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# PURPOSE

# This document describes the processes that Retail Food Program Staff use to conduct haccp plan audits at retail food establishments that require haccp plans under the Minnesota Food Code (MN Rule Chapter 4626).

# SCOPE

# This document applies to all inspections of retail food establishments which require a haccp plan per MN Rule parts 4626.0340, 4626.0367, 4626.0420, 4626.0610, and 4626.1730. Compliance with a haccp plan may be a condition of a variance from code and therefore tied to the variance renewal process. Refer to FOOD.30.18 for variance renewal procedures. This document is not intended to be used in the review manufacturing related HACCP systems required by 21 CFR or HACCP systems required by MDA or USDA meat inspection programs.

# BACKGROUND

# retail food establishments are required by the MN Food Code to conduct certain activities under approved haccp plans. These activities include: cooking foods that do not meet the requirements in MN Rule part 4626.0340, operating and maintaining molluscan shellfish tanks under MN Rule part 4626.0610, treating juice under MN Rule part 4626.0367, reduced oxygen packaging of foods under MN Rule part 4626.0420, or conducting a specialized process.

# MN Rule part 4626.1730 requires retail food establishments to submit properly prepared haccp plans to the regulatory authority for approval. These plans are initially reviewed and approved using the procedures identified in *FOOD.30.28 - HACCP Plan Review – Retail Food SOP*.

# On-going routine verification of haccp plans are conducted under audit by the regulatory authority during on-site inspections. Verification is necessary to ensure that the haccp plan effectively reflects current retail food establishment operations.

# This includes a review of records identified in the HACCP plan maintained by the firm and available for inspection. The firm must maintain records for the typical inspection cycle to allow for regulatory review (minimum of one (1) year).

# RESPONSIBILITY

# Retail Food Program Manager – The Retail Food Program Manager will assign a Retail Food Supervisor to oversee the Retail haccp plan review process.

# Retail Food Supervisor - The Retail Food Supervisor will ensure all assigned staff in their respective program area receive the appropriate training and follow the procedures described.

# Retail Food Inspector – The Inspector will follow the procedures described as applicable to their position and notify their supervisor when the procedures cannot be followed.

# DEFINITIONS

**Critical control point (CCP):** "Critical control point" is defined in MN Rules 4626.0020 Subp. 19 and means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

**Food Process Variance:** a variance from code that may include a haccp plan as a condition of the variance and directly involves food handling practices and/or food products. This includes variances associated with specialized processes.

**Hazard Analysis Critical Control Point (HACCP) Plan: “**HACCP plan" is defined in MN Rule 4626.0020 Subp. 40 and further means a written document that delineates the formal procedures for following the hazard analysis and critical control point principles developed by the National Advisory Committee on Microbiological Criteria for Foods where required by the MN Food Code (MN Rules chapter 4626) in a Retail Food Establishment.

**Reduced Oxygen Packaging (ROP):** Reduced oxygen packaging is defined in MN Rules 4626.0020 Subp. 68.

**Retail Food Establishment**: any individual, person, firm, corporation, company, association, cooperative, or partnership who sells food directly to a consumer (as defined in the MN Rule 4626.0020 Subp. 35) and holds any classification of food handler license per MN Statute 28A.05 or 28A.06.

**Specialized Process:** Foods produced as listed in MN Rules part 4626.0415, Specialized Processing Variance Requirements.

**Variance from Code**: A dispensation to ignore or deviate from certain regulatory requirements as described in MN Rule 4626.1690 – 4626.1715 and as provided for in MN Statues 14.05 subd 4.

# PROCEDURES

## Inspection Preparation and Establishment File Review

## For all retail food establishments performing activities that require a HACCP plan, conduct a complete HACCP Audit in conjunction with the routine inspection schedule.

## Conduct the HACCP audit at a time when haccp Plan operations can be observed or demonstrated by the firm, and/or records are available for review.

## If not able to conduct a HACCP audit, a separate, announced inspection may be scheduled to complete an audit only in the following instances:

## The inspector conducting the routine inspection has not received training approval to independently conduct HACCP inspections

## Staff that have HACCP-related duties at the facility are not present during the routine inspection or no HACCP monitoring records are available to review.

## Prior to the inspection, review the applicable documents and inspection history related to the firm and the HACCP plan. The purpose of the review is to gain a better understanding of the food safety management system in place as well as identify an appropriate time for conducting the inspection to get the better chance to observe active retail HACCP processing.

## This review must include all of the following documents when they are available:

## Past inspection reports

## Prerequisite programs when required

## Training programs

## Approved HACCP plan

## Associated variances from code

## Initial Interview

## During the inspection, request the Person-In-Charge (PIC) identify the following physical locations in the firm: the written haccp plan, any associated variances from code, haccp plan monitoring records, and any product currently in process or stored product within the facility that was made using those procedures.

## Interview the PIC, or food employee involved with haccp plan operations, about the items they produce, including items that may not be available at the time of inspection.

## Based on the information provided by the PIC or food employee, determine if there have been any menu changes, process additions, or changes to the written haccp plan.

## Review the Process Flow

## Identify specific product(s) which require a haccp plan that are actively being produced during the inspection.

## If no products are being actively produced, identify specific products in-process, being stored or offered for sale.

## If no products are on site, identify the highest risk HACCP products produced by the firm based on interview.

## Develop a detailed flow chart for the complete process of the identified product(s) through interview and direct observation of the PIC and other applicable food employees. For instance, when no active production is occurring, a physical review of the equipment and facilities used is still required.

## Identify the critical control points (CCPs) where food safety hazards are reasonably likely to occur in the flow chart.

## Compare the inspector developed flow chart and identified CCPs against the firm’s flow chart to determine if discrepancies exist.

## If discrepancies are identified, determine if the discrepancies create a significant public health risk.

## Consider the following question: Are there hazards that were not identified and subsequently not controlled? Discuss the reason for any discrepancy with the PIC or food employee and continue by observing monitoring occurring at that CCP.

## If discrepancies are not a significant public health risk, make note in the inspection report comments. For example: issues that do not affect the identification of hazards related to the process such as combining packaging and labeling into one step.

## Observe CCP Monitoring

## Observe all CCP monitoring that is occurring during the inspection including how the results are recorded in the CCP monitoring records. Determine if critical limits are being met and that critical limits are monitored according to the procedures noted in the haccp plan.

## If no active CCP monitoring is occurring, request employee(s) demonstrate what is monitored, how it is monitored, and how the monitoring activities are recorded.

## Take CCP measurements using assigned inspection tools when available to verify the measurements taken by employees. Examples of inspection tools that may not be available are pH meters and scales. Verify the accuracy of such equipment (i.e., check pH calibration or weight/measure check/verification for scale).

## Record Review

## Review CCP monitoring records that have been created within the last 12 months or since the last routine inspection, whichever is shorter. This review is to determine if critical limits are being met, CCP monitoring records are consistently kept, and corrective actions are recorded per the haccp plan. Focus the record review on the process(s) observed during the inspection.

## Select one specific product during the inspection and review the complete set of production records for that product. A complete set of records follows the entire process flow for producing a single product.

## For example, a complete set of records for beef sticks may include all of the following: cure record, a smoking record, a cooling record, and ROP packaging record, a cold storage record and a pull/discard log record.

## Additionally, select one complete set of records for every other month of production from the last 12 months or since the last routine inspection for the specific products. A minimum of 6 complete record sets must be reviewed (when available).

## For example, a seasonal operation open six months annually would require one set of records for each month to total six more sets of records to review. Additional records must be reviewed as needed when record deficiencies are identified to determine trends.

## Review all Corrective Action records that have been created within the last 12 month or since the last routine inspection, whichever is shorter. This review is to determine if corrective actions are taken and recorded when critical limits are not met.

## If no corrective actions have been taken since the last routine inspection and the CCP monitoring records indicate that no corrective actions were necessary, interview the PIC regarding when and what actions would be taken if critical limits are not met.

## Review verification records that have been created in the past 12 months or since the last routine inspection, whichever is shorter. This review is to determine if verification of CCP monitoring records and monitoring equipment are taking place and being recorded per the haccp plan.

## Select verification records for CCP monitoring records and monitoring equipment accuracy that related specifically to the CCP monitoring records that were selected for review in 6.6.1.

## Some verification records may be included in the CCP monitoring form, such as with a batch record verification signature.

## Some verification records may be separate, such as scale accuracy checks and thermometer calibrations.

## Evaluate Other Applicable Procedures

## For all haccp plans, compare incoming materials and added ingredients noted from the process flow review in section 6.4 to the finished product label to determine if discrepancies exist.

## For ROP haccp plans, review finished products, written materials and implementation for the specific requirement in MR 4626.0420 “Reduced Oxygen Packaging Criteria” to determine if discrepancies exist. Products are adequately labeled – Refer to *Attachment C: Retail HACCP ROP Labeling Requirements*.

## Review operational procedures for preventing contamination from hands, prevention of cross contamination, restriction of equipment and facilities to trained personnel, and sanitation procedures for food contact surfaces. .

## For haccp plans associated with approved food process with haccp variances, refer to *FOOD.30.18 – Variance Request Review and Renewal – Retail Food SOP*.

## Evaluate Knowledge and Training

## Using open ended questions and observations from the inspection, determine if the PIC and other employees responsible for implementation of the haccp plan understand the hazards, controls and applicable procedures. Employees should be able to identify deviations and understand the required corrective action to be taken as specified in the haccp plan.

## Ask the owner/overall manager about their knowledge of the regulatory need and responsibilities related to the HACCP plan.

## Ask the PIC questions regarding specific CCPs and why control is necessary.

## Ask the monitoring employees what actions are taken when critical limits are not met and deviations occur. If employees reference specific occurrences of corrective actions being taken, compare with corrective action records.

## HACCP Audit Guide

## For a routine HACCP audit, refer to the *HACCP Audit and Variance Worksheet* based on the observations and information gathered during the inspection. This guidance document is a tool to assist in your evaluation of the implementation of the haccp plan and should be reviewed prior to and during the routine retail inspection report. This form will assist in identifying deficiencies that require orders to be written in the routine Retail Food inspection report.

## References that can be used for this review also include, but are not limited to, the *MN Food Code*, *MDA Model Retail HACCP Templates* and *Evaluation Tool for Acidified Rice Plans Guidance Document*.

## For haccp plans that have never gone through the review process or where significant unresolved deficiencies exist, require the firm to submit an electronic (preferred) or hard copy of the plans and submit to [www.MDA.HACCP.Variance@state.mn.us](http://www.MDA.HACCP.Variance@state.mn.us) or mail to assigned HACCP support staff for complete review per *FOOD.30.28 - HACCP Plan Review – Retail Food*. Notify the firm of their rights to mark information as confidential.

## Documenting Retail HACCP Audit in Inspection Report

## Collect a copy of any approved HACCP plan in use if not currently recorded in SharePoint.

## Issue orders on the inspection report for all deficiencies noted from the inspectional observations relating to the haccp plan, itself, or with the monitoring records. If deficiencies were identified from inspection interview rather than direct observation, make sure the report clearly identifies the issue as well as the source of the violation.

## Utilize the *HACCP Audit and Variance Worksheet* and Standardization Verification Summary Form as a tool to assist in assessing compliance with the haccp plan.

## If significant (material) changes have been made to the processes or products that are not reflected in the approved haccp plan, issue an order to re-submit the plan for review and approval by the regulatory authority. Refer to *FOOD.30.28 -HACCP Plan Review – Retail Food*.

## Refer the inspection report to Compliance in USAFS for review if significant or on-going non-compliant conditions are observed during the haccp plan audit.

## Renewal of Food Process with HACCP Variance (if applicable)

## Refer to *FOOD 30.18 – Variance Request Review and Renewal – Retail Food SOP* for variance renewal procedures.

## Product Disposition and Field Compliance Actions

## Request an immediate corrective action be taken if:

##  The situation poses a possible/ immediate threat to public health, such as a CL not being met at a CCP during the inspection, or

##  The retail food establishment has not been documenting CCP results, verification checks, or corrective actions but can immediately begin to do so.

## Verify that the firm has corrected the identified operational problem. Do not continue on the inspection until confidence is established that the firm is taking the appropriate corrective action. Take detailed notes and collect evidence of the observation and corrective action(s) taken.

## In cases when the firm does not have control over a process, inform the PIC they must discontinue that type of production and issue the relevant orders. This may apply in instances when a haccp plan is not in place and the firm is not actively monitoring and controlling hazards.

## In cases when the firm has a haccp plan in place but the CCPs are not in control, inform the PIC to discontinue the process, make adjustments to the haccp plan, train employees, and/or comply with the haccp plan based on the specific deficiencies. Consult with your supervisor as needed.

## Evaluate the situation to determine proper disposition of the product or recalls must be issued. This must be considered when CLs have not been met. Refer to *FOOD.30.27 - Field Compliance Actions* and consult Food Inspection Supervisors as needed for this determination.

## An additional inspection may be necessary, refer to *FOOD.30.02 - Reinspection and Follow-Up Inspection SOP* for specific direction.

* 1. **Establishment File Records**

## If a retail food establishment has an approved HACCP Plan on site, but the plan is not in SharePoint per a review conducted according to 6.2, request that the retail food establishment provide a copy of the approved plan by either emailing a copy to MDA.HACCP.Variance@state.mn.us, or mailing a hard copy to the MDA-FFSD 625 Robert Street North, St. Paul, MN 55155.

# RELATED DOCUMENTS (includes References, Attachments)

FOOD.30.02 - Reinspection and Follow-Up Inspections SOP

FOOD.30.27 - Field Compliance Actions SOP

FOOD.30.28 - HACCP Plan Review – Retail Food

FOOD.30.18 – Variance Request Review and Renewal – Retail Food

HACCP Audit and Variance Worksheet

MN Rule 4626 – MN Food Code

MDA Model Retail HACCP Plan Templates

Variance Application

Attachment B – Use of Gases in MAP and CAP

Attachment C - Retail HACCP ROP Labeling Requirements

Evaluation Tool for Acidified Rice Plans Guidance Document

# EQUIPMENT/MATERIALS NEEDED

# USA Food Safety – electronic inspection system

## Inspection equipment

## SAFETY

# N/A

## CIRCULATION

This policy will be circulated to the following: Retail Food Program staff. The current version will be stored electronically on the FFSD document control site.