



MASSACHUSETTS
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A REGULATOR'S GUIDE:

Validation and Verification Of HACCP Plans In Retail Food Establishments

Presenter

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Today's Topics

- Background Information
- Purpose
- Acknowledgements
- Regulator's Guide Contents
- Accessing the Regulator's Guide

Acknowledgements

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Acknowledgements

Some of the content in this guidance document was adapted from a previously published course for regulators entitled “*Validation and Verification of HACCP Plans in Retail Food Establishments*”, developed by the Massachusetts Department of Public Health Food Protection Program, made possible by an FDA Innovative Food Safety Grant. (Next slide)

Validation and Verification of **HACCP** Plans in Retail Food Establishments

(Food Service and Retail Food Stores)

A Course for Retail Food Regulators

Learner Guide



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I also wanted to call out the Sample Field Verification Checklists found at the back of the guidance document, which were reproduced from the *Field Reference Guide for Special Processes at Retail*, published by The Center for Agriculture and Food Security and Preparedness in conjunction with The University of Tennessee, Knoxville, College of Veterinary Medicine. (Next slide)

Field Verification Checklists

FIELD REFERENCE GUIDE

Special Processes at Retail

The Center for
Agriculture and
Food Security
and Preparedness



THE UNIVERSITY of TENNESSEE **UT**
KNOXVILLE
COLLEGE OF VETERINARY MEDICINE

Background

- During the past decade, retail food establishments have expanded their operations to include food processing-type operations, such as reduced oxygen packaging, acidification, fermentation, smoking, curing, and drying, often using sophisticated technologies and equipment.
- These specialized processes present a significant health risk if not conducted under strict operational procedures.
- For this reason, each physical facility conducting one or more specialized processes must submit a properly prepared and approved HACCP plan prior to beginning operations.
- In many instances, a variance is also required because these processes often require specific food safety controls not otherwise addressed in The Food Code. If a variance is required, the HACCP plan must be pre-approved by the regulatory authority prior to starting the operation.

- For jurisdictions that have adopted The Food Code and/or additional requirements, regulators are responsible for ensuring that HACCP plans are effectively implemented to eliminate or significantly reduce identified hazards that may contribute to foodborne illness.
- Regulators are responsible for ensuring that such plans, as written, are valid in addition to verifying their effective implementation in the field.
- In order to assist retail food regulators in fulfilling these responsibilities, the Massachusetts Environmental Health Association (MEHA) received funding from the Centers for Disease Control and Prevention, Office for State, Tribal, Local and Territorial Support to develop this guidance document.

Purpose

- Assist regulators with identifying specialized processes or operations that require a variance and/or a HACCP plan when conducted in a retail food establishment.
- Help explain the administrative provisions in The Food Code that addresses variance requests, contents of a HACCP plan, and conformance with approved procedures for mandated HACCP plans.
- Prepare regulators to identify hazards and control measures when conducting HACCP plan validations and field verifications in retail food establishments using The Food Code, as well as other government, academic, and scientific information.

Primary Source

Regulatory information in this guidance document is based primarily on the U.S. Public Health Service 2013 FDA Food Code with 2015 Amendments (hereinafter referred to as The Food Code) and supplemental MA regulations *105 CMR 590.000: State Sanitary Code Chapter X: Sanitation Standards for Food Establishments*, therefore regulators may need to modify information based on their jurisdictional requirements.

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Applicable Regulations:

Specialized Processes or Operations Requiring a HACCP Plan

- § 3-404.11 Treating Juice Packaged in a Retail Food Establishment
- § 3-502.11 Variance Requirement (processes that require a variance)
- § 3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria
- § 3-801.11 Pasteurized Foods and Prohibited Food in HSPs

Administrative Provisions

- § 8-103.10 Modifications and Waivers
- § 8-103.11 Documentation of Proposed Variance and Justification
- § 8-103.12 Conformance with Approved Procedures
- § 8-201.13 When a HACCP Plan is Required
- § 8-201.14 Contents of a HACCP Plan

Regulatory authority may grant a variance by modifying or waiving the requirements of this Code if in the opinion of the regulatory authority – a health hazard or nuisance will not result from the variance. If a variance is granted, the regulatory authority shall retain the information specified under § 8-103.11 in its records for the food establishment

A variance is a written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements of The Food Code if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.

Regulation: § 8-103.11 Documentation of Proposed Variance and Justification

Before a variance from a requirement of this Code is approved, the information that shall be provided by the person requesting the variance and retained in the regulatory authority's file on food establishment includes:

- A. A statement of the proposed variance of the Code requirement citing relevant Code section numbers;
- B. An analysis of the rationale for how the potential public health Hazards and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; and
- C. A HACCP plan if required as specified under § 8-201.13(A) that includes the information specified under § 8-201.14 as it is relevant to the variance requested.

Regulation: § 8-103.12 Conformance with Approved Procedures

If the regulatory authority grants a variance as specified in § 8-103.10, or a HACCP plan is otherwise required as specified under § 8-201.13, the permit holder shall:

- A) Comply with the HACCP plans and procedures that are submitted as specified under § 8-201.14 and approved as a basis for the modification or waiver; and
- B) Maintain and provide to the regulatory authority, upon request, records specified under §§ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;
 - 1. Procedures for monitoring critical control points,
 - 2. Monitoring of the critical control points,
 - 3. Verification of the effectiveness of an operation or process, and
 - 4. Necessary corrective actions if there is failure at a critical control point

Regulation: § 8-201.13 When a HACCP Plan is Required

- A) Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the regulatory authority for approval a properly prepared HACCP plan as specified under § 8-201.14 and the relevant provisions of this Code if:
1. Submission of a HACCP plan is required according to law;
 2. A variance is required as specified under § 3-502.11, ¶ 4-204.110(B), or Subparagraph 3-401.11(D)(3); or
 3. The regulatory authority determines that a food preparation or processing method requires a variance based on a plan submittal specified under § 8-201.12, an inspectional finding, or a variance request
- B) A permit applicant or permit holder shall have a properly prepared HACCP plan as specified under § 3-502.12.

For a food establishment that is required under § 8-201.13 to have a HACCP plan, the plan and specifications shall indicate:

- A) A categorization of the types of TCS food(s) that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the regulatory authority;
- B) A flow diagram by specific food or category type identifying critical control points and providing information on the following:
 - 1. Ingredients, materials, and equipment used in the preparation of that food, and
 - 2. Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
- C) Food employee supervisory training plan that addresses the food safety issues of concern;
- D) A statement of standard operating procedures for the plan under consideration including clearly identifying:
 - 1. Each Critical Control Point (CCP),
 - 2. The Critical Limits for each CCP,
 - 3. The method and frequency for monitoring and controlling each CCP by the food employee designated by the person-in-charge (PIC),
 - 4. The method and frequency for the PIC to routinely verify that the food employee is following standard operating procedures and monitoring CCPs,
 - 5. Action to be taken by the PIC if the critical limits for each CCP are not met, and
 - 6. Records to be maintained by the PIC to demonstrate that the HACCP plan is properly operated and managed; and
- E) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal.

MODULE 1

REGULATORY APPLICATIONS OF HACCP IN RETAIL FOOD ESTABLISHMENTS

- Specialized Processing Methods or Operations Requiring a Variance AND a HACCP Plan
- Specialized Processing Methods or Operations Requiring a HACCP Plan, but NO Variance
- Specialized Processing Methods or Operations That DO NOT Require a Variance or a HACCP Plan

Specialized Processes are processes or procedures requiring specific food safety controls not otherwise addressed in The Food Code.

Specialized Processing Methods Requiring a Variance AND a HACCP Plan

Regulation § 3-502.11

A food establishment shall obtain a variance from the regulatory authority as specified in § 8-103.10 and § 8-103.11 before conducting one or more of the following specialized processes. A HACCP plan is also required under § 8-201.13 and must be approved by the regulatory authority before conducting a specialized process.

- A) Smoking food as a method of preservation (rather than a method of flavor or color enhancement);
- B) Curing food;
 - 1. As a method of food preservation (rather than to enhance flavor) or
 - 2. To render food so that it is not time/temperature control for safety (TCS)
- C) Using food additives or adding components such as vinegar, such as acidification or fermentation)
- D) Packaging Time/Temperature Control for Safety (TCS) food using a Reduced Oxygen Packaging (ROP) method except where the growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* are controlled as specified under § 3-502.12;
- E) Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption;
- F) Custom processing animals that are for personal use as food and not for sale or service in a food establishment;
- G) Preparing food by another method that is determined by the regulatory authority to require a variance, such as treating juice to achieve a 5-log reduction of pathogens; or
- H) Sprouting Seeds or Beans

Note: You may often see overlap in some of these processes, such as curing, smoking, and drying.

Specialized Processing Methods or Operations Requiring a HACCP Plan, but NO Variance

Treating Juice to Attain a 5-log Reduction of Most Resistant Microorganism of Public Health Concern

Regulation § 3-404.11

- ¶ (A) Treated under a HACCP PLAN as specified in ¶¶ 8-201.14(B) - (E) to attain a 5-log reduction of the most resistant microorganism of public health significance.

Reduced Oxygen Packaging (ROP) without a Variance, Criteria

Regulation § 3-502.12

- ¶ (B): ROP packaged TCS food must control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes* by meeting specific criteria.
- ¶ (C): ROP packaged fish must be frozen before, during, and after packaging.
- ¶ (D): ROP packaged TCS food using a cook-chill or sous vide process must meet specific criteria.
- ¶ (E): ROP packaged specific cheeses must meet specific criteria.

Special Requirements for Highly Susceptible Populations - Additional Safeguards - Pasteurized Foods - Special Requirements for Highly Susceptible Populations (HSP)

Regulation: ¶ 3-801.11(F)(3) - Pasteurized Foods and Prohibited Food

If a food establishment that serves a highly susceptible population, wants to prepare raw, whole shell eggs in quantities other than single service portions they must conduct the process under a HACCP plan that:

- (a) Identifies the food to be prepared,
- (b) Prohibits contacting ready-to-eat foods with bare hands,
- (c) Includes specifications and practices that ensure:
 - (i) Salmonella Enteritidis growth is controlled before and after cooking, and
 - (ii) Salmonella Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in subparagraph ¶ 3-401.11 (A)(2),
- (d) Contains the information specified under § 8-201.14 (D) including procedures that:
 - (i) Control cross contamination of ready-to-eat food with raw eggs, and
 - (ii) Delineate cleaning and sanitization procedures for food contact surfaces, and
- (e) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

Note: Although not mandated by The Food Code, some regulatory agencies require a variance whenever a HACCP plan, or pre-approved written procedures are required.

Treating Juice

Regulation ¶ 3-404.11 (B)

Unpasteurized juice that is not treated to yield a 5-log reduction of the most resistant microorganism of public health significance (not for HSP) may apply a warning statement on the package as specified under § 3-602.11 and in 21 CFR 101.17(g).

“WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.”

Reduced Oxygen Packaging (ROP) without a Variance, Criteria

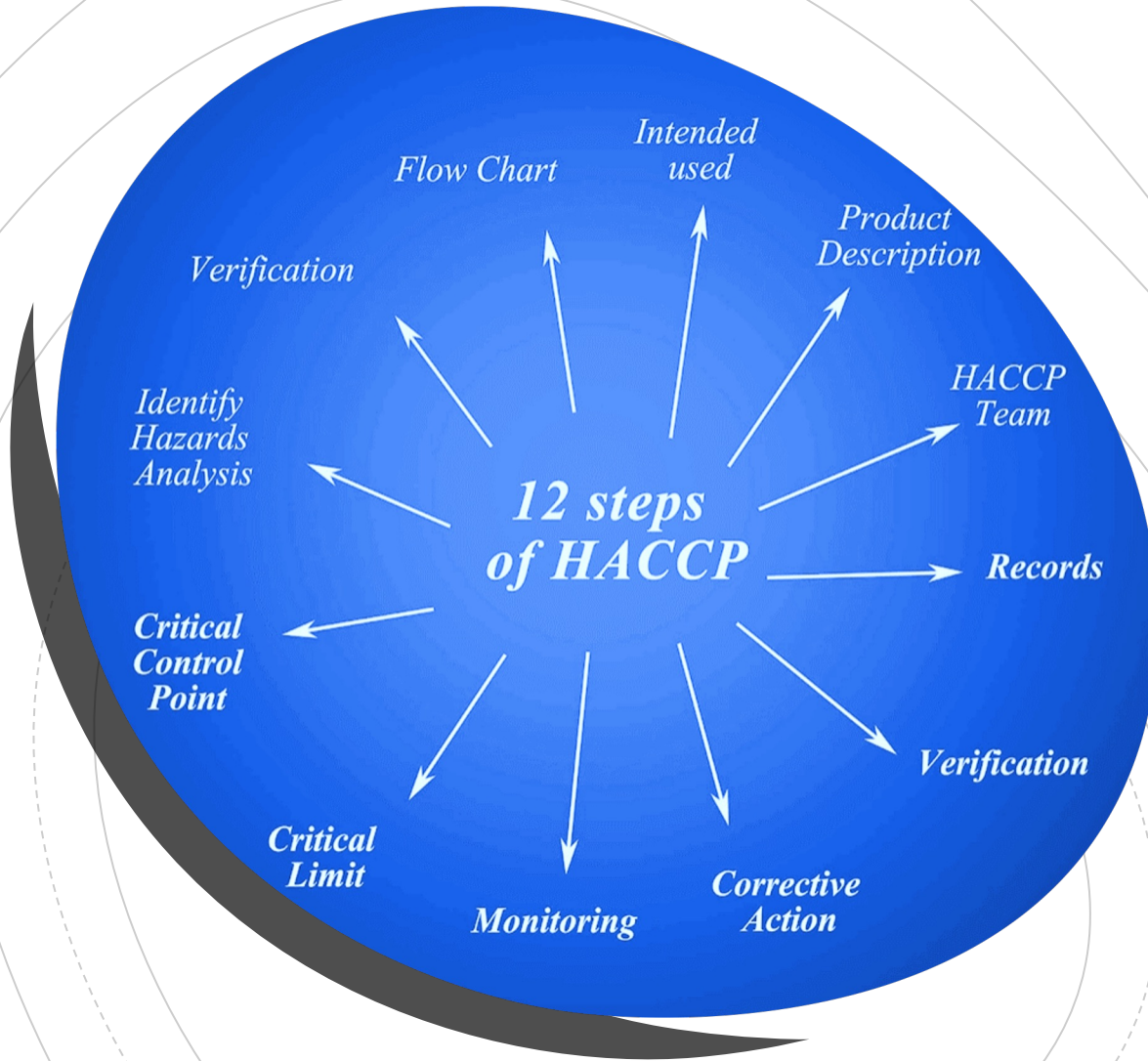
Regulation ¶ 3-502.12 (F)

A HACCP plan **is not** required when a food establishment uses a reduced oxygen packaging method (ROP) for TCS food that is always:

1. labeled with the production time and date,
2. held at or below 41°F during refrigerated storage, and
3. removed from its package in the food establishment within 48 hours after packaging

MODULE 2

HACCP Review



MODULE 3

Specialized Processes Requiring a HACCP Plan

- Acidification/Adding Components to Render Food Non-TCS
 - Reduced Oxygen Packaging (ROP) – *TCS Foods Only*
 - Molluscan Shellfish Life Support System Display Tanks
 - Custom Processing Animals
 - Curing
 - Smoking (to extend shelf life)
 - Fermenting, Drying (other methods)
 - Packaging Juice
 - Sprouting Seeds or Beans
 - Pasteurized Foods and Prohibited Food – Whole Shells Eggs
- Special Requirements for Highly Susceptible Populations

Module 3 - Specialized Processes

Each section contains the following information:

- Regulatory Citation
- Public Health Rationale or Background
- Key Terms
- Processing Controls and Guidelines
- Guideline for Validating the Specific Process

Example: Custom Animal Processing



Regulation: § 3-502.11 Specialized Processes

All domesticated meat and poultry whose product is intended for sale must be slaughtered and processed in a U. S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) inspected facility. The facility must be subject to mandatory or exempt inspection by USDA/FSIS. All USDA/FSIS inspected facilities are subject to licensure by the MA Department of Public Health (DPH).

Any food establishment intending to process either meat and poultry raised for private use, or “*field dressed*” game animals intended for private use, is required to apply for a variance and submit a HACCP plan for pre-approval prior to starting the process.

Key Terms

Custom Processing

Preparing/processing of animals who have died by means other than slaughtering and whose product is not to be sold or given away and is only for the use of the owner of the animal, his family and/or non-paying guests.

Field dressed

Field dressed means that the body cavity has been opened and the internal organs removed.

Game Animals

Game Animal means an animal, the products of which are food, that is not classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2 Definitions, or as poultry, or fish. Game animals include mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and non-aquatic reptiles such as land snakes. Game animals do not include ratites.

Public Health Rationale

The purpose of requiring a variance and a HACCP plan, when custom processing animals that are for personal use as food is to ensure that this process is conducted in a sanitary manner. It is also necessary to ensure that these animals, intended for private use, do not get into the food chain, as they are considered an unapproved food source.

The primary concern regarding this type of specialized process is that these animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness in humans. Some of these diseases can be severe in the human host.

It is imperative, to avoid cross-contamination, that these animals, which are not inspected under USDA, be processed separately from all other products for sale to the consumer. Strict adherence to proper hand washing techniques and cleaning and sanitizing procedures is also required to prevent microbiological contamination and prevent cross-contamination.

Although when discussing sanitation, the emphasis is placed on the environment, the products themselves must not be overlooked. Dirty or spoiled meat products entering a sanitary environment are not only unacceptable in themselves but place the environment at risk as well.

Controls & Guidelines

- The following guidelines are recommended to ensure that any custom processed animals stored in the establishment must be contained and handled so that there is complete separation from all other products for sale to the consumer.
- Provide a written list of days and times when game animals are processed.
- Attach a tag, with the words “NOT FOR SALE” in letters at 3/8” in height, to all incoming carcasses. Tags must also include a space for assigning a designated carcass number. (A label may also be stamped directly onto the carcass.)

Controls & Guidelines

- Keep a record (log book) of the name and address of the owner of each carcass, the species, date received, dressed weight and the assigned designated carcass number to the tag. Records should be maintained for at 90 days and should be available, during reasonable hours, for inspection by regulators.
- Any equipment used to process game animals or meat must be thoroughly cleaned and sanitized before it can be used for processing domestic meat, poultry, fish, ready-to-eat foods and other retail products.
- Store all custom processed animals and animal products on separate shelves while in cold storage. A “NOT FOR SALE” tag, with corresponding record number from the original tag, should be attached to any shelves or packages storing custom processed animals or animal products.

Guideline For Validating Custom Processing Animals HACCP Plans

Prerequisites and Standard Operating Procedure(s) (SOPs)

- ☐ Most recent inspection reports indicate compliance with all regulations. Pre Existing violations, which may result in biological/physical/chemical contamination of product, have been correcte
- ☐ Instructions provided for cleaning and sanitizing all equipment used to process game animals or meat before processing domestic meat, poultry, fish, ready to eat foods and other retail products
- ☐ Separate storage areas provided in cold storage unit(s) for custom processed animals and animal products
- ☐ "NOT FOR SALE" tag/label, with corresponding record number from the original tag/label, provided for shelves or containers holding custom processed animals or animal products

Hazard Analysis Included

- ☐ Microbiological contamination, such as viruses, rickettsiae, bacteria, or parasites

CCP(s) Identified

- ☐ Receiving tagging/labeling

Critical Limit(s) Identified

- ☐ Carcasses or portions of carcasses immediately tagged/labeled with "NOT FOR SALE" notices

Monitoring Procedures Identified

- ☐ Every carcass, or portion thereof, visually inspected for presence of tag/label
- ☐ Person(s) identified for monitoring presence of tag/label

Corrective Actions and Documentation Procedures Identified

- ☐ Verify segregation of improperly tagged/labeled product
- ☐ Verify disposal: product of unknown origin or product contacting custom processed animal(s)
- ☐ Corrective actions recorded in log (sample page included)
- ☐ Cause of deviation determined

Verification Process Identified (Short Term/Long Term)

- ☐ Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC
- ☐ Signed and dated HACCP plan reviewed and modified at least annually or as needed by PIC

Records are Identified

- ☐ Tag/label
- ☐ Written list of days and times when game animals are processed
- ☐ Receiving record (log book) including:
 - ☐ name and address of the owner of each carcass
 - ☐ species
 - ☐ date received
 - ☐ dressed weight
 - ☐ assigned designated carcass number to the tag
- ☐ Records/tags/labels maintained for at least 90 days
- ☐ Corrective action record

Employee Training Plan Documented (sample of training log provided)

- ☐ Employee Health and Hygiene
- ☐ Cross Contamination Prevention Procedures
- ☐ Corrective Actions
- ☐ Cleaning and Sanitizing Procedures
- ☐ Monitoring Procedures Meet Critical Limits
- ☐ Recordkeeping Requirements

HACCP Field Verification Checklist - Adding Components or Food Additives

Establishment Name:

Address:

Person-in-Charge: Phone: e-mail:

Date Written Plan Validated:

Food Product and Process:

Inspection Type:

- ☐ **HACCP Plan Review**
☐ **Record Review**
☐ **On-Site Verification**

Inspector:

YES	NO	Validated HACCP Plan Available for Review
*		Comments: (Intended to extend shelf life or make non-PHF/non-TCS?)

Comments:

YES	NO	Establishment has Implemented Effective SOP and SSOP Pre-Requisites (Document violations on your Food Establishment Inspection Report)
		Time/Temperature Controls
		Cleaning and Sanitation
		Inspected and/or Reputable Suppliers of Meat, Fish or other Ingredients
		Water quality and management
		Protection of Food/Ingredients from Chemicals/Contamination
		Recipe/Menu Production Standards
		Critical Equipment Operation/Calibration/ pH meter/
		Facilities/Equipment Maintenance
		Employee education and training
		Storage and/or Distribution
		Other

Comments:


Are Critical Control Points (CCPs) and Critical Limits identified by the establishment's verified HACCP plan being met?

YES	NO	Food Item or Process e.g. receiving, cooler storage, tank storage	Critical Control Point	Critical Limits	Comments/ Problems Noted
*				Per CFR, if appropriate	

Are monitoring records required by the establishment's verified HACCP plan available?

YES	NO	Type of Record	Monitoring Frequency and Procedure	Record Location (Where kept?)
		Receiving		
		Recipe/Menu Production		
		CCPs		
		Sanitation		
		Calibration/Monitoring Equip.		
		Corrective Actions		
		Training		
		Verification		
		Product Inventory/Distribution		
		Other		
YES	NO	Accurate Description of Product/Process and Intended Uses		
		Food flow, menu, packaging and formulation are consistent with flow chart and approved HACCP plan		
*		Temperature, pH, water activity, Humidity and other critical control points and critical limits are followed per HACCP Plan and CFRs, if applicable		
		Employee demonstrates calibration and pH, temperature or CCP measurement for inspector		
		Employee uses forms for recording recipe, calibration and pH, temperature or other measurement during inspection		
Comments:				
YES	NO	Hazards		
		Individual(s) responsible for maintaining system and verification that required records are being completed and properly maintained is identified by establishment		
		Are the records for the present day accurate for the observed situation in the facility?		
		Employee demonstrates knowledge of CCPs and critical limit for their retail process when asked.		
		Employee demonstrates understanding of importance of critical limit(s) when asked.		
		Are routine calibrations required, performed, and documented on the appropriate form according to the plan?		
		Are monitoring actions performed according to the HACCP plan?		
		Are there specific strengths or weaknesses with the current monitoring or record keeping regimen? If yes, note in comments		
Comments:				

Are monitoring records required by the establishment's verified HACCP plan available?

YES	NO	Type of Record	Monitoring Frequency and Procedure	Record Location (Where kept?)
		Receiving		
		Recipe/Menu Production		
		CCPs		
		Sanitation		
		Calibration/Monitoring Equip.		
		Corrective Actions		
		Training		
		Verification		
		Product Inventory/Distribution		
		Other		
YES	NO	Accurate Description of Product/Process and Intended Uses		
		Food flow, menu, packaging and formulation are consistent with flow chart and approved HACCP plan		
*		Temperature, pH, water activity, Humidity and other critical control points and critical limits are followed per HACCP Plan and CFRs, if applicable		
		Employee demonstrates calibration and pH, temperature or CCP measurement for inspector		
		Employee uses forms for recording recipe, calibration and pH, temperature or other measurement during inspection		
Comments:				
YES	NO	Hazards		
		Individual(s) responsible for maintaining system and verification that required records are being completed and properly maintained is identified by establishment		
		Are the records for the present day accurate for the observed situation in the facility?		
		Employee demonstrates knowledge of CCPs and critical limit for their retail process when asked.		
		Employee demonstrates understanding of importance of critical limit(s) when asked. 		
		Are routine calibrations required, performed, and documented on the appropriate form according to the plan?		
		Are monitoring actions performed according to the HACCP plan?		
		Are there specific strengths or weaknesses with the current monitoring or record keeping regimen? If yes, note in comments		
Comments:				

YES	NO	Employee Shows Knowledge of Corrective Actions if Critical Limit Exceeded or Not Met
		When critical limits established by the plan are not met, are immediate corrective actions taken and recorded?
		Employee knows who to contact to take corrective actions. Uses corrective action monitoring form and holds food for corrective action as needed.
		Person-in-charge shows knowledge of corrective action and proper disposal of food unfit for consumption
		Do the corrective actions taken reflect the same actions described in the establishment's plan?
Comments:		
YES	NO	Training
*		Does the establishment have a training program to support the plan? If deficient, describe in comments. (Include use of any special equipment)
		When training is provided, is it documented and are the records available?
		Employee demonstrates calibration and pH, temperature, humidity or CCP measurement for inspector upon request
Comments:		
YES	NO	Do managers and employees demonstrate knowledge of the plan?
		Comments:
YES	NO	Other issues or comments needing attention
		Comments:

Corrective Action Needed

- ☐ None (Establishment is in compliance)
- ☐ Order for correction issue (Inspection Report Form or Letter)
- ☐ Emergency suspension of operation
- ☐ Seizure of food
- ☐ Voluntary disposal
- ☐ Employee restriction/exclusion
- ☐ Employee training
- ☐ Other: _____

Inspector: _____ Date of Inspection: _____

MODULE 4

Validating and Verifying the HACCP Plan

- Key Terms
- Variance/HACCP Plan Approval Process
- Written HACCP Plan Review
- Elements of the HACCP Plan Validation Process
- HACCP Plan Review and Revalidation
- Validation of New/Modified HACCP Plans
- Elements of the HACCP Plan Verification Process
- Non-compliant HACCP Systems
- Enforcement/Corrective Actions
- Follow-up Field Verification Inspections

MODULE 4

Validating and Verifying the HACCP Plan

- Sample Variance Request Forms
- Sample HACCP Plan Review Application Form
- Sample Generic HACCP Plan Validation Checklist
- Sample Generic HACCP Field Verification Checklist
- Sample HACCP Field Verification Checklists

Variance Request Form

Date: _____

Name of Business (if applicable): _____

Property Address or Location: _____

Name of Property / Business Owner / Applicant: _____

Title: Phone Number: _____

Email: _____

List the section(s) of the regulation which you are requesting variance:

Reason(s) the regulation cannot be met:

Alternative or additional protective measures to be taken to assure a comparable degree of protection to health or the environment:

Length of time variance is requested for: _____

Note: Please submit a complete application with all relevant and supporting information necessary to properly evaluate this request. Incomplete applications cannot be processed and will be returned to the applicant. A public hearing before the Board of Health will be scheduled once a complete application is received.

Print Name of Applicant: _____ Date _____

Signature of Applicant: _____

REQUEST FOR A VARIANCE

Date: ____/____/____ Establishment ID Number: ____ _

Establishment Name:

Establishment Owner/Permit Holder

Physical Address:

_____ City:

_____ County: _____ Zip: _____ Mailing

Address (if different): _____

Are you applying for multiple locations: ____ Yes ____ No

(If yes, please attach a list of the other facilities including their physical addresses and the counties in which they are located.)

Contact Person: _____ Title:

_____ Contact Telephone Number () _____ Fax Number ()

*Email Address:

_____ *confirmation
of receipt will be by email. If you do not wish to receive email notification, CHECK HERE []

Please use the checklist below for verification all necessary items are included with your application:

Type of variance requested:

- ☐ Acidification (e.g., sushi rice)
- ☐ Smoking Food for Preservation (e.g., meat, fish)
- ☐ Curing Food (e.g., sausage, corned beef, pickled herring)
- ☐ Reduced Oxygen Packaging (e.g., vacuum packaging, modified atmosphere packaging)
- ☐ Molluscan Shellfish Life-Support Tank
- ☐ Custom Processing of Animals for Personal Use (not for sale)
- ☐ Sprouting Seeds or Beans
- ☐ Other _____

Type of food product for which you are requesting the variance:

A statement of the proposed variance of the Code requirement citing relevant Code section numbers:

A statement regarding how the proposed process varies from the Regulations/Code(s): (Attach additional pages if needed.)

An analysis of the rationale (justification) for how the potential public health hazards addressed by the relative Code sections will be alternatively addressed by the proposal: (Attach additional pages.)

A HACCP (Hazard Analysis Critical Control Point) plan, if required, including the following:

(Please see attachment "HACCP Plan Requirements" for guidance.)

- **Types of potentially hazardous foods (time/temperature control for safety foods) that are specified in the menu**
- **A flow diagram by specific food or category type identifying critical control points and providing information on the following:**
 - Ingredients, materials, and equipment used in the preparation of the food
 - Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved
- **Food employee and supervisory training plan that address the food safety issues of concern**
- **Standard operating procedures for the plan clearly identifying:**
 - Each critical control point (CCP)
 - The critical limits for each CCP
 - The method and frequency for monitoring and controlling each CCP by the food employee designated by the person in charge (PIC)
 - The method and frequency for the PIC to routinely verify that the food employee is following standard operating procedures and monitoring CCP's
 - Action to be taken by the PIC if the critical limits for each CCP are not met
 - Records to be maintained by the PIC to demonstrate that the HACCP plan is properly operated and managed

Additional scientific data, a validated process, or a challenge study by a certified laboratory as required by the Regulatory Authority, supporting the determination that food safety is not compromised by the proposal: (Please include with the application.)

Please submit your application and supporting documentation to:

Model Hazard Analysis Critical Control Point (HACCP) Plan Review Application	
Establishment Name:	Tel:
Address:	Fax:
Owner/ Person-in-Charge	E-mail:
HACCP Plan Contact:	Tel:

Please note that prerequisites for plan approval are 1) compliance with 105 CMR 590.000 and 2) the implementation for effective standard operating procedures (SOPs) for:

- Food Protection Management
- Employee Health and Hygiene
- Time/Temperature Controls
- Cleaning and Sanitizing
- Approved Food Sources
- Protection From Contamination
- Protection From Chemicals
- Facilities/Equip. Design & Maint.

Please review/use this checklist to verify that you have included the following in your plan:

- ☐ Purpose of Submission (i.e. Variance or Code Requirement - Include Code Preference)
- ☐ Name of food product and process for which the plan is being submitted
 - Include formulation of ingredients, if required
 - Include facility layout, if required
 - Include copy of labeling, if required
- ☐ A flow chart, showing how the product flows through the establishment, including an accurate description of how the food is prepared, held, served, transported etc.
- ☐ Identification of each Critical Control Point (CCP) in the process.

For Each CCP

- ☐ A description of the hazard(s)
- ☐ A description of monitoring procedure(s) and a sample of form(s) that will be used to document the monitoring activities
- ☐ A description of verification procedure(s) and sample of form(s) that will be used to document the verification activities by PIC
- ☐ A description of plan verification and validation procedure(s) (example: annual review, scientific data, modand sample of form(s) that will be used to document the verification activities by PIC)
- ☐ A statement that an update, signed copy of the plan will be maintained on the premises for review by the regulatory authority.
 - Name of the person responsible for administering and updating the plan.
 - A statement that the regulatory authority will be informed of any significant changes in the process that may affect the accuracy or effectiveness of the plan prior to implementation, and
 - A statement that updated plans will be submitted to the regulatory authority, upon request.
 - Laboratory data, if required
- ☐ Employee training plan and sample form(s) that will be used to document employee training

All of the information submitted is accurate to the best of my knowledge. All violations noted during previous food safety inspections have been corrected and the operation is in compliance with 105 CMR 590.000 Minimum Sanitation Standards for Food Establishments - Chapter X

I understand that failing to comply with this plan and/or falsification of monitoring, corrective action, or verification records may result in a suspension of operations in accordance with 105 CMR 590.010 (§ 8-103.12).

Permit Holder or Person-in-Charge _____

Signature/Title Date _____

Date	Reviewer	Comments	Accepted

Implementation Date:

Principle # 1 of HACCP - Hazard Analysis and Flow Chart

The documents written to support Principle #1 of HACCP are some of the most critical and demanding documents in the written plan. Under Principle #1, the following need to be included in a logical order:

- ☐ Name of the food product and the special process for which the HACCP plan is being submitted.
- ☐ Is a variance petition included? Is sufficient data provided to support the petition?
- ☐ Detailed formulation and complete list of ingredients.
- ☐ Packaging and food contact materials, if used. Show that all are approved for food use. Is package ROP?
- ☐ Facility layout and information on whether a dedicated workspace is provided to conduct the special process.
- ☐ Copy of labeling – Check for any required warning concerning temperatures or shelf-life and disposal of food.
- ☐ Hazard analysis.
- ☐ Intended use of product/institutional use/HSP?
- ☐ How it will be sold or served, including package size.
- ☐ Shelf-life.
- ☐ A detailed flow chart showing the holding and preparation of the food product from receiving raw ingredients through packaging and any subsequent distribution. Flow chart should include each specific step and should include cooking, filling and specific temperatures, times, pH or other hurdles that are designed to control food hazards.

Principle #2 of HACCP – Establish Critical Control Points

The following should be provided for you to review:

- ☐ A description of the pertinent hazards associated with this food and special process.
- ☐ Critical control points on the flow chart that are designed to control hazards associated with the food.
- ☐ Description of how the CCP will control the pertinent hazards and specific reference information source.

Principle #3 of HACCP – Establish Critical Limits

A CL must be provided for each CC.

- ☐ Is the critical limit correct based on Food Code?
- ☐ Can the CL be measured? How?
- ☐ Will this CL control the hazard(s)?

Principle #4 of HACCP – Establish Monitoring Procedures

The following should be provided.

- ☐ List of items to be monitored. The list will vary somewhat depending upon the special process.
- ☐ Forms or checklists used for monitoring each item.
- ☐ Who will monitor the item? When will it be monitored and how often?
- ☐ Examples of items that might be monitored: sanitation, pH, aw, calibration of equipment, temperatures, recipe (each batch), corrective actions, employee training, plan verification and review, HACCP revisions - changes in the recipe or protocols, receiving, food disposal, other.
- ☐ Indicate if monitoring is an OBSERVATION or a MEASUREMENT.
- ☐ Is instrument calibrated?
- ☐ Is employee training documented?
- ☐ How will records for continuous monitoring be provided? (example: cook chill/drying meat/fermenting).



Principle #5 of HACCP – Establish Corrective Actions

The following should be provided:

- ☐ Have a specific corrective action for each CCP that is out of compliance.
- ☐ Who will be responsible for the corrective action?
- ☐ How will each occurrence be documented?
- ☐ Plan for food disposal when necessary (SOP).
- ☐ Does the established monitoring plan identify all deviations?

Principle #6 of HACCP – Establish Record Keeping Procedures

The following should be provided:

- ☐ Where are records?
- ☐ How long will records be kept?
- ☐ Specify records to be kept.
- ☐ Plan revision schedule.
- ☐ Where are SOP and SSOP Records? Employee training records, monitoring records location?

Principle #7 of HACCP – Establish Verification Procedures

The following should be provided:

- ☐ WHO is responsible for verification?
- ☐ What is the procedure for verification and the frequency?
- ☐ What will be verified? Will records also be verified?
- ☐ Will the verification confirm that established procedures are followed?
- ☐ Will the verification be documented in writing and any actions taken recorded?
- ☐ Is the HACCP system reviewed annually to keep information up-to-date?

Model HACCP Field Verification Report Form		
Establishment Name:		
Address:		
Person-in-Charge		
Date Written Plan Validated		
Food Product and Process		
Validated Plan	In	Out
HACCP plan validated by the regulatory authority available for review		
Prerequisites	In	Out
Establishment has implemented effective standard operating procedures and is in compliance with 105 CMR 590.000 (Document violations on Food Establishment Inspection Report Form)		
Accurate Description of Product/Process and Intended Use	In	Out
Food flow is consistent with flow chart (attached)		
Hazard(s)	Critical Control Point(s)	Preventative Measure(s) / Critical Limit(s)
Monitoring Procedures	In	Out
Food Employee Knowledge of Corrective Actions if Critical Limit(s) Exceeded or Not Met for each CCP	In	Out
Verification Process	In	Out

Glossary



Glossary contains explanations of concepts in a particular sense, the term is related to the notion of ontology that transform a glossary into an ontology

References & Resources

FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments

2014 Compliance Guideline

This guidance document is designed to help very small meat and poultry establishments that manufacture jerky identify:

- The key steps in the jerky process needed to ensure safety; and
- The scientific support available to help develop a safe process and product.



FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) December, 2021

Document ID: FSIS-GD-2021-14

This guideline provides information on the Agency regulatory requirements associated with safe production of ready-to-eat (RTE) products with respect to the destruction of *Salmonella* and other pathogens. It applies to small and very small meat and poultry official establishments although all meat and poultry establishments may apply the recommendations in this guideline. It relates to [9 CFR 318.17\(a\)\(1\)](#), [9 CFR 318.23](#), [381.150\(a\)\(1\)](#), and [9 CFR 417](#).