How to Conduct an Environmental Assessment

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INTRODUCTION

In 2013, the Massachusetts Department of Public Health (MDPH), Bureau of Environmental Health (BEH) Food Protection Program (FPP) was awarded a cooperative agreement (RFA-FD-13-006) to maintain and sustain a Rapid Response Team (RRT). The RRT program was created to address the need for improved and integrated rapid response to food and feed emergencies. As part of this cooperative agreement with the U.S. Food and Drug Administration (FDA), the FPP within MDPH/BEH worked with a contractor to design an Environmental Assessment (EA) handbook that will be a companion document to the EA training video being developed for state food safety programs. This informational handbook provides a broad, yet accessible, reference guide to conducting a quality and effective EA for manufactured food facilities. It also fulfills the cooperative agreement’s “Mentorship” program objective for developing and offering tools and resources to assist other RRTs in developing their response capabilities.

This handbook is intended to help environmental health specialists in the field to effectively plan and implement an environmental sampling procedure, and coordinate assessment with any related public health investigation of suspect foodborne illnesses. State food safety programs can utilize the booklet as a field guide to help identify contributing factors and environmental antecedents that could have resulted in contamination of food product(s) during the timeframe of interest. Specifically, this document provides written guidelines on the sampling team roles and responsibilities, sample equipment required, potential zones or areas to collect samples, and various sampling techniques to avoid contaminating the sampling sites and samples to be collected. It also contains an environmental assessment checklist addressing key elements of the planning process. The guidelines were developed from a thorough review of EA literatures, information collected by the RRT EA Workgroup, and best practices identified by federal and state agencies that have conducted EAs. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the FDA.
SAMPLING TEAM

At minimum, sampling teams should consist of a Sampler (or Collector), an Assistant (or Handler), and a Scribe (or Recorder). One of these members must be designated as team leader. The team members must be trained and should review protocols prior to deployment.

SAMPLING TEAM LEADER

• This designation may be assigned to one of the following positions: Sampler, Assistant, or Scribe

• Responsibilities include completion (or delegation) of the following tasks:
  o Managing communications between the team prior to collection (hold a pre-meeting call, review procedures and forms)
  o Managing communications among multiple teams under the same outbreak response, if necessary
  o Notifying the laboratory personnel of quantity and types of samples and when they might arrive
  o Arranging for sampling supply kit delivery, pickup, or transport to sampling site
  o Ensuring the team has the necessary equipment and forms
  o Preparing sample labels prior to collection and preparing for contingencies regarding sample labeling
  o Reviewing the firm’s file and map of the facility (if available) to identify preliminary sampling site locations
  o Work with team members to identify final sampling sites after a walkthrough of the facility
  o Ensuring all significant sites are sampled and minimum sample quantities are met (per sampling assignment or laboratory guidelines)
  o Ensuring timeliness of sample delivery to the laboratory
  o Ensuring chain of custody is maintained throughout the entire sampling assignment
  o Preparing a brief summary of daily activities
  o Communicating final laboratory results to the firm (if appropriate)
SAMPLER
Responsibilities include the following tasks:

- Work with team members to identify sampling sites, as noted above (considering location, type, and number of samples to be collected)
- Aseptically collecting samples (washing hands, donning gloves, using sterile equipment and containers)
- Ensuring necessary control samples (i.e. unopened sampling supplies) are sent to the laboratory

ASSISTANT
Responsibilities include the following tasks:

- Washing hands and donning gloves
- Assisting the Sampler with donning gloves
- Preparing and presenting sampling equipment to the Sampler
- Preparing and presenting sterile sampling containers to the Sampler
- Labeling sample containers
- Sealing sample containers and placing them in cooler
- Managing sample preparation area, sample storage, supplies, and waste disposal
- Verifying all samples are labeled correctly (match each sample with the Chain of Custody form)
- Packing and shipping samples (maintaining chain of custody)

SCRIBE
Responsibilities include the following tasks:

- Verification and recording sample identifier, temperature, time, sampling implement, and sampling location on sample submission form, if/when appropriate
- Taking photographs of each sample location/collection, if/when appropriate
How to CONDUCT AN ENVIRONMENTAL ASSESSMENT

- Taking GPS readings (using GPS units or cameras with GPS capabilities) of each sample collection (when appropriate)
- Completing sample record and sample submission form

OTHER

Other roles that can be part of a sampling team include Liaison, Second Assistant, Photographer, Inspector, Sample Preparation/Supply Manager, and Data Entry. Full descriptions of these roles can be found in FDA’s RRT Best Practices Manual, 2016, Pages 11-9 – 11-10. All team members should be involved with maintaining the Chain of Custody.

SAMPLING EQUIPMENT

A list of sampling equipment can be found in Appendix B.

SAMPLES AND SAMPLING LOCATIONS

Ideally, collect from 100 up to 300 subsamples per production area in order to maximize the chance of finding the niche of the microorganism. In some circumstances, collecting 10 to 30 samples would be appropriate.

For example, *Salmonellae* tend to be more difficult to detect in a contaminated plant vs. *Listeria*, and a greater number of samples are need for *Salmonellae* environmental sampling in order to have confidence in swab findings/results.

SALMONELLA

- Collect at least 100 swabs/subs; ideally 300 or more subs
- Collect samples from Zones 2-3 (see below), concentrating primarily on Zone 2
- Zone 4 areas can be productive sites for the detection of *Salmonellae*, but can be difficult to link positive findings to a direct risk of product contamination
- Collect samples from equipment itself, particularly mounting and support structures

LISTERIA

A table of target areas for *Listeria* sample collection can be found in Appendix C.

- Primarily collect samples from Zones 1-2, focusing on areas where food is exposed and being processed
• To a lesser extent, collect samples in the Zone 3 area
• Every effort should be made to conduct sampling when the facility has been in production for **at least four hours and before any wet cleaning is performed**

### ZONES

- **Zone 1:** Direct food contact surfaces such as slicers, mixers, conveyors, utensils, racks, work tables, etc.

- **Zone 2:** Areas directly adjacent to food contact surfaces (Zone 1) such as the processing area, exterior of equipment, framework, food carts, equipment housing, gears, ventilation, air handling equipment, and floors.

- **Zone 3:** Areas immediately surrounding Zone 2, including corridors or doorways leading into food production areas. Walls, phones, and forklifts even if physically located in Zone 2, should be considered Zone 3 due to a decreased likelihood of cross-contamination.

- **Zone 4:** Areas immediately surrounding Zone 3, generally considered a remote area. Examples include an employee locker room, dry goods storage warehouse, finished product warehouse, cafeterias, hallways, and loading dock areas.

To minimize the potential for cross-contamination and to focus sample collection initially on the most relevant zones, start sampling at Zone 1 for *Listeria* and Zone 2 for *Salmonellae.*
How to CONDUCT AN ENVIRONMENTAL ASSESSMENT

DOCUMENTATION

A Sampling Plan Form can be found in Appendix D.

- Document and illustrate your observations and the locations of the environmental samples using diagrams, photographs, and journal notes.
- Document any violative conditions observed on an appropriate inspection form.

SAMPLER HYGIENE AND PROTECTIVE GEAR

SAMPLING GARB

- Hair and beard restraint (disposable)
- Hearing protection (earplugs or ear muffs)
- Clean disposable coverall suits
- Clean disposable booties
- Sleeve guards (per company policy)
- Helmet (per company policy)
- Face mask (per company policy)
- Approved footwear
- Single-use gloves

HAND WASHING

After dressing into clean and appropriate sampling garb, the next step is to thoroughly wash your hands. Although you may wear gloves during sampling, thorough handwashing is critical and must be done as you enter the production floor.

1. Wet both hands with warm water.
2. Dispense the soap provided at the station.
3. Work up a lather on both hands and forearms.
4. Scrub for 20 seconds, including your palms, back of your hands, between your fingers, under your fingernails and forearms.
5. Rinse your hands and forearms throughout in warm water – keep fingertips pointed downward.
6. Dry your hands using a single-use paper towel.
7. If water control is not automatic, do not use your bare hands to turn water off.

GLOVES
Wash your hands as you enter the production floor, before putting on gloves.

- Gloves will become contaminated if contact is made with non-sanitized surfaces (floor, outside of equipment, handles, hoses, or carts)
- If contamination occurs, discard the gloves and replace with new ones
- Replace gloves if they become soiled or torn
- Put on a fresh pair of gloves each time you take a sample
- Step away from the sampling site before removing your gloves

SAMPLING TECHNIQUES

SWABBING TECHNIQUES FOR SPONGES
Sample site: You should sample an area that is 12” x 12” (one square foot)

1. Wipe the sponge from left to right, covering the entire square.
2. Turn the sponge over and wipe up and down, covering the entire square.

SWABBING PROCEDURE FOR PRE-MOISTENED SPONGES

1. Grab the bag by the bottom and shake in a downward motion to move the sponge to the top of the bag.
2. Tear open the bag.
3. Push the sponge so that it is above the top of the bag.
4. Tear open the glove packet. Grab the glove by the cuff and place on the sampling hand (Do not set the opened bag down.)
5. Remove the sponge from the bag with the gloved sampling hand. (Do not touch the sample bag with your gloved hand.)
6. Squeeze the bag while removing the device to make a wide opening for when the sponge will be placed back in the bag.
7. Sample the surface by pressing evenly and firmly (as if you are scrubbing) (see swabbing techniques above).

8. After you have completed the swabbing, place the sponge back in the sample bag. (Do not touch the sponge to the outside of the sample bag.)

9. Remove your glove.

10. Squeeze as much air out of the bag as possible. Roll the top of the bag inward and fold over the wire tabs to secure.

11. Place the sponge bag inside another Whirl-Pak or equivalent bag and seal as before. Both bags must be tight enough to provide both a leak-proof seal and minimal airspace during shipment of the moistened sponge.

**SWABBING PROCEDURE FOR SPONGE ON A STICK**

1. Tear open the sample bag.

2. Push the sponge stick handle above the top of the bag.

3. Grab the handle and remove the device from the bag.

4. Squeeze the bag while removing the device to make a wide opening for when the sponge will be placed back in the bag.

5. Sample the surface by pressing evenly and firmly (see swabbing techniques above) (Do not touch the space between the thumbstop and sponge or the sponge itself.)

6. Place the sponge back inside the sample bag. Do not insert the handle past the thumbstop. (Do not touch the sponge to the outside of the sample bag.)

7. Break off the handle by holding the sponge in place from outside the bag and bending the handle back and forth. The sponge will drop to the bottom of the bag.

8. Discard the handle. Roll the top of the bag inward and fold over the wire tabs to secure.
SWABBING TECHNIQUES FOR STERILE SWABS

Sample site: You should sample an area that is about 4” x 4” (approximately 16 square inches) or 2” x 8”

1. Swab left to right, covering the entire square.
2. Swab up and down, covering the entire square.
3. Swab diagonally, covering the entire square.

Rotate the swab tip during the process and use firm pressure.

SWABBING PROCEDURE FOR PRE-MOISTENED SWABS

Wear a fresh set of gloves and use extra caution to prevent hands/gloves from coming in contact with the stem of the swab.

1. Press the pre-labeled swab against the edge of the tube to squeeze out excess medium.
2. Remove the sterile, pre-moistened swab from the tube.
3. Carefully swab surface (see swabbing technique above).
4. Insert the swab back in the tube so that it comes in contact with the medium and is remoistened. Press the swab against the edge of the tube to squeeze out excess solution.
5. Re-swab the same surface by changing direction by 90 degrees.
6. Reinsert the swab to moisten. Press the swab against the inside edge of the tube to squeeze out excess medium.
7. Re-swab the same site by changing to a diagonal direction.
8. Reinsert the swab and screw down the cap. The cap must be on tight to prevent leakage.

COLLECTED SAMPLES

Each collected sample must be clearly labelled with identifying information that matches the information listed on the Chain of Custody form. A Chain of Custody form can be found in Appendix E.

Collected samples must be placed in a dedicated cooler with ice packs in order to keep samples fresh but not frozen. Up to 20 samples are placed into a re-sealable plastic bag with an official sample seal placed around the opening of the bag (when appropriate).
Samples must be submitted to the laboratory as soon as possible. This will vary by pathogen. Time restrictions should be verified with the laboratory.
APPENDIX A/
ENVIRONMENTAL ASSESSMENT (EA) WORKSHEET

ENVIRONMENTAL ASSESSMENT CHECKLIST

EAs are intensive assessments and not routine inspections. An EA should identify and document events that occurred when the product of interest was handled, processed, or served. Each EA is different and this worksheet is not all-inclusive.

GENERAL OBJECTIVES

1. Protect public health by rapidly identifying the source of foodborne illness.
2. Coordinate assessment with any related public health investigation of suspect foodborne illnesses.
3. Identify contributing factors and environmental antecedents that could have resulted in contamination of food product(s) during the timeframe of interest.

PLANNING AND PREPARATION

Premobilization Conference Call:

- Review facility history.
- Review epidemiological information and identify timeframe of interest for assessment.
- Define high-level roles and responsibilities.
- Select laboratory.
- Develop hypotheses for how contamination and environmental antecedents could have occurred.

Detailed EA Logistical Planning Meeting:

- Identify EA objectives (i.e., assess facility process controls in place during timeframe of interest) and tactic to be used (i.e., collect finished product and environmental samples for testing).
- Determine resources and equipment required.
- Notify laboratory and discuss capacity and timeframe.

SITE VISIT

Initial Briefing:

- Introduce team and inform the person in charge (PIC) of the EA's objectives.

Facility Walkthrough:

- Observe all operations for product or process in question.
- Develop and attach a facility layout diagram and identify food flow, processes, production rooms, and equipment, etc.
- Develop or obtain a food flow chart that shows all steps from receiving ingredients to shipping final product; identify opportunities for contamination, survival, and growth at each step on the chart.
- Collect photographic evidence and other sources of objective data that could be used to assess process control points (i.e., temperature logs, test results, records of sanitizer taken, etc.).
Interviews:

Conduct interview and assessment with PIC.
Conduct interview and assessment with managers.
Conduct interview and assessment with employees.

Record Review (request copies of records for review and for the report/file):

Hazard Analysis Critical Control Point Plan:

- Product list
- CCP monitoring procedures
- Flow diagram
- Verification procedures
- Process description

Corrective action procedures
Identification of critical control points (CCPs)
Recordkeeping procedures
Identification of critical limits
Other

Written procedures showing the implementation of approved treatment method or combination of methods used to achieve a reduction in pathogens.

Logs:

- Production
- Temperatures
- Cooking
- Cooling
- Source water testing
- Other

Written policies:

- Training
- Employee health and hygiene
- Hand washing
- Cleaning and sanitizing
- Recall
- Other

Traceback for inputs—Collect copies of the following (indicate with a checkmark which were obtained):

- Invoices from supplier
- Quantities purchased during timeframe
- Lot numbers
- Sell by/expiration dates
- Production logs (identifying the specific lots used during timeframe)
- Supplier information
- Delivery schedules
- Other
Trace forward—Collect copies of the following (indicate with a checkmark which were obtained):

- Distribution/client list
- Product list
- Finished product code information (sell by/use by)
- Package Description
- Quantity produced during timeframe
- Special instructions from finished product label
- Quantity shipped during timeframe
- Batch size
- Production lots involved during timeframe
- Production schedule/logs
- Brand name(s)
- Other

**Sample Collection:**

Check which samples were collected:

- Environmental
- Raw ingredient
- In-line product
- Finished product

**POST-EA ACTIVITIES**

- Analyze and recommend controls
- Debriefing meeting
- Investigative report
- After action review (AAR)
## APPENDIX B/
### SAMPLING EQUIPMENT WORKSHEET

<table>
<thead>
<tr>
<th>Item</th>
<th>Suggested Quantity (per 100 samples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Sampling</td>
<td>__________________</td>
</tr>
<tr>
<td>Anticipated Number of Samples</td>
<td>__________________</td>
</tr>
<tr>
<td>Plastic bin tote (large)</td>
<td>1</td>
</tr>
<tr>
<td>Plastic bin tote (small)</td>
<td>1</td>
</tr>
<tr>
<td>Sampling tray</td>
<td>2</td>
</tr>
<tr>
<td>Sterile cups (4 oz.)</td>
<td>5</td>
</tr>
<tr>
<td>Plastic scoops, single-use (4 oz.)</td>
<td>5</td>
</tr>
<tr>
<td>Sterile forceps, single-use (4&quot;)</td>
<td>5</td>
</tr>
<tr>
<td>Plastic sterile spoons (3 tsp.)</td>
<td>5</td>
</tr>
<tr>
<td>Packing tape</td>
<td>1</td>
</tr>
<tr>
<td>Packing tape dispenser</td>
<td>1</td>
</tr>
<tr>
<td>Paper towel roll</td>
<td>1</td>
</tr>
<tr>
<td>Stopwatch</td>
<td>1</td>
</tr>
<tr>
<td>Alcohol prep pads</td>
<td>10</td>
</tr>
<tr>
<td>Medical scissors, student-type</td>
<td>1</td>
</tr>
<tr>
<td>Permanent marker</td>
<td>2</td>
</tr>
<tr>
<td>Small wrench to remove cart wheels</td>
<td>1</td>
</tr>
<tr>
<td>Isopropyl spray bottles</td>
<td>1 or 2</td>
</tr>
<tr>
<td>Hairnets, extra</td>
<td>2</td>
</tr>
<tr>
<td>Beard covers, if needed</td>
<td>2</td>
</tr>
<tr>
<td>Tyvek booties (pair), extra</td>
<td>1</td>
</tr>
<tr>
<td>Trash bags (13 gallon)</td>
<td>5</td>
</tr>
<tr>
<td>Trash bags (55 gallon), to wrap cart and line coolers (dark grey)</td>
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</tr>
<tr>
<td>Ziploc-style bags (12&quot; x 15&quot;), non-sterile</td>
<td>15</td>
</tr>
<tr>
<td>Whirl-Pak bags (6&quot; x 9&quot;), sterile</td>
<td>150</td>
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<tr>
<td>Metal notebook</td>
<td>1</td>
</tr>
<tr>
<td>Graph paper</td>
<td>1</td>
</tr>
<tr>
<td>Blank sample labels</td>
<td>180 (6 sheets)</td>
</tr>
<tr>
<td>Capless pens, stored in metal notebook</td>
<td>2</td>
</tr>
<tr>
<td>UPS shipping labels, stored in metal notebook</td>
<td>4</td>
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</tbody>
</table>
CD, with yellow sheet and instructions ................................................................. 2
Sample delivery lab guidance ................................................................. 1
Zone Concept handout ........................................................................ 1
Scribe cart instructions ......................................................................... 1
Sterile gloves, nitrile (1 pair, size 9, XL) ........................................... At least 120 (collector size)
Sterile gloves, nitrile (1 pair, size 8.5, L) ........................................... At least 40
Sterile gloves, nitrile (1 pair, size 7.5, M) ........................................... At least 40
Tyvek coveralls with hairnets, booties (Size L) ........... At least 2 sets per person
Tyvek coveralls with hairnets, booties (Size XL) .......... At least 2 sets per person
Tyvek coveralls with hairnets, booties (Size XXL) .... At least 2 sets per person
Tyvek coveralls with hairnets, booties (Size XXXL) ... At least 2 sets per person
Tyvek coveralls with hairnets, booties (Size XXXXL) At least 2 sets per person
Sponge-on-Stick (dry) ................................................................. 60
Hydra sponge (prehydrated) ............................................................ 40
Sterile swabs (prehydrated) ............................................................... 20-30
Dey and Engley (D/E) broth vials, flip-top ............................................. 80
Saline vials, sterile (5 mL) ............................................................... 20, if requested
Freezer packs (found in Rm. 210) .................................................. As needed for transport
Cooler (50 quart) ........................................................................ 1
Cooler (28 quart) ........................................................................ 1, if requested
Scribe cart ..................................................................................... 1
Shipping cooler, Styrofoam in cardboard ........................................ 1, if needed
Extension pole for sampling ......................................................... 1
Digital camera ........................................................................ 1
Camera batteries ........................................................................ 2 extra sets
Memory cards for camera .......................................................... 4 GB or more
Extra coolers ........................................................................ 1
Frozen ice packs ......................................................................... 12 or more
Insulated shipping containers ..................................................... 1 or 2
Flashlight ................................................................................ 1
DO Collect Samples From:

- Moist wet areas with standing water
- Direct food contact surfaces
- Floors and related areas—under floor-mounted equipment, scales (floor- and table-mounted)
- Sanitizing foot mats—if disinfectant is not maintained, this can be a good harboring source
- Cleaning equipment—automated floor cleaning equipment, brooms, mops, waste containers (especially underside), etc.
- Air conveying equipment—pressurized airlines, air hoses, condensate from pressurized air lines, HVAC evaporators, and evaporator condensate pans
- Product conveyors—cables, belts, joints, where product residue accumulates, exposed bearings and rollers
- Motor and electrical housings that are not cleaned and/or sanitized
- Cracked equipment—boots (shock-absorbing equipment), metal joints, etc.
- Under sinks/safety stations—under hand wash or eyewash stations if there appear to be leaks, cracks, etc.
- Equipment—areas that are difficult to reach and clean, non-food contact surfaces, nooks and crannies
- Doorways—floor area leading directly into production areas
- Drains—not during production
- Ice makers—inside, scoops, underside of top of ice chamber
- Ceilings and walls—in production areas, coolers, and freezers
- Door gaskets to coolers and freezers; damp insulation around pipes

DON'T Collect Samples From:

- Dry, clean areas
- Employees—work shoes, hands etc.
- Hand wash or eyewash stations
- Packaging materials—jars, lids, etc.
- Raw material—product raw materials, flour, peanuts, etc., or any food contact surface used exclusively for raw foods
- Outside the plant—roof, parking lot, walkways, etc.
- Areas with running water
- Zone 4
<table>
<thead>
<tr>
<th>ZONE</th>
<th>LOCATION / ITEM IN FACILITY</th>
<th>RELATIVE PROPORTION OF SAMPLING</th>
<th>NOTES</th>
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APPENDIX E/  
CHAIN OF CUSTODY FORM

Massachusetts State Public Health Lab  
305 South Street  
Jamaica Plain, MA 02130

Document Number/Name:  
ENVIRONMENTAL SAMPLE SUBMISSION FORM

Page 1 of 2

Type:  
Location: Food Lab

Implementation Date:  
Version Effective Date:  
Removed from service date:  
Issuing Authority:

Controlled COPY

Reason for Test:  
☐ Outbreak  
☐ Complaint  
☐ Surveillance  
☐ Routine  
☐ Salvage  
☐ Embargo (tag #)  
☐ other

Test(s) Requested:  
____________________________________________________________________

Select one:  
☐ Specimen(s) will be destroyed in ____ days after testing is complete  
☐ Hold specimen(s) until contacted by:  
____________________________________________________________________

Event Code:  
Outbreak Code:

Other Codes:  
Maven ID:

NAME/ADDRESS WHERE SAMPLE WAS COLLECTED

Organization Name:

Address:

Date of Collection:

Contact Person:

Phone Number:

Condition upon collection:

Detailed sample handling:

COLLECTOR INFORMATION

Organization Name:

Address:

Contact Person:

Phone Number:

DETAILED SAMPLE HANDLING:  
☐ Refrigerated  
☐ Frozen  
☐ On ice  
☐ Room Temperature  
☐ Other

Relinquished By:  
Print:  
Sign:  
Date/Time:

Received By:  
Print:  
Sign:  

Comments:  

Relinquished By:  
Print:  
Sign:  
Date/Time:

Received By:  
Print:  
Sign:  

Comments:  

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EVENT CODE: COLLECTION LOCATION:

<table>
<thead>
<tr>
<th>Inspector #</th>
<th>Sample Description (include lot #, date code and type of container)</th>
<th>Sample Temperature at collection</th>
<th>Lab #</th>
<th>Arrival Temp/ Gross Weight</th>
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If necessary, add additional pages and change the page # at the top of the additional lines pages. Date an initial the page # change. Ensure there the Event Code and Collection Location are at the top of each additional page.

See Attached Narrative Form

See Attached QA 4.9.1.1 F#1 Laboratory Sample / Specimen Rejection / Concession Form
SOURCES


Food and Drug Administration, *DFI Field Bulletin #32: Foods – Internal Testing Programs and Environmental Sampling*. February 2009


Silliker Education Services, *Swabbing Techniques for Sampling the Environment and Equipment*. 