDA efficiently obtain samples from multiple farms at centralized locations and facilitates prompt traceback and follow-up if contamination is detected.

2. **What traceback information should be provided to the FDA inspectors at the time of sampling?**

   The agency is likely to ask for a harvest date, grower name and contact information at the time of sampling.

3. **What is the expected time to result? Why?**

   The FDA acknowledges that lettuce is a perishable product and is sensitive to concerns on the part of industry, particularly with respect to the time between sample collection and notification of initial test results.

The FDA is working on multiple fronts to minimize disruption to industry during this assignment. The FDA laboratories that will test the samples will be in operation seven days a week, and the FDA investigators taking the samples will request the contact information needed to facilitate prompt notification of test results to industry once the initial testing and any subsequent testing are complete.

The FDA plans to notify firms of negatives and "cannot rule out" (CRO) samples within three days of sample collection. More specifically, when collecting a sample on a Monday, the agency intends to communicate the initial test results by Wednesday afternoon, or early evening. Similarly, when collecting a sample on a Friday, the agency intends to communicate the initial test results by Sunday afternoon, or early evening.

With respect to the CRO samples, or more precisely, to the time to determine whether they are positive for a target pathogen, generally it will take the FDA an additional week to notify firms of the final test results as they must microbiologically confirm the organism's ability to cause disease. This confirmatory process was similarly used by the independent laboratory in Yuma County. This additional analytical time pertaining to CRO positive samples is unavoidable irrespective of who conducts the testing.

The FDA will further analyze any confirmed STEC or *Salmonella* spp. isolates using whole genome sequencing (WGS). WGS can provide us with key information, including serotype, pathogenicity, and possible linkage to past or ongoing outbreaks of foodborne illness. WGS analysis generally will take an additional week.

4. **Why was a commercial laboratory not utilized during this assignment, as per the recently completed surveillance sampling in Yuma County, Arizona?**

The use of the independent laboratory during the recent Yuma County sampling assignment for Romaine was a pilot activity by the FDA. The agency is evaluating the use of the independent laboratory and under what circumstances they may take a comparable approach in the future. The FDA's evaluation includes many considerations, including chain-of-custody, validation protocol, and data transfer issues, microbiological method to be used.

Additionally, the agency has indicated that the possibility of using an independent laboratory for the assignment to sample Salinas Valley, California grown lettuce was complicated because of the lack of an existing contract with an independent laboratory in the Central Coast of California region. The FDA is bound by the requirements of the Federal Acquisition Regulations; therefore, arranging for a new contract at this time would have delayed the assignment beyond the initial months of the growing season.

5. **Will coolers be notified in advance (24 hours) of a sampling event?**

   During this sampling assignment, the FDA will take extra precautions to help ensure the safety of agency investigators and firm employees during the COVID-19 pandemic. FDA investigators will preannounce their visits to firms per the Agency's COVID-19 safety practices. They will be outfitted with personal protective equipment (PPE) and will carry out their work while adhering to local, state and applicable CDC guidance.

6. **Will multiple lots be sampled during a cooler visit?**

   FDA staff seeks to collect samples that meet the parameters of the assignment on the days that they visit the cooler. It is possible for multiple lots to be sampled during a cooler visit, however any assistance the cooler can provide FDA to identify lots to sample from would be appreciated.

7. **Will multiple commodities be sampled during each visit?**

   The FDA will use its discretion when sampling. Generally, samples collection will be random to help ensure that they are representative of a lot. The agency encourages firms to assist them during the process of identifying product (preferably pre-cooled, and not yet in commerce).

8. **Will product in commerce be sampled?**

   The FDA preference is to collect product not yet in commerce if it is available. Cooler management can discuss information regarding lot designations and harvest schedules with the FDA staff who will be collecting samples to help them understand what harvested product (meeting the stated criteria of the assignment) is available for sampling. While the FDA cannot commit to arrival only on certain days/times, this information can be helpful for their planning purposes.

9. **How will the FDA define a lot?**

   For the purpose of the assignment, the agency will define "lot" as product from the same day, harvest and crew. The agency recognizes that firms have different definitions; therefore, they will use their definition to support consistency and support traceback investigations. For instance, if a cooler has a broader "lot" definition, which includes several harvest days, the FDA's definition is narrower and will apply. In the case of shared lots at the times of purchase, the agency recognized additional challenges and will address them at the time of sampling.

10. Will a company's definition of a lot be considered?

For the purposes of this assignment, FDA considers a "lot" to be product from a day's harvest, from the same land, and same harvest crew. The FDA's definition may differ from one firm to the next. For consistency, the FDA will use this definition during the assignment. If a firm's interpretation is narrower in scope, the cooler management can discuss this information with FDA staff for consideration at the time of sample collection.

11. What types of lettuces will be sampled?

The FDA will collect and test iceberg, leaf, and romaine lettuces grown in Salinas Valley, California.

12. Will FDA accept the pre-harvest pathogen testing conducted by growers/shippers as a substitute?

No, the FDA will not consider pre-harvest testing results in selection of samples from a cooler. Western Growers continues its ongoing dialogue with the FDA on how to make future sampling assignments more efficient and effective, including the use of commercial laboratories to improve time-to-results and the role of pre-harvest testing results.

13. How will FDA handle the volume of samples at the laboratory facilities and what is the plan of action if the lab experiences a back log?

The FDA will use a sampling schedule to decide how many samples to collect, considering factors such as available staff, laboratory capacity, availability of produce, and harvest timeframe.

14. Will the FDA comply with a firm's COVID protocol including, giving advanced notice for a visit and answering health questions?

FDA investigators will preannounce their visits to firms per the Agency's COVID-19 safety practices. They will be outfitted with personal protective equipment (PPE) and will carry out their work while adhering to local, state and applicable CDC guidance. However, we are not aware of how the FDA will approach individual firm's COVID protocols.

15. What considerations will be given to harvested product from the same lot that is purchased by more than one firm?

Cooler management can discuss this information with the FDA staff who will be collecting samples. The cooler management can explain that a specific commodity ranch lot, crew and day may be shared by more than one firm.

16. When is sampling scheduled to begin?

The agency recently announced that this sampling will take place from May through November 2021. FDA staff has already deployed to Salinas with sampling having started on May 18, 2021.

17. Will multiple commodities be sampled during each visit? Or will each visit be for specific commodities?

This scenario may be possible (collecting multiple commodities) but keep in mind, FDA staff will be seeking to collect samples that meet the parameters of the assignment on the days that they visit the cooler, and any assistance the cooler can provide FDA to identify lots to sample from would be appreciated.

18. Will it be truly 'random' samples, or samples from specific growers/ranches?

FDA staff will be visiting commercial coolers at random for the purpose of collecting samples that meet the parameters of the assignment. Samples collected will be dependent on product that is available for sampling at the time of the visit. For the assignment, FDA is interested in iceberg, leaf, and romaine lettuce that have been grown anywhere in Salinas Valley, CA.

19. Are we to assume "leaf lettuce" is in reference to Green Leaf (and corresponding varieties) and not tender leaves or baby leaves?

Green and red leaves are included in this assignment. However, baby leaf lettuces (including baby romaine) are outside this assignment's scope.

If you have additional questions, please submit them to Western Growers via Scott Nichols (snichols@wga.com).