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# 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.

# 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 inspections, 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.

# 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 potentially being operated in an unsanitary manner it is necessary to show that the manufacturing operations or conditions at the facility are likely to or have contributed to the bacterial load of the product.

# RESPONSIBILITY

# 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, determine the type of samples to collect, and the approval of the Sample Collection Team.

**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.

**Inspector –** The Inspector will follow procedures for the collection and submittal of environmental samples per this SOP and other applicable documents.

# 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.

**Response and Outreach Supervisor –** The Response 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.

# 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 co-pack food for wholesale. It does not include a retail facility where the food is sold only in that retail facility.

# PROCEDURES

# Determine the need to collect environmental samples

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

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

# Current or historical evidence of positive samples based on the firm’s environmental monitoring programs;

# 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;

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

# Listeria monocytogenes as the pathogen of concern– production of ready-to-eat potentially hazardous foods such as pasteurized and unpasteurized milk, high fat dairy products, sandwiches or wraps, dips, fresh soft or semi soft cheese (cottage cheese, cream cheese, ricotta, brie, camembert, feta) or cheese spreads, peanut butter, fresh cut fruits and vegetables, cooked or smoked seafood raw molluscan shellfish, or deli-type salads;

# Salmonella as the pathogen of concern – ready-to-eat low moisture products including chocolate, powdered infant formula, peanuts or other tree nuts (raw almonds), 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.

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

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

# 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;

# Positive finished product sample results.

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

1. Reportable Food Registry (RFR) report indicating Listeria or Salmonella in a finished product
2. MDA or other regulatory agency Listeria or Salmonella positive finished product sample results
3. A foodborne illness investigation where a specific food or food manufacturing facility has been confirmed or is implicated (by statistical association to ill persons)
4. Emergency event such as fire, flood, or storm which may have introduced the pathogen into a facility
5. Findings during a MDA routine inspection (inspectional conditions, record review, etc.)

# Sample Collection Assignment Communication

# 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 work plan. This document will be housed on the FDA Contract Inspections FY (fiscal year) SharePoint page in the Environmental Sampling current FY folder.

# The Manufactured Food Program Manager, or Incident Commander or Operations Chief (when an investigation is managed under the 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.

# Determine the number of samples to be collected

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

# 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.

# If the target pathogen is Salmonella, at least 100 samples are to be collected; ideally 300 if there are a 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.

# 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 potential sample sites. This is in addition to closed control samples.

# 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.

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

# Assign a Sample Collection Team

# 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.

# 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.

# 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 the Incident Command structure).

# 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 inspector availability to deliver samples to the lab (when possible). A Sample Collection Team Lead is assigned (who also fulfills one of the team member positions). Duties of the Sample Collection Team Lead can be found in *FOOD.WI.30.17 - Environmental Sampling Lead Inspector Guide*.

# The general duties and roles of sample collection team members are listed in *Appendix A – Environmental Sampling Team – Individual Task Assignments*, located at the end of this document. Roles/duties can be adjusted based on the assignment or the team’s skills to make the team most efficient.

# Collect samples

# The Sample Collection Team will collect samples using the Zone Concept which identifies and prioritizes processing areas from zone 1 (food contact) to zone 2, 3 and 4 (non-food contact) based on risk assessment.

# 6.4.2. A description of the Zones and sampling site selection guidance is available in *Appendix B - Zone Descriptions and Sampling Guidance*, located at the end of this document.

# Identify lot numbers for any product produced in or stored adjacent to these swab locations and record on the *Environmental Sample Collection Record* or separate document (as applicable).

# 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.

# Provide the following information as applicable to the firm being inspected (either hard copy or web link)

* + 1. MDA sampling methods/timeline (Salmonella and/or Listeria as applicable)
    2. Guidance Documents (as applicable for the pathogen of concern)
       1. GMA – Control of Salmonella in Low Moisture Foods
       2. FDA – Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-to-Eat Foods

# Submit samples

# Submit samples according to *FOOD.WI.30.13 - Environmental Sampling at Manufacturing WI*.

# Refer to the *Food Programs Sample Acceptance Criteria* for direction regarding the following: temperature control, receipt temperature, and delivery timelines and *FOOD.30.46 – Creating Food Samples in USAFS WI* for entry of samples into USAFS*.*

# RELATED DOCUMENTS (includes References, Attachments)

* Environmental Sample Collection Record
* FDA Draft Guidance for Industry: Control of Listeria monocytogenes Ready-To-Eat Foods
* Grocery Manufacturers of America (GMA) – Control of Salmonella in Low Moisture Foods
* FOOD.WI.30.13 - Environmental Sampling at Manufacturing WI
* FOOD.WI.30.17 - Environmental Sampling Lead Inspector Guide
* FOOD.30.46 – Creating Food Samples in USAFS WI
* Sample Request Form
* Current Year FDA Contract Sampling Project Work Plan
* MDA Sampling methods/timeline (Salmonella and Listeria)

# EQUIPMENT/MATERIALS NEEDED

N/A

# 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.

# CIRCULATION

This document is circulated to the following: Manufactured Food Program Staff and the RO Supervisor. The current version will be stored electronically on the FFSD document control site.

**FOOD.30.10 Appendix A**

Environmental Sampling Team - Individual Task Assignments

|  |  |
| --- | --- |
| **Four Person Sampling Team**   1. Scribe  * Record sample number and detailed location on sample collection record * Record the sample number and location on the facility map * Assist with packaging finished samples and supplies  1. Sample Prep and Supply Manager  * Manage sample prep area, supplies and trash * Label samples * Take photograph of sample location/collection * Assist with packaging finished samples and supplies  1. Sampler  * Take samples * Assist lead in deciding sample locations * Assist with packaging finished samples and supplies  1. Sampler Assistant  * Assist sampler with donning gloves * Prepare swab sample * Run samples between sample prep area and sampler * Assist with packaging finished samples and supplies * \*\*Sample Team Lead will complete the sample submission in USAFS. | **Three Person Sampling Team**   1. Scribe  * Record sample number and location on the sample collection record * Record sample number and location on the facility map * Take photograph of sample location/collection * Assist with packaging finished samples and supplies  1. Sampler  * Take samples * Assist lead in deciding sample locations * Assist with packaging finished samples and supplies  1. Sampler Assistant  * Assist sampler with donning gloves * Prepare swab sample * Label samples * Manage sample prep area, supplies and trash * Assist with packaging finished samples and supplies * \*\*Sample Team Lead will complete the sample submission in USAFS. |

**FOOD.30.10 Appendix B**

**Environmental Sampling – Zone Descriptions and Sampling Guidance**

**Zone Descriptions**

Zone 1: refers to all direct food contact surfaces such as slicers, mixers, conveyors, utensils, racks, work tables, etc. When it has been determined that *Salmonella* is the pathogen of concern, food contact surfaces are normally not sampled unless specifically requested in the assignment. In contrast, when *Listeria monocytogenes* is determined as the pathogen of concern, sampling of food contact surfaces is essential to sample.

Zone 2: encompasses the areas directly adjacent to food contact surfaces (zone 1). When it has been determined that *Salmonella* is the pathogen of concern, this is the area where environmental contamination is most likely to directly affect safety of the product. In a small production room, zone 2 encompasses all non-food contact surfaces in the processing area, such as the exterior of equipment, framework, food carts, equipment housing, gears, ventilation and air handling equipment, and floors. In a much larger room (e.g. 20,000 square feet) zone 2 is the area around the exposed product in which you could envision a pathway to product contamination either through the actions of man or machine; for example, even a far corner of the room could be considered zone 2 if foot traffic or forklifts move through that area and these traffic patterns also go very near a line where exposed food is conveyed or held, or ventilation patterns cause airflow from these remote areas.

Zone 3: is the area immediately surrounding Zone 2. Zone 3 is an area which, if contaminated with a pathogen, could lead to contamination of zone 2 via actions of humans or movement of machinery. Examples of zone 3 areas include corridors and doorways leading into food production areas or areas in a large production room that are further away from food handling equipment than typical zone 2 areas. Walls, floors, phones, forklifts and “mules”, even if physically located in zone 2, should be considered zone 3 due to a decreased likelihood of cross-contamination.

Zone 4: the area immediately surrounding zone 3, generally considered a remote area. Zone 4 is an area which, if contaminated with a pathogen, could lead to contamination of zone 3 via the actions of humans or machinery. Examples of zone 4 areas include an employee locker room if not immediately adjacent to food production rooms, dry goods storage warehouse, finished product warehouse, cafeterias, hallways, and loading dock areas.

**Salmonella Sampling Guidance**

*Salmonellae* survive well in low moisture environments, especially those that are dry for long periods of time and occasionally get wet. *Salmonellae* survive drying particularly well and are difficult to kill withheat when they are dehydrated or in low moisture products such as chocolate and peanut butter.

When conducting sampling for *Salmonellae*, food contact surfaces (Zone 1) are normally not sampled unless specifically requested by the assignment. *Salmonellae* are most often found in low-lying, non-food contact surface areas of a processing a facility and sampling therefore should be focused mainly in Zone 2 and Zone 3, and only very rarely in Zone 1. It is recommended that no environmental samples be collected from Zone 4. When sampling very small production rooms, every surface not considered a Zone 1 would be considered a Zone 2 due to the high likelihood of cross contamination.

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| **Salmonellae samples** | |
| **DO Collect Samples From:** | **DON’T Collect Samples From:** |
| Floors and related areas - under floor mounted equipment, scales (floor and table mounted) | Employees - work shoes, hands, etc. |
| Sanitizing foot mats if dry | Hand wash or eyewash stations except where noted to be in a condition as described above |
| Cleaning equipment - central vacuum systems, automated floor cleaning equipment (e.g. Tenet type walk-behind or riding sweepers, brooms, mops, etc). Pay particular attention to the collection of floor sweepings or the dry contents of vacuum cleaner bags or tanks | Packaging materials - jars, lids, etc. |
| Air conveying equipment - air filters, air ducts, intake and exhaust vents, food residue on equipment and floors | Direct food contact surfaces - cleaned often and not likely to have residual organism growth. |
| Product conveyors - cables, belts, joints where product residue accumulates if the residue is old and dry | Raw ingredients - raw peanuts, refined sugar, etc. unless specifically assigned to do so |
| Unsealed control and drive chamber; electrical/mechanical service boxes that are not cleaned and/or sanitized. Look for dry dust and residue in these boxes. | Outside the plant - roof, parking lot, etc. |
| Cracked equipment - boots (shock absorbing devices), metal joints, etc. | Areas with running water and very wet areas |
| Under sinks/safety stations - under hand wash or eye wash stations of they appear to be cracked, leaking, etc. | Zone 4 |
| Equipment - areas that are difficult to reach and clean, non-food contact surfaces, nooks and crannies if dry. | Floor drains – not during production |
| Doorways - floor area in doorways leading into or out of the production facility or onto the roof |  |
| Pallets - floor under wooden pallets and pallets themselves |  |
| Areas surrounding floor drains – those with rough or exposed aggregate |  |

**Listeria sampling guidance**

The various ways *Listeria* can enter food processing plants, its ability to grow and survive for long periods of time in the environment, on foods, and in food processing plants and its ability to grow at low temperatures and to survive in or on food for prolonged periods under adverse conditions make it a pathogen of concern for refrigerated, ready-to-eat foods.

When sampling for *Listeria*, sampling of food contact surfaces (Zone 1) is essential. In general, when sampling for *Listeria* most samples should be collected from Zones 1 and 2, to a lesser degree in Zone 3. Sampling for Listeria should be performed in, on, and around food contact equipment; focusing on areas where food is exposed and being processed, particularly post-lethal treatment/pasteurization. Generally, Zone 4 areas are unproductive for Listeria and positive findings in Zone 4 are very difficult to link to a risk of product contamination, thus no environmental samples should be taken from Zone 4 areas.

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| **Listeria Samples** | |
| **DO Collect Samples From:** | **DON’T Collect Samples From:** |
| Moist/wet areas with standing water | Dry, clean areas |
| Direct Food Contact Surfaces | Employee’s work shoes, hands, etc. |
| Floors and related areas – Under floor mounted equipment, scales (floor and table mounted) | Hand wash or eyewash stations |
| Sanitizing foot mats – if disinfectant is not maintained this can be a good harboring source and point of transfer to other areas of the facility | Packaging materials - jars, lids, etc. |
| Cleaning Equipment – automated floor cleaning equipment, brooms, mops, waste containers, especially underside, etc. | Raw agricultural products – raw peanuts, etc. or any food contact surface used exclusively for raw foods |
| Air conveying equipment – pressurized air lines, air hoses, condensate from pressurized air lines, HVAC evaporators and evaporator condensate pans | Outside the plant - roof, parking lot, walkways, etc. |
| Product Conveyors – cables, belts, joints, where product residue accumulates, exposed bearings and rollers, sponge or felt rollers used to remove moisture from product | Zone 4 |
| Motor and Electrical Housings that are not cleaned and/or sanitized | Floor Drains – not during production |
| Cracked Equipment – boots (shock absorbing equipment), metal joints, etc. |  |
| Under sinks/safety stations – under hand or eyewash stations if appearance of 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 |  |
| Areas surrounding floor drains – those with rough or exposed aggregate |  |
| 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 |  |