

DRAFT Guide to Handling a Regulatory “Swabathon”

This document was prepared based on the dialogue within round table discussions of the United Fresh Food Safety & Technology Council held January 10, 2017.

What is a Swabathon?

- FDA inspectors collect a large quantity of swabs looking for *Listeria monocytogenes*
- This may be done as part of a routine inspection or for cause, *e.g.*, after an inspection or as part of an epidemiological (epi) inspection trying to tie the epi data to a facility
- The reason for the inspection and size of the facility usually affect the quantity collected, with reported quantities ranging from 85 to 250 (or more for cause)

What areas are swabbed?

- This again depends on the reason for collecting the swabs
- Some plants report only Zones 1 and 2 for routine inspections; others had anywhere from none in Zone 1 to all four Zones
- Note that if the room being swabbed is less than 10,000 sq.ft., all areas that would normally be classified as Zone 3 or 4 will be classified as Zone 2
- You should feel comfortable asking the inspector to explain why certain areas are targeted

Is swabbing done pre-op or after some production has occurred?

- Most companies reported that the inspectors have required the line(s) to be swabbed to run for a minimum time, usually four hours, prior to swabbing
- One company reported that their attorney had advised them that this could not be required, although most attorneys feel that FDA has clear statutory authority to inspect and sample whenever a plant is running.
- If FDA insists on swabbing after some production, the company should explain to FDA what the impact will be on the production, *i.e.*, product will be held until test results are received and may have to be trashed if results are not timely received.
- There is concern as to the value of post-production sampling of Zone 1 for fresh-cut produce operations due to the possibility of pathogens coming in on the raw product and no kill step being applied

How are samples collected?

- Typically a team of three inspectors collects swabs:
 - One to prepare the swabs
 - One to perform the swabbing
 - One to document the swabbing locations (written and often photographs)

Should we take duplicate swabs?

- There are differing opinions on this:
 - Take them to get results sooner than typically expected from the FDA's swabs
 - Don't take them due to the fact that if the FDA's results are positive and yours are negative it doesn't matter; conversely if FDA's results are negative and yours are positive, you may have evidence of contaminated food contact surfaces

If swabs are collected post-production what should I do with the product run prior to swabbing?

- This depends on the shelf-life of your product. The FDA does not require you to hold the finished product but nearly all companies do because the risks associated with a positive result, *i.e.*, recall and potential exposure of the public to a public health risk

When can I expect to receive results?

- Reported waiting periods for results range from a few days to three weeks or more
- Suggest getting contact information for inspector and then following up within a few days to inquire about results

Tips for mitigating the effects of a Swabathon

- Develop a relationship with your District FDA office so that if difficulties arise during any inspection you know who to call
- Most FDA inspections, whether routine or for cause, will include swabbing. Therefore, upon arrival of inspectors it could be advantageous to stop production until their intent is known.
- As with any regulatory inspection, don't treat the inspectors as though they are "the enemy." Exhibiting confidence and having a positive demeanor will improve their confidence and may lead to you being able to negotiate the timing of the swabbing.
- Explain to the inspectors the impact of swabbing post-production (e.g. large quantities of finished and in-process product will have to be destroyed due to the short shelf life
 - Make alternate suggestions that meets the objective of investigator but limit product exposure
- Discuss the fact that if Zone 1 is swabbed post-production that it would not be immediately known if a positive result were due to the produce or the line. They are probably more concerned with the environment (food contact surfaces) containing pathogens.
- If swabbing is done post-production be sure to perform a full sanitation of at least the areas swabbed prior to re-starting production and, if re-starting during the same lot day, change the code on subsequent production to reflect the Clean Break
- Determine whether or not to retain or ship product produced prior to swabbing