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1. **PURPOSE**

The purpose of this procedure is to provide direction for uniformly determining overall risk category and inspection frequency for food manufacturing and distributing operations that are currently regulated by the Minnesota Department of Agriculture Food and Feed Safety Division (MDA-FFSD).

1. **SCOPE**

This procedure applies to MDA-FFSD regulated food establishments that are considered manufacturers or distributors as defined in this procedure. This procedure applies to all firms subject to the applicable regulations, whether the firm holds a MDA Food Handler license, is not yet licensed, is excluded from licensing requirements in MN Statute 28A.15 or is primarily a Retail Food Handler, but has Manufactured Food as a secondary business program. This procedure also applies to Manufactured Food Program inspections at dairy or meat plants regulated by MDA – Dairy and Meat Inspection Division when the food products are NOT covered by USDA or MN Equal-to meat inspection programs, the Pasteurized Milk Ordinance, or another MDA Dairy Program inspection procedure. See *Dairy Inspection and Manufactured Food Programs Memorandum of Understanding and Working Agreement*.

1. **BACKGROUND**

In 2000, a risk-based inspection approach was developed which included prioritizing inspections based on the risk category assigned to all food establishments (retail and wholesale). The risk category was based on the establishment’s operation as it related to the risk of causing foodborne illness. The division developed criteria for high, medium, and low risk categories. The inspection frequency was determined based on the risk category of the food establishment. This was developed in part by using the U.S. Food and Drug Administration (FDA) Retail Food Code Annex 5: “Conducting Risk-based Inspections”. There is a separate procedure, *FOOD.30.16 – Retail Risk Category SOP*, that applies to retail food operations based on the Retail Food Regulatory Program Standards (RFRPS).

In reassessing the SOP and the Appendix (risk classifications), consideration was made regarding the types of process(es) conducted and/or of food produced at a facility, with further consideration for the following factors: foods with microbial/chemical hazards that are more challenging to control consistently, foods with epidemiological implication in foodborne disease outbreaks, and products or processes where Listeria or Salmonella are pathogens of concern in the processing environment. Firms that manufacture food specific to a target population are classified high risk (represented as MH18 Medical Foods or other foods consumed only by Highly Susceptible Populations). Previous versions of this SOP addressed increased inspection frequency based on high volume manufacturers. In applying that criteria in the past, in no case was the inspection frequency ever increased because of that specific factor. For facilities with a previous compliance/enforcement history, the risk classification does not change per se, however the inspection frequency does increase, to more quickly assess overall compliance and specific violations.

1. **RESPONSIBILITY**

**Manufactured Food Program Manager –** The Manufactured Food Program Manager will assist in the determination of an increased inspection frequency as needed.

**Manufactured Food Supervisor –** The Manufactured Food Supervisor will assist in the determination of an increased inspection frequency as needed and update the inspection frequency in the electronic inspection system.

**Manufactured Food Inspector –** The Manufactured Food Inspector will determine and select appropriate risk classifications and overall risk category for a facility during each inspection and determine need for an increased inspection frequency in consultation with the supervisor and compliance officer as needed.

**Compliance Officer** – The Compliance Officer will assist in determining the need for an increased inspection frequency in consultation with the inspector and supervisor.

1. **DEFINITIONS**

**Amenable:** products that are subject to the USDA Meat Products Inspection Act and Poultry Products Inspection Act. See *Appendix B – Amenable and Non-Amenable Food Items*.

**Chronic Violator**: a chronic violator is a legal entity that has an approved enforcement action equal to or greater than a Warning Letter and that has had a prior enforcement action equal to or greater than a Warning Letter issued in the last three (3) years.

**Cold storage warehouse:** an enclosed cold space or group of cold rooms located within a building in which foods are stored and held for 30 days or more. Ref MN Statute 28.01 Subd 3.

**Distributor:** any individual, firm, corporation, company, association, cooperative, or partnership who sells food to others for re-sale (warehouse, wholesale food handler), stores or handles food for another, including buildings, trucks, trailers or other portable structures. Additionally, for the purpose of establishing the appropriate risk category, any firm that is a distributor as described above is considered a distributor, no matter the licensing category. A Distributor (as defined in this policy) does not manufacture or process any food. Additionally, a firm that is licensed as a Manufacturer, but whose only operations is storage of food (no processing), is considered a Distributor when establishing the risk category (i.e. Cold Storage Warehouses).

# Enforcement Actions: enforcement actions are informal (non-appealable) or formal (appealable) actions taken outside of an inspection to achieve compliance with regulations. These actions include, but are not limited to Notice of Repeat Violation, Warning Letters, Corrective Action Orders, Administrative Meetings, issuance of penalties (civil or administrative), Criminal Prosecution, License Limitation or Revocation, Injunction, or other court actions. These actions are initiated by a firm’s non-compliance with regulatory requirements as evidenced by an inspection report, violative sample results, or other collected documentation of conditions.

# Field Compliance Actions: field compliance actions are actions performed during an inspection to achieve compliance with regulations. These actions include, but are not limited to, reinspections, cease and desist orders, and embargos. These actions are initiated by a firm’s non-compliance with regulatory requirements as evidenced by an inspection report, violative sample results, or other collected documentation of conditions.

**Food Broker:** a food broker is a person who buys and sells food and who negotiates between a buyer and a seller of food, but who at no time has custody of the food being bought and sold. (MN Statute 28A.05 d).

**Food Salvor:** a food salvor or salvage food processor is any individual, firm, corporation, company, association, cooperative, or partnership who performs the act of cleaning, culling, sorting, scouring, labeling, relabeling, or in any way treating "distressed food" so that it may be deemed to be "reconditioned" or "salvaged food" and therefore is acceptable for sale or use as human food, animal feed, or seed as provided therefor by the commissioner. (MN Statute 31.495 Subd 1).

**Highly Susceptible Population:** include immuno-compromised persons, preschool age children, or older adults; and persons who obtain food at a facility that provides services such as custodial care, health care, assisted living, a child or adult day care center, kidney dialysis centers, hospital or nursing home, or nutritional or socialization services (senior citizen centers).

**Manufacturer:** any individual, firm, corporation, company, association, cooperative, or partnership who processes or manufactures raw materials and other food ingredients into food items, or who reprocess food items, or who package food for sale to others for resale. This includes those who extract, ferment, distill, pickle, bake, freeze, dry, smoke, grind, mix, stuff, pack, bottle, recondition, or otherwise treat or preserve food for sale to others for resale and also to salvage food processors.

Additionally, for the purpose of establishing the appropriate risk category, any firm that conducts manufacturing operations as described above is considered a manufacturer, no matter the licensing category or if excluded from licensing requirements. For example, a firm that manufactures food but is licensed as a Wholesale Food Handler as prescribed by MN Statute 28A.05 because wholesaling/distributing is their principal mode of business is considered a Manufacturer when establishing the risk category. The same would be true for a licensed Retail Food Handler that also manufacturers food for sale to others for resale.

**High Risk Food:** a manufactured food where there is a high potential risk for microbiological or chemical contamination or when consuming a particular food will result in illness or injury due to contamination of the food. There is historical data for the food being epidemiologically associated with foodborne illness outbreaks.

**Non-Amenable:** products that are NOT subject to the USDA Meat Products Inspection Act or the Poultry Products Inspection Act

**Packaged:** packaged means bottled, canned, cartoned, securely bagged, or securely wrapped.

**Potentially Hazardous Food (PHF), also known as Time/Temperature Control for Safety Food (TCS):** A food or a food ingredient consisting in whole or in part of: milk products, eggs, meat, fish, raw shell eggs, poultry or other food or food ingredient which is capable of supporting growth of infectious or toxigenic microorganisms. PHF/TCS food requires time and temperature control to limit pathogenic microorganism growth or toxin formation.

**Process:** Process is the treatment of food substances in such a manner to change its properties with a view to preserving it, improving its quality or making it functionally useful.

**Ready-To-Eat (RTE):** "Ready-to-eat food" means food that is in a form that is edible without washing, cooking, or additional preparation by the firm or the consumer to achieve food safety, and that is reasonably expected to be consumed in that form.

**Repackaging**: moving products from one container into other package - product is exposed (not packaged) at some point in the process.

**Repacking**: individually packaged components being reassembled into a different package/container. All product is in a package and remains so throughout the process.

**Retail food establishment**: any individual, firm, corporation, company, association, cooperative, or partnership who sells food directly to a consumer (as defined in the MN Food Code).

**Risk Category (Level):** Risk category (risk level in USA Food Safety (USAFS)) is the overall risk determination for a facility and includes High (H), Medium (M), and Low (L).

**Risk Classification (Facility Classification):** Risk classification (facility classification in USAFS) is the specific product produced by, or process conducted by, the facility that helps define the overall risk category for the facility.

**Routine Inspection**: An inspection with a predetermined frequency as outlined in *FOOD.30.08-Manufacturer and Distributor Risk Category SOP*, or as otherwise determined by the Manufactured Food Program Manager, with 21CFR117 used as the base regulation to determine overall compliance.

**Specialized Process:** Includes food produced under Seafood HACCP (21 CFR 123), Juice HACCP (21 CFR 120), Low Acid Canned Foods (21 CFR 113), and Acidified Foods (21 CFR 114).

1. **PROCEDURES**
   1. **Select Risk Classifications (Facility Classifications)**
      1. Determine all appropriate risk classifications using the current version of *Appendix A: Risk Categories – Manufacturing and Distributing* (located at the end of this document) based on the manufacturing food establishment’s food business operations during every inspection.

Example: A firm washes, cuts, and packages produce. The firm also repackages salads including a seafood salad and therefore would receive **all** the following risk classifications based on *Appendix A*: *Risk Categories – Manufacturing and Distributing*

MH4, MH7, MH11

* + 1. Determine if the establishment also conducts retail operations. If yes, email the E-Systems Administrator and the Retail Food Program Inspector notifying them that a Secondary Business Program needs to be added to the facility in USAFS. Include the USAFS facility ID number, name of the facility, and retail products/processes being conducted. The E-Systems Administrator will add the Secondary Business Program and the retail inspector will update the risk classifications associated with the retail operations.
    2. Record all specific risk classifications associated with the establishment in USAFS, both Manufacturing/Distributing and Retail. Refer to the applicable USAFS guidance for entering this information.
  1. **Determine the Overall Risk Category (Level)**
     1. Select or review the overall risk category (level), High (H), Medium (M) or Low (L) for the facility or manufactured food business program portion of an operation when there is more than one FFSD Program responsibility. This is based on the highest risk classifications that apply as assessed during each inspection. Refer to the applicable USAFS guidance for entering this information into USAFS.
  2. **Inspection Frequency**

Food Inspector

* + 1. Conduct Inspections at the baseline frequencies listed below for the establishment (or for the manufacturing portion of the operation (business program) if a joint program facility):

High Risk manufacturer/distributor: High risk manufacturer/distributors are inspected at a baseline frequency of once every twelve (12) months.

Medium Risk manufacturer/distributor: Medium risk manufacturer/distributors are inspected at a baseline frequency of once every eighteen (18) months.

Low Risk manufacturer/distributor: Low risk manufacturer/distributors are inspected at a baseline frequency of once every twenty-four (24) months.

* + 1. Conduct a full routine inspection at newly licensed facilities

At the time of licensing when the firm is operational at that time, such as for ownership changes, assigned FDA Contract Inspections, food warehouses etc. OR,

within 90 days of licensing

* + 1. When the inspection frequency cannot be met as described above, inspectors are to prioritize their inspections based on *Manufactured Food Program Work Priorities.*
    2. If an inspection is due and there is an open enforcement case for that facility, notify the Supervisor for guidance on when to conduct the inspection.

Food Supervisor

* + 1. Increase the routine inspection frequency by six months from the last routine inspection for one inspection cycle if the establishment:
       1. Had a sanitary notice issued during the current inspection; or
       2. Had a FIELD COMPLIANCE ACTION occur during the previous inspection that was not complied with and was referred to the Compliance Unit; or
       3. Has had an ENFORCEMENT ACTION greater than a Warning Letter, with recommendation for increased frequency upon case closure, in the past twelve months; or
       4. Upon notification from the Compliance Officer, meets the definition of a CHRONIC VIOLATOR; or
       5. Is referred to the Compliance Unit and further discussions between inspector, supervisor, program manager, and the Compliance Unit determines that increased inspection frequency is needed.

Example: A firm is classified as overall Medium Risk and is issued a Sanitary Notice on 1/2/2019. The firm was found in compliance on the reinspection conducted 1/6/2019. Increase frequency to every twelve months for one year, so an inspection will need to take place by 1/2/2020.

\***Note** that an action described above at a Joint Program Facility may be issued by the Retail Program but may have impact on the manufacturing portion of the facility as well, indicating a need for an increased inspection frequency.

* + 1. Document this change in frequency by adding an internal note with the reason for the increased inspection frequency per the applicable USAFS Guidance/Work Instruction.
    2. Return the firm to the normal assigned inspection frequency when the next routine inspection has been completed and the inspection results indicate there is no need for an increased inspection frequency.
    3. On notification from the inspector that an inspection is due and there is an open enforcement case, consult with the Compliance Unit to further assess when the inspection should occur.
    4. Set the Inspection Frequency to zero (0) in USAFS for firms that have no need for a routine inspection, (e.g. food brokers and manufacturers that only have Dairy Inspection responsibilities per the *Dairy Inspection and Manufactured Food Programs Memorandum of Understanding and Working Agreement*.)

**7.** **RELATED DOCUMENTS (includes References, Attachments)**

Dairy Inspection and Manufactured Food Programs Memorandum of Understanding and Working Agreement

Manufactured Food Program Work Priorities

USAFS Guidance/Work Instruction

1. **EQUIPMENT/MATERIALS NEEDED**

N/A

1. **SAFETY**

N/A

1. **CIRCULATION**

This document is circulated to the following: Manufactured Food Program Inspection Staff, Manufactured Food Supervisors, Manufactured and Retail Food Program Managers, Compliance Unit, and MFRPS Coordinator. The current version will be stored electronically on the FFSD document control site.

**Appendix A**

**Risk Categories – Manufacturing and Distributing**

**HIGH RISK MANUFACTURERS**

High risk manufacturing establishment category consists of firms that complete one or more of the following:

1. Produce potentially hazardous foods/ time/temperature control for safety (PHF/TCS) that are considered ready to eat or are considered specialized processes as defined in the definitions section of this SOP;
2. Conduct high risk production such as canning, low acid foods, acidifying foods.
3. Process potentially hazardous food frequently implicated in foodborne illness such as unpasteurized juices, raw shellfish, cream filled pastries, or filled macaroni products.

MDA-FFSD considers these manufactures to be high risk based on the type and processing of foods (potentially hazardous foods or foods associated with foodborne illness), their ready-to-eat status (likelihood that there will not be a further kill or wash steps to eliminate risk potential), or these manufacturers engage in production and processing that is defined by regulation as specialized processing.

**SPECIFIC PROCESS TYPE HIGH RISK/FACILITY CLASSIFICATIONS**

MH1 - Low Acid Canned Foods

MH2 - Acidified Foods

MH3 - 100 % Juice - a Juice HACCP plan is required

MH4 - Fish/Seafood products - a Seafood HACCP plan is required

MH6 – Sandwiches

MH7 – Salads

MH8 - Vegetable freezing plants

MH9 – Beverages requiring refrigeration for food safety (juice blends, soy or nut milk, cold brew coffee (not LACF) etc.)

MH11 - Fresh cut produce (produce items, peeled, cut, chopped on-site)

MH12 - Repackaging PHF/TCS only

MH13 - Other foods that are ready to eat potentially hazardous foods (PHF/TCS s) not listed above such as a bakery producing cheesecake, pumpkin pie, cream filled pie/pastry, etc.

MH14 - Peanut or other Nut Butters

MH18 - Medical Foods or other foods consumed only by Highly Susceptible Populations

**MEDIUM RISK MANUFACTURERS**

Medium risk manufacturing establishment category consists of manufacturers that process food products that are either ready to eat foods or potentially hazardous, but not both. MDA-FFSD considers these manufacturers to be medium risk because the food product being processed has some risk associated with it, but it does not rise to the risk level associated with foods that are both potentially hazardous and ready-to-eat or require special processes to control risk.

**SPECIFIC PROCESS TYPE MEDIUM RISK/ FACILITY CLASSIFICATIONS**

MM1 - Candy manufacturer

MM2 - Snack food manufacturer- potato chips, pretzels, nuts, granola bars, etc.

MM3 - Bottled water

MM6 - Food Banks repackaging foods

MM7 – Cereal/granola manufacturer

MM8 - Fermented and Acid Food Processors (such as kraut, mayonnaise, BBQ sauce, salsa, kombucha, kimchi, salad dressings, and other condiments that receive a heat treatment)

MM10 - Bakeries with Non- PHF/TCS s

MM15 - Dry ingredients/mixes/spices

MM18 - Other foods not previously listed that are non- PHF/TCS and RTE, and PHF/TCS that is not RTE

MM 21 - Spray Drying (Salmonella as pathogen of concern)

MM22 - Food Salvors

**LOW RISK MANUFACTURERS**

Low risk manufacturers consist of firms which do not process products that are ready-to-eat or potentially hazardous. MDA-FFSD considers these manufacturers to be low risk because the food product being processed is not potentially hazardous and there will be a further kill, wash or other processing step prior to consumption.

**SPECIFIC PROCESS TYPE LOW RISK/ FACILITY CLASSIFICATIONS**

ML1 - Flour mills

ML2 - Malting plants

ML3 - Dry bean cleaning or packaging plants

ML4 – Coffee roaster or tea (dry)

ML5 - Wild rice processors

ML6 – Facilities producing product under USDA inspection (meat, poultry, shell eggs, liquid eggs)

ML7 - Other processors of non-PHF/TCS not listed above including mobile bottling operations

ML8 - Soft drinks (pop, soda, energy drinks)

ML9 – Ice manufacture

ML10 - Sugar (and other sweeteners) processors

ML11 - Dietary supplements

ML12 - Edible oil processors or extractors

ML13 - Repacking non- PHF/TCS only

ML14 - Maple syrup processors

ML15 - Honey processors

ML16 - Brewery

ML17 - Winery

ML18 - Distillery

**HIGH RISK DISTRIBUTORS**

High risk distributors consist of distributors that are required to have a Seafood HACCP plan. MDA-FFSD considers these distributors to high risk because they require a HACCP plan due to possible risks associated with seafood.

**SPECIFIC PROCESS TYPE HIGH RISK/ FACILITY CLASSIFICATIONS**

DH1 - Food warehouses requiring a Seafood HACCP plan

**MEDIUM RISK DISTRIBUTORS**

Medium risk distributors consist of distributors that have refrigerated storage or distribute perishable food products such as produce distributors (refer to 28A.03 (5) (a)). MDA-FFSD considers these distributors to be medium risk because they are required to maintain temperature control of their refrigeration, or they are distributing product that is more susceptible to adulteration during storage and distribution. Additionally, Seafood HACCP regulations apply, but a seafood HACCP plan is not required.

**SPECIFIC PROCESS TYPE MEDIUM RISK/ FACILITY CLASSIFICATIONS**

DM1 - Food warehouses with refrigerated or frozen seafood/fishery storage that includes only foods not requiring a Seafood HACCP plan.

DM2 - Refrigerated warehouses for foods requiring time/temperature controls for food safety (PHF/TCS Foods) (Non-seafood)

DM3 - Cold Storage warehouse (refrigerated and/or frozen)

DM4 - Produce warehouses without any processing

DM5 - Food Banks without any processing

**LOW RISK DISTRIBUTORS**

Low risk distributors consist of distributors that have frozen storage or ambient, shelf-stable storage. MDA-FFSD considers these distributors as low risk because there is a lower risk for temperature abuse with these types of storage facilities.

**SPECIFIC PROCESS TYPE LOW RISK/ FACILITY CLASSIFICATIONS**

DL1 - Freezer warehouses without foods subject to the Seafood HACCP regulation.

DL2 - Food warehouses with ambient storage only such as beverage, bakery and snack food warehouses

DL3 - Food wholesalers that are mobile units only with no warehouse storage

DL4 - Food Broker

**Appendix B: Amendable and Non-Amenable Food Items**

**Amenable species – products under USDA Jurisdiction**

* Cattle, sheep, swine, goats, horses, mules or other equines, ratites and squab.
* Domestic chickens, turkeys, ducks, geese, and guineas.
* Products containing 2% or more cooked poultry; 10% or more cooked poultry skins, giblets, fat and poultry meat in combination.
* Products containing more than 3% raw meat; 2% cooked meat; or 30% or more fat, tallow or meat extract; includes tamales, convenience meals, egg rolls meat salads, sambusas
* Open face sandwiches – wraps, burritos
* Meat pizzas and meat sauces (3% red meat or more); spaghetti sauce with meatballs; open face roast beef sandwiches; hot dogs; corn dogs; beef/vegetable pot pies.
* Chicken sandwich – open face; chicken noodle soup
* Shell egg of domesticated chicken, turkey, duck, goose or guinea.
* Egg breaking and pasteurizing operations.
* Egg products including dried, frozen, or liquid eggs with or without added ingredients.
* Catfish

**Non-amenable species – products under FDA Jurisdiction**

* Non-specified red meats: bison, rabbits, game animals, zoo animals, Cervidae (deer, elk, moose) – EXCEPT when USDA Inspection is required under MN Statute
* Non-specified birds: wild turkeys, wild ducks, wild geese
* Products with 3% or less raw meat; 2% or less cooked meat; or less than 30% fat, tallow, or meat extract.
* Products with 2% or less cooked poultry meat; less than 10% cooked poultry skins, giblets, fat
* Closed face sandwiches –i.e. between 2 slices of bread or on a bun
* Labels/labeling of shell eggs. Egg washing, sorting, packing.
* Freeze dried egg products, imitation egg products, egg substitutes, dietary foods, dried np-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut or other ethnic delicacies.
* Cheese or vegetable pizza
* Meat flavored spaghetti sauce with less than 3% red meat; meat flavored spaghetti sauce with mushroom and less than 2% meat; pork and beans; sliced egg sandwich (closed face); frozen fish dinner, rabbit stew; shrimp-flavored noodles; venison jerky; buffalo burgers; alligator nuggets; noodle soup chicken flavor.