FY22/23 On-Farm Sampling of Leafy Greens Grown in the Salinas Valley Region

Why Leafy Greens?

Foodborne illness outbreaks involving leafy greens linked to or potentially linked to the Salinas Valley, California, region have continued to occur, with at least one outbreak occurring every year for the past four years.[1] The Salinas Valley region produces about 70 percent of U.S. grown lettuce.[2] Leafy greens are some of the most consumed vegetables in the American diet but are typically eaten without undergoing a 'kill step,' such as cooking, to reduce or eliminate bacteria. This regulatory assignment is a part of the FDA's Leafy Greens STEC Action Plan that includes ongoing surveillance of leafy greens, consistent with the FDA's mission to promote and protect the public health.

What samples will the FDA collect?

The FDA plans to collect product samples and may collect environmental samples at some farms/ranches. With respect to the product samples, the agency will collect iceberg, leaf and romaine lettuce directly from production fields within farms/ranches in the Salinas Valley agricultural region of California. The product samples will consist of whole heads of lettuce, untrimmed whenever possible. The FDA does not plan to collect trimmed, cored, wrapped or topped-and-tailed lettuce.

What if lettuce is not available at a farm/ranch?

Investigators may collect other leafy greens, prioritizing spinach.

Are all Salinas Valley region farms/ranches subject to this FDA regulatory sampling assignment?

No. Under this assignment, the FDA will collect samples only from farms/ranches identified by traceback investigation in recent years as being potentially associated with a foodborne illness outbreak in which lettuce or leafy greens were identified as the likely or suspect food vehicle.

What microbial hazards is the FDA testing for?

Salmonella spp. and *E. coli* O157:H7

When will the FDA collect the samples?

FDA field staff will collect samples from September 19 to October 30, 2022.

How many samples does the FDA plan to collect for this assignment?

The FDA plans to collect up to about 240 product samples in total, primarily lettuce but also including spinach or other leafy greens, if necessary. The FDA will collect approximately one to four lettuce samples at each farm/ranch, depending on its acreage and the scope of the operation. Each lettuce sample will consist of 10 subsamples, and each subsample will consist of one whole head of lettuce, untrimmed

[1] FDA - Public Health Advisories from Investigations of Foodborne Illness Outbreaks. Advisories by Year.
[2] USDA: 2017 Census of Agriculture – Table 29.

whenever possible. Samples of other leafy greens likewise will consist of 10 subsamples. The FDA also may collect environmental samples (e.g., water, soil and scat) as appropriate based on observations made at the time of sampling and a farm/ranch's past inspection history.

How will the samples be collected?
The agency will notify the farm/grower of the collection visit typically a few days in advance. FDA field staff will seek to coordinate with and request the aid of farm/ranch personnel in harvesting product that the FDA field staff identify to sample. FDA field staff also will be prepared to harvest product themselves, as needed, and will collect samples using standard techniques set forth in the FDA's Investigations Operations Manual (Chapter 4.3), which describes the use of sterile equipment and aseptic procedures.

Who will conduct the testing?
The FDA will test the samples at its labs in Alameda and Irvine, CA; Bothell, WA; and Denver, CO.

When will the FDA provide notification of test results?

Finding	Time to Notification
Negative Results, and/or Preliminary Indication*	Product samples: Typically, within three days of sample collection. Environmental samples: Typically, within five days of sample collection.
Confirmed Results	Typically, within an additional week (following preliminary indication).
Whole Genome Sequencing	Typically, from two to three weeks of sample collection.

* "Preliminary Indication" suggests the sample may yield a final result that could indicate a public health threat. Analytical testing remains ongoing and final results have not yet been determined. These samples may ultimately be determined to be negative or positive in their final result.

What regulatory action will the FDA take if it detects *Salmonella* spp. or *E. coli* O157:H7?
The FDA will notify the responsible party at the farm/ranch (typically, its owner or operator), and others identified by the farm/grower, with respect to the test results. The FDA will discuss with the farm/grower what voluntary action the farm/grower intends to take regarding the produce associated with the positive sample result. The FDA also will assess whether an on-farm, follow-up inspection is warranted and what actions may be needed to identify potential routes and sources of contamination. A follow-up inspection would seek to help the farm/ranch management identify practices or conditions that may present microbial risks so that they could improve the microbiological safety of their operation(s) and, ultimately, prevent potentially contaminated product from reaching consumers.

Should a farm/ranch hold product pending notification of test results?
Decisions on whether to harvest or hold product sampled by the FDA rest with the party responsible for the crop associated with the collected samples. The FDA requests that if product is not harvested or, if harvested product is held, the responsible party notify the agency for its situational awareness. If the responsible party does not hold product and the FDA detects one of the target pathogens, a voluntary product recall may be warranted.

The California Department of Food and Agriculture (CDFA) is inspecting farms in the Salinas Valley. Is this sampling related to the CDFA inspections?
The CDFA inspections and FDA sampling assignment are separate, related initiatives. CDFA and FDA are working in alignment, and sharing information as appropriate, to identify possible sources and routes of contamination of leafy greens grown in the Salinas Valley region, with the goal of helping farms/ranches to improve the microbiological safety of their operation(s).

I have additional questions. Where do I direct them?
The FDA has set up a dedicated email address for this assignment: salinassampling@fda.hhs.gov.