Minnesota Department of Agriculture
Food and Feed Safety Division

Document FOOD.30.01	Page **1** of **19**
Version #: **2.1**	Effective Date: 1/26/2017
Title: **Inspection Protocol – Food Manufacturing**	

Table of Contents

1. PURPOSE

The purpose of this document is to provide the requirements for the inspection of Manufacturing, Distributing, and/or Wholesale Food firms currently regulated by the Minnesota Department of Agriculture Food and Feed Safety Division (MDA-FFSD).

2. SCOPE

This procedure applies to all inspections of Manufacturing, Distributing, and Wholesale Food operations, including inspections conducted under contract with the Food and Drug Administration (FDA). Inspectors are required to follow this protocol unless the inspection type is not covered in the policy.

The policy does not include any additional requirements for other inspection types such as foodborne illness investigations, complaints, licensing and sampling, or other directed investigations. However, some inspection procedures in this SOP may be applicable during these other types of inspections. This policy also does not apply to the inspection of meat or dairy products regulated by MDA-Dairy and Meat Inspection Division that fall under the USDA or MN Equal-to inspection programs, the Pasteurized Milk Ordinance, or other MDA Dairy product inspection procedure.

3. BACKGROUND

Minnesota Statute, 31.04, 31.08, 34A.04, 34A.12 (and any other applicable laws and regulations) provides the legal authority for Department staff to enter, inspect, copy records, take photographs and sample to determine compliance with the Minnesota laws including, but not limited to, MN Chapters 17, 28, 28A, 29, 30, 31, 31A, 32 and 34A and Agency rules promulgated there under.

This document was established using existing policies. This protocol complies with the requirements stated in the Manufactured Food Regulatory Program Standards under Standard 3 section 3.3.2.

4. RESPONSIBILITY

Manufactured Food Program Manager – The Manufactured Food Program Manager will assist in determining next steps when a refusal of inspection is encountered.

Manufactured Food Inspection Supervisor - The Supervisor will assist in determining next steps when a refusal of inspection is encountered; reassign specialized inspections as needed; and assist in determining when further actions may be required.

Manufactured Food Inspector – The Inspector will prepare for the inspection; conduct the inspection as assigned; and communicate with the Supervisor and Program Manager as needed.

5. DEFINITIONS

Good Manufacturing Practices (GMP): Regulations 21 CFR 110 or 21 CFR 117 that apply to food processors/manufacturers, distributors, and warehouses. They are the basis for determining whether the practices, conditions, and controls used to process, handle or store food products are safe and whether the conditions in the facility are sanitary.

Hazard Analysis Critical Control Point (HACCP) Based Inspection: An inspection conducted utilizing scientific knowledge and direct observation to evaluate a firm's food handling activities including processing, storage and distribution. An inspector identifies and then assesses hazardous 'points' in the process, the amount of control over those hazardous points, and documentation of the hazards, process, and any monitoring conducted by the firm.

Highly Susceptible Population: Persons who are more likely than other people in the general population to experience foodborne disease because they are:

1) Immunocompromised: those having an impaired immune system and therefore more susceptible to foodborne pathogens; and

2) Obtaining food at a facility that provides services such as custodial care, health care, or assisted living , such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center or school.

Most Responsible Person (MRP): Owner, operator, or agent who is present at the firm and is responsible for the operation at the time of inspection.

Ready to Eat (RTE): "Ready-to-eat food" means food that is in a form that is edible without additional washing, cooking, or other preparation by the firm or the consumer to achieve food safety and that is reasonably expected to be consumed in that form. It may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

Repeat Violation (Chronic Violation): A specific violation observed and documented during at least two (2) inspections in a row, also known as a chronic violation.

Risk Factors: practices or procedures that pose the greatest potential for foodborne illness. Risk factors as determined by the CDC and FDA are Food Source, Inadequate Cooking, Improper Holding Temperatures, Cross Contamination, Poor Personal Hygiene, and Environmental Contamination.

Specialized Process: Manufactured Foods produced under 21 CFR, parts 113 Low Acid Canned Food (LACF), 114 Acidified Food (AF), 120 Juice, and 123 Seafood or as defined in the Food Code.

6 PROCEDURE

6.1 Pre-Inspection

6.1.1 Review and have the appropriate equipment and forms needed to conduct the inspection.

a. Refer to the *Equipment List-Manufacturing* for required inspectional equipment

b. When conducting an inspection at a food manufacturer/processor, follow procedures in *FOOD.WI.30.14 – Pre-Inspection Preparation – Manufactured Food*. These procedures are not required for inspections of food warehouses/distributors.

6.1.2 Verify that the temperature measuring device (thermometer) has been verified and calibrated according to the procedures outlined in *FOOD.30.09 - Temperature Measuring Device Use and Accuracy SOP*.

6.1.3 Review all relevant inspection documents and information before going to the establishment.

a. Determine hours and season of operation to ensure the firm will be in operation when the inspection is conducted.

b. Review the following information in USAFS and/or inspector files:

i. Previous inspection reports noting out-of-compliance observations and repeat violations

ii. Documentation indicating a specialized inspection is required; contact a supervisor for reassignment if the appropriate training has not been completed

iii. Consumer complaint reports that require follow-up

iv. Letters or other documents regarding enforcement actions that may require follow-up

v. Violative sample reports that may require follow up.

c. Contact supervisor or previous inspector (if available) for clarification of any information contained within the firm's file as necessary.

6.2 Initial Interview

6.2.1 Upon entry to the facility:

a. Make appropriate inductions, identify oneself, present credentials and explain the purpose and scope of the inspection to the Most Responsible Person (MRP). All MDA staff present during the inspection must present credentials to the MRP.

b. Issue a Notice of Inspection (NOI) – Refer to USAFS Inspection Guidance/WI.

c. Establish MDA jurisdiction for all licensed and unlicensed facilities. Review the firm's MDA Food Handlers license. Verify that the legal entity, DBA, license type, location address, mailing address, and fee paid

are correct. Any inaccurate information should be addressed as described in USAFS Guidance/WI or other applicable procedures.

6.2.2 Determine the appropriate regulations – 21 CFR 110 or 117

a. Ask the MRP the appropriate questions (including FSMA PC Compliance Data Questions) to determine the regulations that are applicable for the firm during the inspection.

b. Note that the new regulations have different effective dates based on the size of the firm.

c. Further information regarding the Preventive Controls for Human Food regulation can be found online: *Guidance for Industry: What You Need to Know about the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Small Entity Compliance Guide*.

6.2.3 Consider the inspection as a refusal of inspection if the firm does not allow any of the following: entry into the facility, entry into specific facility areas, review of records, collection of samples, or taking photographs. It is also considered a refusal of inspection if the firm is uncooperative or hostile. A refusal may occur at the start of an inspection or during the inspection.

a. Re-review or provide the firm with the statutory authority references, such as: MS 31.04, 31.02(g), 34A.04, 34A.12.

If the refusal is related to taking photographs, cite the two case laws, as noted in FDA Investigations Operations Manual (IOM) section 5.3.4.1.

b. Inform the firm that MDA will initiate legal action. If the firm continues to refuse, contact a Manufactured Food Supervisor, Program Manager or another member of FFSD Management. Supervisors or Managers will determine if immediate access is necessary and take appropriate next steps.

c. If the firm continues to refuse and at the direction of a supervisor or manager, complete an inspection report and issue an order for refusal of inspection including the details of the refusal in the observation statement.

6.3 Focus of Inspection

6.3.1 Determine the focus of the inspection based on the purpose of inspection (routine, complaint, licensing, sampling, etc.) and by assessing the facility.

6.3.2 Select an appropriate product(s) for the inspection. Product review should be done to select the highest risk foods to evaluate. Refer to the *FOOD.30.08 - Manufacturer and Distributor Risk SOP* to determine the highest risk foods.

6.3.3 Evaluate the following information to help assess the focus of the inspection:

a. Products being produced on the day of inspection.

b. Products that previously been the focus of an inspection.

c. Intended use of the products.

d. Time of processing of specific products.

e. Type of packaging being used.

f. Intended Storage Temperature: Ambient, Refrigeration, or Frozen.

g. Intended consumer(s) of these products: General Public or Highly Susceptible Population.

h. Potential hazards associated with the food.

i. Sanitation Practices.

j. Process/ Product flow: Raw to RTE.

k. Specialized Processes

6.3.4 Focus of the inspection may be changed if a significant violation is observed when conducting the inspection, either by direct observation, statements by management or employees, record review, etc.

6.3.5 Make an assessment of the overall operation even though the detailed inspection focus is on the selected product/process.

6.3.6 If the firm is not currently processing during the inspection, base the inspection on the highest risk product. Conduct the inspection by interviewing management and production personnel, reviewing records and written procedures, reviewing processing equipment, etc.

6.4 Walk-through Inspection activities

6.4.1 Demonstrate proper sanitary practices during the inspection. This would include following the basic GMPs as well as any additional requirements the firm may have in regards to personal hygiene, safety, and sanitation.

6.4.2 Conduct a walk-through of the facility, including a review of the exterior portion of the facility.

6.4.3 Assess the methods, facilities, and controls used in manufacturing, storage, and distribution of foods. This includes all onsite facilities and vehicles owned or leased by the firm being inspected.

6.4.4 Cover each step of the process during the walk through, including: receipt of raw materials, storage of raw materials, processing product, storage of finished goods, and shipment of products.

6.4.5 A flow diagram for the product of focus of inspection should be completed as a worksheet to identify each process step and the procedures completed at each step. Indicate critical factors, control points, critical control points, process timing and possible associated records. Use this information to evaluate hazards, controls the firm has in place, and compliance to the regulation. The flow diagram does not need to be submitted as part of the inspection.

6.4.6 Evaluate employee activities critical to safe and sanitary production and storage of food. Provisions used for assessing these activities can be found in 21 CFR,

Part 110.10 or 21 CFR, Part 117.10: disease control, cleanliness, education/training, and appropriate supervision. The following observations or assessments must be made throughout the inspection:

a. Firm's procedure(s) regarding employee cleanliness and sanitation.

b. Flow of employee traffic: entrance(s) to the processing area, location of locker room(s) and bathrooms, locations of different work stations, raw product areas vs. finished product areas, employee movement into different processing areas, and any other areas that may affect the safe and sanitary production and storage of food.

c. Employees' uniform and dress including but not limited to: shirts, pants, jackets, lab coats, shoes, jewelry, hairnets, gloves, and any other piece of clothing that could contribute to an unsanitary production and storage of food.

d. Employees' actions including but not limited to: hand washing, cross contamination of food contact surfaces with nonfood contact surfaces, and good hygienic practices.

e. Documentation of employee training regarding sanitary practices.

f. Oversight and routine monitoring of proper employees practices.

6.4.7 Assess the likelihood that conditions, practices, components, and/or labeling could cause product to be adulterated or misbranded.

a. Connect observations made to potential product adulteration or misbranding. Examples of considerations include:

- Gaps on entry or overhead doors in addition to the presents of rodents in a facility provides a stronger association or likelihood of product being or becoming adulterated vs the door violation on its own;
- A leaking roof in a raw product receiving area where the food will be subsequently heat treated may not represent as great of a risk as a leaking roof in a ready to eat or post-process production area;
- The lack of a handsink in a processing area and observation employee handwashing violations and contact with RTE food vs. only the handsink violation;
- Presence of old food residue and mold on a food contact surface when potentially hazardous food is being produced;
- A non-food grade machine lubricant being used on machinery over food contact surfaces while food is being processed
- A cooling unit dripping condensate directly onto food or food contact surfaces during processing

b. Review allergen control policies, possible cross contact issues, and possible undeclared allergens. Verify allergen labeling on raw materials, products in process, and finished goods. The *Allergen Inspection Guide – Manufacturing* may be completed as a worksheet during the walk through if the firm processes any food with allergenic ingredients.

c. Evaluate labels of finished products for basic label requirements, nutrition facts, and allergen declarations.

- Review the label(s) for the product(s) in production at the time of the inspection. Review other labels as time allows.

d. Collect violative labels as needed to document repeat label violations or for further review in one of two ways described below:

- Photographs of ALL sides of a packaged food product (refer to *FOOD.WI.30.59 – Documenting Digital Photographs-Video Evidence-Manufactured Foods WI*)
- A scan or photocopy of a label or print-out of the label from the facility (attach to the Inspection Maintenance page in USAFS)

6.4.8 Recognize violative conditions and practices and record findings per *FOOD.30.05 – Inspection Report SOP*.

a. Perform a HACCP based inspection which identifies hazards specific to the selected product, critical control points in the process, and potential areas for contamination or adulteration related to product handling and the processing environment.

b. Observe the processing of the product selected for the inspection focus. Place emphasis on the hazards and controls related to the processes and products observed. See 21 CFR 110.80 or 21 CFR 117.80 for processing control requirements and 21 CFR 110.35 or 21 CFR 117.35 for sanitary operations.

c. For critical violations, observation statements written to support an order issued must include specific areas or situations that would lead to instances of actual or potential adulteration of food products.

d. Examples of Violative Conditions and Practices are: Presence of old food residue and mold on a food contact surface, employee handling RTE product with soiled hands, rodent or insect contaminated foods, non-food grade machine lubricant being used on machinery over food contact surfaces, cooler dripping condensate on food or food contact surfaces, undeclared allergens, or cumulative time/temp abuse occurring during the cooling or storage of a potentially hazardous food.

6.4.9 Distinguish between significant vs. insignificant observations and isolated incidents vs. trends.

a. Determine which observed violations are significant - those which are closely linked to public health risk and/or product adulteration.

b. Emphasis during the inspection must be placed on deficiencies related to significant violations and trends. Insignificant violations should also be addressed. However, they should be addressed after more significant deficiencies are discussed with the firm.

c. Examples of significant vs. insignificant observations: focusing on areas where cross contamination of cooked and raw products might occur should occur prior to addressing a food employee chewing gum and wearing nail polish, or emphasizing RTE salad processing and handling before addressing soiled non-food contact surfaces.

d. Examples of isolated incident vs. trends observations: Identify patterns in documentation over time rather than focusing on single incidences that were corrected and not repeated, observe employee handling practices across different products that create a potential for contamination and indicate deficiencies with monitoring of employee practices, identify sanitation deficiencies in similar areas of production related to facility construction or layout.

e. Ensure the firm takes appropriate intervention measures and/or corrective actions for each significant observation that is determined to be out of compliance to the extent possible. Public health risks and instances of product adulteration require immediate onsite correction of the deficiency as well as disposition for products that may have been affected. Follow procedures in *FOOD.30.27 - Field Compliance Actions SOP*.

6.4.10 Conduct a review of the firm's pre-requisite programs. This should include the following (as applicable):

a. GMP practices specific to employee hygiene and employee illness

b. Pest control

c. Chemical control

d. Water quality evaluation

e. Allergen controls

f. Foreign material control

g. Environmental monitoring systems

h. Sanitation monitoring

i. In-coming materials inspection or standards

j. Preventive maintenance programs

k. Employee training

l. Corrective and preventive actions related to food safety

m. Risk assessment/evaluation

n. Equipment calibration and verification

6.4.11 Review and evaluate the firms' records and effectively apply the information obtained during the inspection.

a. Conduct a record review after the walk-through of the facility and document this information on the inspection report. Refer to *FOOD.WI.30.60 - Record Review – Manufactured Food WI* for guidance on type, number, and timeframe of record(s) to review.

b. Correlate patterns, identify items that have not been addressed by the firm, and verify potential process deviations that may have occurred since the last inspection.

c. Identify records which are applicable to the focus of the inspection either prior or during the walk through. Correlate the records reviewed to observations taken during the walk-though.

d. Additional records may be needed for review based on specialized processes, risk level, or production volume.

6.4.12 Review the firms recall procedures.

a. Identify if the firm has a recall plan in place.

b. Ask questions about the plan in including the following: trigger for the firm to recall product, understanding of Reportable Food Registry requirements, follow up performed with other customers if necessary, mock recall activity, and handling of recalled product.

6.4.13 Review the firms' consumer/customer complaint procedures.

a. Determine if the firm has procedures for handling complaints

b. Review any written procedures and complaints received. If the firm does not have any written procedures, ask for an explanation as to how they would be handled.

c. The focus of the review should be regarding complaints regarding illness or injury as opposed to quality factors.

d. Identify any trends noted regarding specific products, production dates, processes, production lines and follow up with additional record review or on-site review.

6.4.14 Collect adequate evidence and documentation to support inspection observations.

a. Collect evidence to fully support observations if significant violative conditions are identified within the firm. Evidence collection will vary depending on the type of observation requiring support.

b. Photographs should be representative of the conditions observed during the inspection and should represent the conditions observed during the inspection. The scope of the photograph should be identified through the

variation of close up photographs and large encompassing views. Refer to the *FOOD.WI.30.59 - Digital Media –Manufactured Foods WI* for handling of digital media and appropriate documentation.

c. Examples of evidence collection to support significant violative conditions could include: copies of records noting deficiencies in monitoring of critical limits, finished product with an unacceptable finished pH, damaged packaging in support of insect infestation, photographs of insanitary food contact surfaces or processing environment conditions.

d. Samples must be collected according to the applicable sampling procedures or guidance.

e. Evidence collected must be uploaded to the inspection in USAFS. If the records contain proprietary or confidential information, the firm must mark the document as such.

6.4.15 Verify that corrections have been made to the deficiencies identified during the previous inspection.

a. Review all previously identified deficiencies during the current inspection.

b. If the previous deficiencies have not been corrected, repeat orders must be issued in the inspection report.

c. Refer to *FOOD.30.05 - Inspection Report SOP* for further information regarding documentation of previously identified deficiencies.

6.4.16 Determine if further action is required.

a. Determine if a Reinspection or Follow up Inspection is needed. Refer to *FOOD.30.02 - Reinspection and Follow-Up Inspection SOP*.

b. Inform a Supervisor when inspectional findings indicate that a directed investigation is needed (refer to *RESP.50.01 – Investigation Procedures – Food or Environmental Contamination SOP)* . Examples may include the following:

- Record review indicates the firm has repeated positive environmental sample results for Listeria and no or insufficient corrective actions have been taken
- Record review of the firms finished product sampling shows positive samples for Salmonella

6.5 Communication and Behavior

6.5.1 Behave professionally throughout the inspection.

a. Do not discuss information regarding other firms' businesses, processes, or practices.

b. Limit personal conversation so as to not impede the inspection flow.

c. Do not speak to other agencies' activities or policies, including notification of inspection, work plans, inspection procedures, etc.

d. Dress appropriately for the activities.

e. Maintain a dignified, tactful, courteous, and diplomatic attitude.

f. Observe accurately and objectively.

g. See also MN Statute 43A.38 - Code of Ethics for Employees in the Executive Branch.

6.5.2 Make appropriate introductions and explain the purpose of the questions being asked to any employees interviewed during the inspection.

6.5.3 Do not sign any forms or documentation provided by the firm that limits the inspection authority and/or rights to gather evidence in any way.

a. Documents that limit inspection authority may include the following: confidential disclosure forms, compliance with firm's GMPs, a waiver to exempt the firm from liability should an accident occur and you are injured on the firm's premises, letters concerning access to confidential information the firm does not want released, request for information/data you request during the inspection be put in writing, etc.

b. Inspectors are allowed to sign in and out of the facility. However, read the document carefully to confirm the sign-in sheet does not contain any language that conflicts with this policy.

c. If a firm refuses inspection without a signature on one of the documents listed above, the investigator shall inform the firm that it will be considered a refusal of inspection and the department will initiate appropriate legal action.

d. If the firm so chooses, they may provide copies of the documents to the Minnesota Department of Agriculture (MDA) for review. The legal counsel for MDA will review the document and advise the FFSD if an inspector may sign the document.

6.5.4 Protect the firm's data in accordance with the Minnesota Data Practices Act. MN Statute 13.

a. Data is only available to those whose access is provided by law, department employee's whose job reasonable requires access, or by court order.

b. When the Department of Agriculture determines no action is to be taken in an inspection or an investigation becomes inactive or closed, data collected will become public unless otherwise protected by law.

6.5.5 Individuals are not legally required to supply personal, private, or confidential data about themselves; however, such data may be subpoenaed. An individual that supplies personal, private, or confidential information may reasonably expect the data to be used in enforcement actions.

6.5.6 Use suitable interviewing techniques.

- **a.** Actively engage in dialogue with the firm's owner(s) and employees.
- **b.** Be very specific when asking questions and requesting information from the firm.
- **c.** Use common language which is familiar to the firm.
- **d.** Note nonverbal communication such as: uneasiness, nervousness, preoccupation with other responsibilities, etc.
- **e.** Ask open-ended questions and ask follow-up questions to obtain the desired information.
- **f.** Reconcile any discrepancies in information provided by the firm.
- **g.** Be respectful of peoples' time during the inspection.

6.5.7 Explain findings clearly and adequately throughout the inspection.

- **a.** Inform the responsible person with you during the walk-through of the deficiencies at the time they are observed.
- **b.** Explain the public health significance associated with each deficiency.
- **c.** Verify the MRP understands of any deficiencies or observations. This could be done by requesting the MRP to repeat the deficiency or observation back to the inspector.
- **d.** Request any applicable documentation the firm may have in regards to the deficiency.
- **e.** Clearly document deficiencies in the inspection notes for later use in the Inspection Report. The following information should be noted for each deficiency: who, what, where, when, and the amount in regards to food receipt, handling, processing, storage, and shipping.
- **f.** Verify the descriptions of the facility areas, pieces of equipment, processes used, etc. with the firm to help facilitate the understanding of the inspection report by the firm.
- **g.** Avoid giving specific recommendations for desired corrective actions. There may be many ways for the firm to comply and/or the recommendation may not achieve the desired compliance. It is appropriate to offer suitable solutions but it is the firm's responsibility to make the final decision as to the solution that will bring the firm into compliance.

6.5.8 Alert the firm's MRP or other responsible individual during the walk-through when an immediate corrective action is required. Requiring correction on-site conveys the seriousness of the violation to the establishment. If operations are briefly stopped to address a food safety issue, a more favorable impact on future behavior may result that might not have been achieved through discussion alone.

a. Request an immediate corrective action be taken if the situation poses a possible/ immediate threat to public health.

b. Verify that the firm has corrected the problem. Inspectors should not continue on the inspection until the inspector is confident that appropriate corrective action is in the process of being taken.

c. Take detailed notes and evidence of the observation and corrective action(s) taken.

6.5.9 Answer questions and provide information in an appropriate manner.

a. Review the inspection report to the MRP and discuss any deficiencies observed.

b. Provide time and opportunity for questions or discussion from the firm related to orders issued, comments documented, etc.

c. Verify understanding of the orders, timeline, and possible appropriate actions to correct the violations.

6.5.10 Write findings accurately, clearly, and concisely on the Inspection Report and provide a copy of the document to the firm's MRP. Refer to *FOOD.30.05 - Inspection Report SOP*.

6.6 Seafood HACCP Component

6.6.1 Inspectors leading Seafood HACCP inspections must attend and successfully complete the FDA Seafood HACCP Regulators Course (FD249).

6.6.2 Obtain and use the current issue of the *Fish and Fishery Hazards and Control Guide*. Be familiar with its organizational content in order to correctly identify and evaluate the hazards associated with the product and process.

6.6.3 Conduct Seafood HACCP Inspections when the firm is known to be in production, including when high risk products are produced.

a. Complete HACCP records review when an inspection cannot be reschedule to view the firm in operation. Gather information by asking questions and having the firm demonstrate what they do.

6.6.4 Focus the inspection according to the highest risk product being processed or stored on the day of inspection. Do not repeatedly review the same plan from one inspection to the next. Examples of high risk fishery products are listed below:

a. Refrigerated seafood products packed in Reduced Oxygen Packaging (ROP).

b. Processed uneviscerated finfish (cooked, acidified, salted, dried, or partially dried)

c. Raw molluscan shellfish and products that include raw molluscan shellfish that will not be cooked prior to consumption

d. Cooking, smoking, fermentation, acidification, or drying process for RTE dried seafood

e. Scombrotoxin-forming (histamine-forming) species

f. Ready to Eat seafood processors who do not cook, smoke, ferment, or acidify, but receive, store, manufacture, or otherwise process RTE seafood

g. Formulated seafood Products containing multiple ingredients (soups, salads, meals, spreads, dips, sandwiches) and where sulfites or Yellow 5 are used

h. Aquacultured seafood (primary processor)

6.6.5 Conduct a technical review HACCP Plans for additional high risk fishery/seafood products not being produced/stored

a. Technical review consists only of a review of the written HACCP plan to determine if appropriate/reasonable hazards and controls are identified

b. Do not review monitoring records or corrective action records

c. Cite violations based on HACCP plan deficiencies only.

d. Technical review of other HACCP plans are to be conducted under the following circumstances

- The firm produces other high risk products that were not being manufactured at the time of the inspection, and/or
- The firm produces other products that are infrequently produced, and/or
- Other HACCP Plans exist that have not been evaluated by MDA or FDA

e. Document that a technical review of plans was conducted.

6.6.6 Determine the firm's seafood related operations and sanitation procedures during the walk-through and develop a flow chart.

a. Determine and document specific names of products including species, package size and type (including ROP, MAP, LACF, packaged food, etc), manufacturer name and location; processes/product status (RTE – cooked, pasteurized, smoked, pickled/acidified, raw – to be other details cooked by the consumer, etc.)

b. Observe the implementation of monitoring verification, corrective action and sanitation procedures during production.

6.6.7 Conduct a Hazard Analysis during the walk through and complete the *Inspector Conducted Hazard Analysis* form. If HACCP plan or implementation violations are cited then submit the inspector conducted hazard analysis and the firms HACCP Plan. If you determine that a HACCP plan is not required, document in the Inspection Report Published Comments the product(s) produced/held.

6.6.8 Review the firm's HACCP plan following completion of the walk-through.

a. Verify that the required components are present and appropriate including the inspector identified hazards and remaining HACCP Principles

b. Verify that the plan(s)

- Is specific to the plant/location/facility being inspected
- Appropriately identifies specific products covered (e.g. not 'histamine or non-histamine species' but names the species of concern)
- Are reviewed, signed and dated annually. Document the date of the review and who signed (corporate level, HACCP trained individual at the plant, or other)

6.6.9 Determine if the HACCP plan(s) is (are) being implemented as written.

6.6.10 Review appropriate HACCP records including: sanitation monitoring, CCP monitoring and corrective actions, and verification records (including calibration).

a. Record review should be deliberate and represent the entire process; tie the records together so you are seeing all CCP monitoring and verification records for the same lot (and repeat for multiple lots).

b. Refer to *FOOD.WI.30.60 - Records Review – Manufactured Foods WI* for guidance on type, number, and timeframe of record(s) to review. Document the records that were reviewed (title, time-frame or specific dates) and a brief summary of the findings.

6.6.11 Determine if the firm has appropriate controls in place when the inspector hazard analysis identifies that a HACCP Plan is required but the firm has no HACCP Plan in place. Follow procedures in *FOOD.30.27-Field Compliance Actions SOP* to take control of product that may be violative/adulterated/misbranded.

6.6.12 Assess the firm's monitoring of the eight key areas of sanitation listed in seafood regulation 21 CFR, part 123. Firms may not be required to monitor all of the key sanitation areas. The inspector should determine the relevant elements and adjust the inspection accordingly.

6.7 Juice HACCP Component

6.7.1 Inspectors leading Juice HACCP inspections must attend and successfully complete Juice HACCP and Conducting Juice Inspections Course (FD219).

6.7.2 Obtain and use the current version of the *Guidance for Industry: Juice HACCP Hazards and Controls Guidance* as well as the course manual and be familiar with the organizational content of both in order to correctly identify and evaluate the hazards associated with the product and process.

6.7.3 Conduct Juice HACCP Inspections when the firm is known to be in production when at all possible.

a. Complete HACCP records review when an inspection cannot be reschedule to view the firm in operation. Gather information by asking questions and having the firm demonstrate what they do.

6.7.4 Determine the firm's juice manufacturing operations and sanitation procedures by conducting a walk-through and developing a flow chart.

a. Determine and document specific names of products, package size and type.

b. Observe the implementation of monitoring verification, corrective action and sanitation procedures during production.

6.7.5 Conduct a Hazard Analysis during the walk through and complete the Inspector Conducted Hazard Analysis form. If HACCP plan or implementation violations are cited then submit the inspector conducted hazard analysis and the firms HACCP Plan. This information can be compared to the HACCP plan after the inspection to verify any inconsistencies in the firm's defined hazards and the inspector's observations.

6.7.6 Review the firms HACCP Plan following completion of the walk-through.

a. Verify the required components are present and appropriate including inspector identified hazards and other HACCP principles.

b. Verify that the plan(s)

- Is specific to the plant/location/facility being inspected
- Appropriately identifies specific products covered
- Are reviewed, signed and dated annually. Document the date of the review and who signed (corporate level, HACCP trained individual at the plant, or other)

c. Determine if the HACCP plan is being implemented

6.7.7 Review the appropriate HACCP records including but not limited to: sanitation monitoring, CCP monitoring and corrective actions, and verification records (including calibration).

a. Records review should be deliberate and represent the entire process – this means tie the records together so you are seeing all CCP monitoring and verification records for the same lot (and repeat for multiple lots). Refer to *FOOD.WI.30.60 - Records Review – Manufactured Foods WI* for guidance on type, number, and timeframe of record(s) to review.

b. Document the records that were reviewed (title, time-frame or specific dates) and a brief summary of the findings.

6.7.8 Determine if the firm has appropriate controls in place when the inspector hazard analysis identifies that a HACCP Plan is required but the firm has no HACCP Plan in place. Follow procedures in *FOOD.30.27 - Field Compliance Actions SOP* to take control of product that may be violative/adulterated/misbranded.

6.7.9 Assess the firm's monitoring of the eight key GMP areas of sanitation listed in the Juice HACCP regulation 21 CFR part 120. Firms may not be required to monitor all of the key GMP areas. The inspector should determine the relevant elements and adjust the inspection accordingly.

6.8 Acidified Foods Inspections

6.8.1 Inspectors leading Acidified Foods inspections must attend and successfully complete Conducting Acidified Foods Inspections Course (FD202).

6.8.2 Refer to MDA's current *Acidified Foods Inspection Program Guidance*.

6.8.3 Complete Form FDA 3511-2 "FDA Acidified Food Inspection Report" for each inspection conducted and upload to the inspection in USA FS

6.9 Low Acid Canned Foods (LACF) Inspections

6.9.1 Inspectors leading Low Acid Canned Foods inspections must attend and successfully complete Conducting Low Acid Canned Food Inspections (FD 203).

6.9.2 Refer to MDA's current *LACF Inspection Program Guidance* and the current year *Canning Program Work Plan*.

6.9.3 Complete FDA Form 3511 "FDA LACF Inspection Report" for each inspection conducted and upload to the inspection in USA FS.

7. RELATED DOCUMENTS (includes References, Attachments):

Allergen Inspection Guide – Manufacturing Document

Acidified Foods Guidance Document

Low Acid Canned Food Inspection Program Guidance

Current Year Canning Program Work Plan

FOOD.WI.30.59 - Documenting Digital Photographs-Video Evidence – Manufactured Foods WI

Equipment List-Manufacturing

FOOD.30.05 - Inspection Report SOP

FOOD.30.08 - Manufacturer and Distributor Risk SOP

Sampling Procedures and associated WI

Guidance for Industry: What You Need to Know about the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Small Entity Compliance Guide.

FDA Form 3511-2 (FDA Acidified Food Inspection Report)

FDA Form 3511 (FDA LACF Inspection Report)

FOOD.WI.30.60 - Record Review – Manufactured Foods WI

FOOD.WI.30.14 – Pre-Inspection Preparation – Manufactured Foods WI

RESP.50.01 – Investigation Procedures – Food or Environmental Contamination SOP

8. EQUIPMENT/MATERIALS NEEDED

Inspection equipment listing (training materials or evaluation listing)

9. SAFETY

All MDA employees must follow the personal protective equipment requirements and field safety guidelines outlined in the initial and annual Food Inspector safety training. Never enter an area or perform any job task that you think will result in injury or illness. If you do identify any unsafe conditions – STOP the inspection immediately and consult with the facility management or your supervisor regarding a corrective action for the hazard(s). Lastly, stick to the specific focus of your position and as always – THINK SAFETY!

Food inspection staff must follow the Verbal and Physical Assault of State Agriculture Inspectors Policy. If the firm's operators have a history of hostile behavior, speak with your supervisor before conducting inspection.

Before performing an inspection, ask firm about any physical or chemical safety issues in the firm. If the inspector has concerns about in-facility safety, please contact supervisor.

10. CIRCULATION

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

11. APPROVAL/DOCUMENT HISTORY

Document History		
Version #	**Status (I, R)**	**Change History**
1	**I**	Initial Policy Drafting.
2	**R**	Updated procedure to reflect division structure change from DFID to FFSD; added procedures to reflect use of USAFS; addition of FOOD.WI.30.60-Records Review WI; added review of recall procedures, review of consumer complaints, review of firms pre-requisite programs; added seafood HACCP inspection procedures; added label review procedure language; removed reference to FDA contract inspection procedures; inspection footwear and outer garments preparation moved to FOOD.WI.30.14.
2.1	**R**	Removed reference to FOOD.50.07-Data Protection and Data Requests SOP as the procedure will be rescinded. Added FDA Forms 3511 and 3511-2 to the related documents section. Original procedure approved on 1/26/17. Incomplete statement noted in Section 6.2.2(c). Statement completed per procedure FFSD.SOP.90.01 – Document Development and Control.

DocuSigned by: 51BD2563BF5444D...	1/31/2017
Approved By:	**Date**
Approved By:	**Date**

I = Initial document; R = Revised document