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Handling a Regulatory Sampling Request

This document was prepared by a subgroup of the United Fresh Food Safety & Technology Council Steering Committee. It is not legal advice. Please contact a food law attorney about legal questions.

How does FDA choose what products to sample?
Each year, FDA identifies items for their "sampling assignment," usually based on previous issues with that category. You can find details of the program here: https://www.fda.gov/Food/ComplianceEnforcement/Sampling/ucm473112.htm. In most targeted sampling assignments, FDA intends to collect about 1600 samples over the course of 18 months. During the course of any inspection (routine or for cause), FDA can include sampling as part of an inspection. Sampling does not have to be part of a commodity-specific sampling assignment.

What information does FDA need to provide to ask for a sample?
FDA should present credentials (badge and identification card) and a Form FDA 482, Notice of Inspection.

Can I refuse if an investigator asks for a sample?
Registered or not, if food is "manufactured, processed, packed, or held" in an establishment, that establishment is subject to inspection and sampling under section 704 of the Food, Drug, and Cosmetic Act. "Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge." Section 704(d).

You may charge FDA for the sample, if you wish.

If there is an attempt to refuse inspection and/or sampling, the establishment can expect FDA to return with an inspection warrant signed by a U.S. Magistrate Judge from a United States District Court. That inspection warrant is likely to grant even broader inspection powers to the agency than those customarily exercised under FDA's direct statutory authority. Refusal of inspection is also a prohibited, *i.e.*, criminal, act.

If preharvest pathogen testing was already conducted on the product, you can offer to share the details of the testing program, including results/trends with investigators. It is unlikely this will dissuade them from abandoning the assignment, but may aid in the scope of the sampling.

How should I manage a request for sampling?

- The tone of your conversation is important as is your attitude toward the investigators. Recognize they have a job to do and working with them not against them will be more to your benefit.
- It's recommended that you put that lot on hold and stop shipment of that lot until negative results have been confirmed. This is a business decision. If product is not held and a positive is

found, you will need to recall. Assuming you place the lot on hold, discontinue harvest of that field until negative results are received.

- Document sample collection via photo or video, as per your internal photography policy, recognizing that if you take photos/videos, it will be harder to dissuade FDA from taking its own. Consider allowing FDA to take close-up photographs that will aide them in the sample collection. This will potentially reduce sampling time.
- Follow your internal company policy regarding taking duplicate samples, recognizing that your negative test result will not "undo" a regulatory positive, and that any positive sample by your company (even in the face of a negative FDA sample) will result in the company having to take its own corrective action.
- Ask which laboratory will conduct the test, and request contact information for the official who can provide test results.
- Sign the sample receipt form provided by FDA (form FDA 484), and if you are placing product on hold, ensure this is noted on the form. This may help expedite analysis by the lab.

Sampling at the cooler or in a processing facility

- Encourage FDA agent to collect samples from lots that have not already been shipped into commerce.
- If the product has gone through a vacuum tube or other equipment where other products pass through, consider conducting a documented "clean break" that includes water change and sanitation.
- Do not rely on FDA to properly identify the bin, carton, container of product. Record lot information yourself and help FDA identify it properly on their paperwork. Record all pertinent information that would allow you to isolate Grower-Ranch-lot, harvest date, crew, harvest machine, and any other information that would help identify how the lot sampled could be segregated from other lots.
- If product has already been shipped into the marketplace you should notify the recipients that FDA has conducted routine microbiological sampling on that lot and to hold off on using it until negative results have been confirmed.

Sampling in the field

- Encourage FDA agent to collect samples from lots that have not already been harvested or shipped into commerce.
- Do not rely on FDA to properly identify the field, section, block, etc. Record lot information yourself and help FDA identify it properly on their paperwork. Record all pertinent information that would allow you to isolate field location. If possible mark sample locations with flags. If they collect samples from a field truck of harvested product try to isolate and identify the rows from which that product had been harvested.
- If product has already been harvested and shipped into the marketplace you should notify the recipients that FDA has conducted routine microbiological sampling on that lot and to hold off on using it until negative results have been confirmed.

Gather other important data for all samples in addition to the lot information such as:

- Preharvest pathogen testing results (if conducted)
- Water treatment records (if conducted)
- Weather conditions

- Last water date
- Field conditions
- Time of day

When will I get test results?
While FDA should call you with test results (both positive and negative), many members find that results are communicated more quickly if you call them. FDA expects negative results in 3-4 business days. If they "cannot rule out" (CRO) a positive, it will be sent for confirmatory testing, which could take another 6-8 business days. During that time, you can call FDA and ask about the status of the sample.

Related resources:
Handling a Swabathon; Handling a Regulatory Inspection