2021-2022 Domestic Fresh-Cut Cantaloupe Sampling Assignment

Prepared by United Fresh Produce Association on October 18, 2021

Background: In August 2021, United Fresh because aware of an FDA sampling assignment related to fresh-cut cantaloupe produced from domestic whole cantaloupe. The following information reflects our current understanding of this sampling assignment, which is subject to change. This sampling assignment is not listed on the FDA microbiological sampling page, so this information is being provided as a service to the industry. United Fresh, members, and allied associations are working with FDA to improve the efficiency of this sampling assignment and limit the waste in product and other resources related to the structure of this sampling assignment.

- What is being sampled?
    - Fresh-cut cantaloupe of domestic origin is being sampled by FDA
- What will samples be tested for?
    - Samples are being tested for *Salmonella* and *Listeria monocytogenes*
- What method will be used?
    - We assume that FDA will follow the relevant methods in the FDA BAM
- What is the timeframe for this sampling assignment?
    - This sampling assignment began in June 2021 and will continue for 1 year
- What entities are being sampled?
    - FDA is sampling registered facilities including fresh-cut processors, wholesalers, and distributors, including retail distribution centers. Samples are not being taken from retail or restaurant locations
- Why are DCs being sampled? Why isn't the assignment focused at the fresh-cut processor level?
    - United Fresh is working with FDA to explain the complexities associated with points other than the fresh-cut facility. FDA states that the broader scope provides more points for them to sample.
- Is FDA providing prenotification?
    - Yes, in accordance with FDA's COVID procedures, FDA is providing roughly 1-2 days advance notice.
- How many samples are being taken?
    - FDA is taking 240 samples throughout the 1 year assignment
- How is a "sample" defined?
    - A sample consists of 30 subsamples, each of which is roughly 100 grams. In other words, FDA will be collecting a total of about 3,000 g of product
- What are the statistics associated with this sampling assignment?
    - Because this is a smaller sampling assignment, FDA considers it a 'surveillance assignment' and has not calculated the statistical relevance of the sampling scheme
- How long will it take for firms to receive results?
    - FDA has not provided an estimated time to result but recognizes the perishability of the product
- Must firms hold product that is sampled?

    - While FDA does not require that companies hold product that was sampled, industry best practice is generally that product (including raw material) is held pending the test results
- Is FDA sampling product that is already in commerce?
    - FDA aims to avoid sampling product that has already entered commerce but has the right to sample what is available.
- Is FDA only sampling fresh-cut cantaloupe, or are they sampling mixed products (e.g., fresh fruit cups)?
    - We are encouraging FDA to only sample fresh-cut cantaloupe, but are aware that on occasion they have sampled mixed products containing fresh-cut cantaloupe.
- Will FDA accept product from a short run?
    - FDA seeks to sample product that is produced under your normal process. If your normal process is that short runs are used to produce items that will be tested for pathogens (e.g., there is an SOP for pathogen testing that directs short runs) then yes, this will be accepted.
- If samples are taken at distribution centers, will the results be communicated to the fresh-cut processor, the distributor, or both?
    - There seems to be inconsistency regarding communication and notification, and we are working with FDA to clarify this.
- Must locations provide traceability information for samples? What is expected?
    - We have heard that distributors have been asked for traceability information and although all companies should have good traceability systems, it is unclear why this is being requested.
- If a sample is positive for a pathogen, will a recall be necessary?
    - If implicated product is still in the marketplace, a recall will be necessary.
- Will there be an inspection along with the sampling?
    - There will likely be an inspection at fresh-cut processing facilities. The inspection could be limited in scope (e.g., paperwork review) or could be more comprehensive.
- Why is the focus on domestic cantaloupe?
    - It's unclear why this target was selected
- Given that domestic cantaloupe is not used for fresh-cut production for most of the winter, will this sampling assignment be affected?
    - We are working with FDA to understand adjustments to this sampling assignment
- Will the results of the sampling assignment be published, once completed?
    - Yes, FDA has indicated that they will publish the summary results. They have denied our request to provide the kinds of quarterly updates that are typically provided for other sampling assignments
- Where can I find more information on this sampling assignment?
    - There is no published information on this sampling assignment. United Fresh has requested better communication and transparency
- Who can I contact with more questions?
    - Dr. Jennifer McEntire, SVP Food Safety & Technology, at jmcentire@unitedfresh.org