Minnesota Department of Agriculture
Food and Feed Safety Division

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Version #: **2**	Effective Date: 5/10/16
Title: **Environmental Sampling – Food Manufacturing**	

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1. PURPOSE

This document describes the procedures used by Minnesota Department of Agriculture (MDA) Food and Feed Safety Division (FFSD) staff for collection of environmental swab and sponge samples in FOOD MANUFACTURING FACILITIES.

2. SCOPE

This procedure applies to the collection of environmental swab/sponge samples at FOOD MANUFACTURING FACILITIES as part of an U.S. Food and Drug Administration (FDA) Food Contract inspection, FDA/MDA joint inspections or investigations, or during other MDA investigations or surveillance sampling. The procedures described are applicable to sampling for Salmonellae and Listeria but not E. coli 0157:H7 or other Shiga-toxin producing E. coli or any other pathogens. This document is not intended to describe procedures used for routine sampling at retail food facilities, commercial feed establishments, dairy farms, or MN Equal To meat plants.

3. BACKGROUND

Sampling for products susceptible to microbial contamination and the environment in which they are produced may help identify the presence of pathogenic microorganisms in a food production environment before they can cause illness. Environmental contamination found during inspections in food manufacturing facilities and samples collected during those inspections may identify links to foodborne illness outbreaks. To establish evidence that the establishment is being operated in an unsanitary manner it is necessary to show that the manufacturing operation or conditions at the facility are likely to, or have contributed to bacterial load of the product. Procedures closely mirror those established by FDA in Field Bulletin #30.

4. RESPONSIBILITY

Manufactured Food Program Manager – The Manufactured Food Program Manager will make the final determination regarding assigned firms and analysis for environmental sampling unless this task is completed by the Division Director or Incident Commander or Operations Chief. The Manufactured Food Program Manager is responsible for the review of all policies and procedures and issue final approval of all Manufactured Food Program policies and procedures unless this person is the author as defined by FOOD.90.01.

Response, Training, and Outreach Supervisor – The Response, Training, and Outreach (RTO) Supervisor will assist the Manufactured Food Program Manager in the selection of appropriate firms for environmental sampling and the determination of the type and number of samples to collect.

Incident Commander or Operations Chief – The Incident Commander or Operations Chief will make the final determination regarding assigned firms and analysis for environmental sampling as well as the members of the Sample Collection Team when an investigation is managed under the Incident Command structure.

Training Coordinator – The Training Coordinator will ensure that all staff are trained in carrying out the responsibilities of this SOP.

Food Inspection Supervisor - The Food Inspection Supervisor will, with guidance from the Manufactured Food Program Manager, assist in the selection of appropriate firms for environmental sampling, the determination of the type of samples to collect, and the approval of the Sample Collection Team. They will also ensure that all assigned staff in their respective area follow the procedures described.

Inspector – The Inspector will follow procedures for the collection and submittal of environmental samples per this SOP and other applicable documents. The inspector will notify their supervisor when the procedures cannot be followed.

5. DEFINITIONS

FDA Contract Sampling Project Work Plan - A document created to define sample collection details, make assignments of contracted firms and Inspectors, and establish timeframes for sample collection for environmental and other samples collected under the current years FDA Food Contract. This document is created annually at the start of the Contract year by the designated Food Inspection Supervisor or Manufactured Food Program Manager or designee.

Food – Food includes every article used for entering into the consumption of, or used or intended for use in the preparation of food, drink, confectionery, or condiment for humans. Further clarification can be found in MN Statute 34A.01.

Food Manufacturing Facility – For the purpose of this SOP, a food manufacturing facility is not defined by license type (per MN Statue 28A, 32) but by type of operation. It includes operations that process or manufacture raw materials and other food ingredients (including dairy) into food items, or who reprocess food items, or who package food for sale to others for resale. It does not include a retail facility when the food is sold only in that retail facility.

6. PROCEDURES

6.1. Determine the need to collect environmental samples.

6.1.1. Select appropriate firm(s) for surveillance samples using one or more of the following criteria:

a. Current or historical evidence of sanitation issues at a firm;

b. Current or historical evidence of positive samples based on the firm's environmental monitoring programs;

c. Positive finished product sampling results (either collected by the firm or in the marketplace by a food regulatory agency) or recalls associated with the firm;

d. Historical information about the product being produced or industry as a whole, etc. Examples of possible firms/products include the following:

i. Listeria as the pathogen of concern– production of ready to eat potentially hazardous foods such as sandwiches or wraps, dips, soft or semi soft cheese or cheese spreads, peanut butter, fresh cut vegetables or fruit, smoked seafood, or deli-type salads;

ii. Salmonella as the pathogen of concern – ready to eat low moisture products including chocolate, peanuts or other tree nuts, breakfast cereals, dry seasonings, spices or herbs, dried fruits, peanut or other nut butters, snack food items (such as granola bars, or chips)**.** When assigned under FDA Food Inspection Contract for Environmental Sample Collection, firms are chosen during the Contract work planning process; however the final determination is made by FDA. The assigned firms and approximate inspection dates will be referenced in the current years' version of the FDA Contract Sampling Work Plan.

e. Other FFSD initiated surveillance assignments at food manufacturing operations may be initiated on an as-needed basis as directed by FFSD Program Management.

6.1.2. Select appropriate firm for investigation samples using one or more of the following criteria.

a. Known or suspect contamination in a firm's food processing environment that may have contributed to contamination of a food item with Salmonella or Listeria;

b. Positive finished product sample results.

Examples of incidents that may trigger investigation sampling include the following:

i. Reportable Food Registry (RFR) report indicating Listeria or Salmonella in a finished product

ii. MDA or other regulatory agency Listeria or Salmonella positive finished product sample results

iii. A foodborne illness investigation where a specific food or food manufacturing facility has been confirmed or is implicated (by statistical association to ill persons)

iv. Emergency event such as fire, flood, or storm which may have introduced the pathogen into a facility

v. Findings during a MDA routine inspection (inspectional conditions, record review, etc.)

6.1.3. Sample Collection Assignment Communication

a. The Manufactured Food Program Manager will assign the collection of Surveillance samples to be collected under the FDA Food Contract via the current year FDA Contract Sampling Project Work Plan. This will be emailed to all Inspection staff and Supervisors at the start of the Contract year.

b. The Manufactured Food Program Manager, or Incident Commander or Operations Chief (when an investigation is managed under and Incident Command structure) or designee will issue a Sample Request Form for notification of assignment for the collection of other surveillance samples (determined on an ad-hoc basis) or Investigation samples.

6.2. Determine the number of samples to be collected

6.2.1. Determine the number of environmental samples collected based on the following considerations:

a. Collect enough samples from the processing plant environment in order to fully evaluate the environment and detect even low levels of contamination. Since it is not unusual for a contaminated plant to yield only 1-2% positive environmental samples, an adequate number is needed to ensure that a thorough evaluation has occurred.

b. If the target pathogen is Salmonella, at least 100 samples are to be collected; ideally 300 if there are sufficient number of potential sampling sites. This is in addition to closed control samples. Salmonellae tend to be more difficult to detect in a contaminated facility and a greater number of samples are needed for in order to have confidence in negative findings.

c. If the target pathogen is Listeria, at least 50 samples are to be collected, ideally 100 or more if there are a sufficient number of sample sites. This is in addition to closed control samples.

d. If the size of the firm does not afford valuable sample sites to obtain the numbers above, sampling may still proceed, however the significance of the results to sample numbers collected will be considered.

6.2.2. The final number of samples collected is determined by the Sample Collection Team Lead based on the appropriate sample collection sites.

6.3. Assign a Sample Collection Team

6.3.1. Sampling collection teams will be assigned for both an investigation or for surveillance sampling in order to ensure that samples are collected efficiently, with limited opportunity for contamination, and to ensure an appropriate level of documentation.

6.3.2. For surveillance samples collected under the FDA Contract, the sample collection team will be approved by a Food Inspection Supervisor and is stated in the FDA Contract Sampling Project Work Plan

6.3.3. For other surveillance samples and investigation samples, the sampling team is determined by the Food Inspection Supervisor, Manufactured Food Program Manager, or Incident Commander or Operations Chief (when an investigation is managed under and Incident Command structure).

6.3.4. The preferred sample collection team consists of four people; a minimum of three is required. The team should include the area/assigned inspector (when possible); other members are chosen based on previous experience on sample collection teams, manufactured food inspection expertise, and inspectors availability to deliver samples to the lab (when practical). A Team Lead is assigned (who also fulfills one of the team member positions). Duties of the Team Lead can be found in *FOOD.WI.30.17.v.1 Environmental Sampling Lead Inspector Guide***.**

6.3.5. The general duties and roles of sample collection team members are listed in *Appendix A – Environmental Sampling Team Duty Assignments*. Roles/duties can be adjusted based on the assignment or the team's skills to make the team most efficient.

6.4. Collect samples

6.4.1. The Sample Collection Team will collect samples using the Zone Concept which identifies and prioritizes processing areas from highest risk and closest to the product to lowest risk and farthest from the product for potential contamination and harboring growth and niches for targeted pathogens.

6.4.2. A description of the Zones and sampling site selection guidance is available in *Appendix B Zone Description and Sampling Guidance*.

6.4.3. Identify lot numbers for any product produced in or stored adjacent to these swab locations and record on the Environmental Sample Collection Record

6.4.4. Collect environmental samples in multiple areas if product, personnel, or equipment used to process the products are moving from one area to another within the facility. Be aware of cross contamination issues in the plant between the floor and food contact surfaces and equipment and sample areas of potential cross contamination as necessary.

6.4.5. Provide the following information to the firm being inspected (either hard copy or web link)

a. MDA Environmental Sampling Guidance for Industry

b. MDA sampling methods/timeline (Salmonella and/or Listeria)

c. Guidance Documents (as applicable for the pathogen of concern)

i. GMA – Control of Salmonella in Low Moisture Foods, and/or

ii. FDA – Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready to Eat Foods

6.5. Submit samples

6.5.1. Submit samples according to *FOOD.WI.30.13.v.1 Environmental Sampling at Manufacturing WI*.

6.5.2. Refer to Sample Acceptance Criteria for direction regarding the following: temperature control, receipt temperature, and delivery timelines.

7. RELATED DOCUMENTS (includes References, Attachments)

- FDA Field Bulletin #30 – Food Program Area Instructions for Environmental Sampling October 2014
- Environmental Sample Collection Record
- FDA Draft Guidance for Industry Control of Listeria monocytogenes in Refrigerated or Frozen Ready to Eat Foods
- Grocery Manufacturers of America (GMA) Control of Salmonella in Low Moisture Foods
- FOOD 50.01 SOP - Investigation Procedures – Food or Environmental Contamination
- FOOD 50.04 Incident Command System (ICS) SOP
- FOOD.WI.30.13.v.1 Environmental Sampling at Manufacturing WI
- FOOD.WI.30.17.v.1 Environmental Sampling Lead Inspector Guide
- Sample Acceptance Criteria
- Current Year FDA Contract Sampling Project Work Plan
- Appendix A Environmental Sampling Team Duty Assignments
- Appendix B Zone Description and Sampling Guidance

8. EQUIPMENT/MATERIALS NEEDED

Refer to FOOD.WI.30.13.v.1 Environmental Sampling at Manufacturing WI

9. SAFETY

Employee safety is always the top priority during any type of field work. Remember to review all facility safety requirements and inquire about any site-specific hazards during your initial check-in with facility management. Comply with all facility personal protective equipment (PPE) requirements (glasses, safety shoes, hard hat, etc.) and stay in contact with your facility representative throughout the inspection process.

10. CIRCULATION

This document is circulated to the following: Manufactured Food Inspectors, Manufactured Food Inspection supervisors, compliance officers, compliance supervisor, and the food program manager. A standing version of this procedure is located in the Food Program SOP Library.

11. APPROVAL/DOCUMENT HISTORY

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Document History		
Version #	**Status (I, R)**	**Change History**
1	**I**	**Initial Policy Drafting.**
2	**R**	**Revision to reflect changes in DFI 30; move procedures to work instruction and Lead Inspector guide**

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Approved By:	**Date**
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I = Initial document; R = Revised document