MASSACHUSETTS
ENVIRONMENTAL HEALTH
ASSOCIATION

A REGULATOR'S GUIDE:
Validation and Verification of HACCP Plans in Retail Food Establishments

A publication of the Massachusetts Environmental Health Association

Developed by Pamela Ross-Kung, MS, RS, President, Safe Food Management

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Introductory Information

Preface

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.

Each physical facility conducting one or more specialized processes must submit a properly prepared and approved Hazard Analysis Critical Control Point (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.

This guidance document is not intended to replace or duplicate existing regulations, but it does offer a reference for more uniform practices.

Purpose

The overall goal of this guidance document is to assist regulators with identifying specialized processes or operations that require a variance and/or a HACCP plan when conducted in a retail food establishment. It should also 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.

This document should also 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.

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The Massachusetts Environmental Health Association (MEHA) is an affiliate of the National Environmental Health Association (NEHA), which was incorporated in 1937. MEHA was established in 1948 and is a non-profit association organized for charitable and educational purposes. The goal and purpose of MEHA is to provide quality training and educational programs while also providing the opportunity for members to meet and exchange ideas and information with other professionals in the field of Public and Environmental Health.

The basis for the content in this guidance document was adapted from a previously published curriculum guide entitled *"Validation and Verification of HACCP Plans in Retail Food Establishments"*, developed by the Massachusetts Department of Public Health Food Protection Program in 2003, made possible by an FDA Innovative Food Safety Grant.

The Sample Field Verification Checklists found in the APPENDIX 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.

If a substantial amount of information was taken from another source, it is referenced at the beginning of the section.

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Michael Boudreau, MPA, REHS / RS, Natick Health Department, MEHA Secretary
Diane Chalifoux-Judge, BS, REHS / RS, Boston Inspectional Services, Health Division, MEHA President
Angelo De Luca, BS, RS, Norwood Health Department
William (Bill) Murphy, MS, RS, CHO, Sudbury Health Department, MEHA Vice President
Thomas W. Nerney, Retail Food Specialist, U. S. Food and Drug Administration
Shanene Pierce, REHS / RS, CPO, MA Department of Public Health, MEHA Treasurer
Stephanie Seller, MPH, MEHA Administrative Coordinator
Rike Sterrett, MPH, REHS / RS, Oxford Health Department
Kathleen Waldron, REHS/RS, Avon Health Department, MEHA Executive Board Member
James White, REHS / RS, MEHA Past President
Robin Williams, BS, REHS / RS, Framingham Department of Public Health, MEHA Past President
Vivian Zheng, MPH, REHS, CP-FS, Wellesley Health Department, MEHA Executive Board Member

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The contents of this guidance document are those of the author and do not necessarily represent the official position of, or endorsement by the Centers for Disease Control and Prevention (CDC), nor does any mention of trade names, commercial practices, or organization imply endorsement by MEHA or the CDC.

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.

The information and recommendations provided in this guidance document are not a binding set of requirements. Retail compliance and enforcement will remain within the interpretations and decisions of the pertinent regulatory agencies.

In addition, all information in this guidance document should be considered in light of new or revised information available after publication.

MODULE 1
REGULATORY APPLICATIONS OF HACCP IN RETAIL FOOD ESTABLISHMENTS

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Regulator's Role and Responsibilities

The Food Code specifies that specialized food processing operations conducted at retail food establishments are required to develop and implement a HACCP plan for that part of the operation. These specialized processes may require the "person-in-charge" (PIC) and food employees to use specialized equipment and demonstrate specific competencies. Requiring a HACCP plan will help ensure that these proposed processes are carried out safely.

Each regulatory authority assuming responsibility for validating and verifying HACCP plans should have the necessary infrastructure conducive to the implementation of HACCP systems, including knowledgeable sanitarians and clear assessment and enforcement policies and procedures.

Regulators are vital in promoting and encouraging "active managerial control" by providing guidance as to when a HACCP plan is necessary and how it can be successfully implemented. The key to successful implementation of HACCP plans depends on collaborative efforts between regulators, food operators, and other food safety professionals.

Regulators in jurisdictions that have adopted The Food Code, or have additional requirements for mandatory food safety plans for the specialized processes and operations, are responsible for ensuring that these plans are effectively implemented to eliminate or significantly reduce identified hazards. All plans in this guidance document will be referred to as HACCP plans.

The first section below lists the specialized processes or operations that require a variance *and* a HACCP plan. The second section lists processes that require a HACCP plan but *do not* require a variance unless mandated by a specific jurisdiction. The third section lists processes or operations that are often thought to need a variance and/or a HACCP plan, but don't require either one.

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

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**.**

Specialized Processing Methods or Operations That DO NOT Require a Variance or a HACCP Plan

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

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
§ 3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria
§ 3-801.11 Pasteurized Foods and Prohibited Food in Highly Susceptible Populations
§ 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

Administrative Provisions

The following sections outline 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.

Key Terms

Active Managerial Control is the implementation and supervision of food safety practices to control risk factors by the person-in-charge.

Highly Susceptible Population are persons who are more likely than other people in the general population to experience

a) Immunocompromised; preschool age children, or older adults; and

b) 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.

Person in Charge (PIC) means the individual present at a food establishment who is responsible for the operation at the time of inspection.

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

Regulation: § 8-103.10 Modifications and Waivers

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

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 ¶ 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.

Regulation: § 8-201.14 Contents of a HACCP Plan

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 2
HACCP REVIEW

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HACCP Review

Public Health Rationale

A Hazard Analysis Critical Control Point (HACCP) plan is necessary when conducting specialized food processes or operations as mandated in the Food Code or by the regulatory authority. Such processes have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. The variance requirement is designed to ensure that the proposed method of operation is carried out safely. The HACCP plan must be maintained at the retail site for review by the regulatory authority.

HACCP Overview

Simply stated, HACCP is a logical and thorough process control system designed to identify and control hazards. HACCP focuses on prevention and control of food safety problems at highly specific (and controllable) points in the process chain. Implementing a well-designed HACCP program provides food manufacturers and food handlers a high level of control over product safety.

HACCP has been around since the 1960's, when the Pillsbury Company introduced it in the production of foods for the space program. The application of HACCP is based on sound technical and scientific principles that assure food safety.

HACCP plans should be specific for each operation. Committed personnel involved in the processing operation should conduct the design and implementation of a HACCP plan.

Although many of the larger food establishments and chains have the expertise available to develop and implement HACCP systems, some of the smaller establishments may require assistance from university extension programs, industry associations, consultants, and/or government agencies for development of their plans.

HACCP System

A complete HACCP system is the result of implementing the HACCP principles in an operation that has a solid foundation of comprehensive, prerequisite programs in place. A HACCP system includes the HACCP plan and all prerequisite programs.

Prerequisite Programs

HACCP is not a stand-alone program. HACCP systems must be built upon a firm foundation of compliance with current Good Retail Practices (GRPs) and Standard Operating Procedures (SOPs). GRPs and SOPs affect the retail environment and should be considered prerequisite programs to HACCP. GRPs cover areas of general hygiene as well as controls that prevent food from becoming contaminated due to unsanitary conditions.

Standard operating procedures (SOPs) are procedures used to accomplish the overall goal of maintaining GRPs. They describe a particular set of objectives associated with sanitary handling of food and the cleanliness of the retail environment, for example, SOP's can help control bacterial hazards specifying procedures to:

1. Avoid product cross-contamination by proper product flow and limiting employee tasks and movement
2. Locate hand washing and sanitizing stations near the food preparation area to facilitate proper hand washing
3. Ensure appropriate equipment maintenance and cleaning/sanitizing procedures

When GRPs and SOPs are in place, HACCP can be more effective because it can allow operators to concentrate on the hazards associated with the food or preparation and not on the retail environment or maintenance of facilities.

Example of programs that are valuable in supporting the HACCP system include:

- Personal hygiene
- Preventive maintenance plans
- Pest control
- Equipment and operation design
- Employee training
- Product identification and coding

HACCP Principles

In November 1992, the National Advisory Committee on Microbiological Criteria for Food (NACMCF) defined seven widely accepted HACCP principles that were to be considered when developing a HACCP plan. In 1997, the NACMCF reconvened the HACCP Working Group to review the Committee's November 1992 HACCP document and to compare it to current HACCP guidance prepared by the CODEX Committee on Food Hygiene.

From this committee, HACCP was defined as a systematic approach to the identification, evaluation and control of food safety hazards based on the following seven principles:

Seven Principles of HACCP

- ➢ Principle 1: Conduct a hazard analysis.
- ➢ Principle 2: Determine the critical control points (CCPs).
- ➢ Principle 3: Establish critical limits.
- ➢ Principle 4: Establish monitoring procedures
- ➢ Principle 5: Establish corrective actions.
- ➢ Principle 6: Establish verification procedures
- ➢ Principle 7: Establish record-keeping and documentation procedures

Principal 1: Conduct Hazard Analysis

The HACCP team should evaluate hazards of significance and preventative measures needed for each food product and process. They should use as many sources of information as possible in this evaluation phase: scientific literature, opinions of experts, laboratory records, and specifications.

A **Food Hazard** is any unacceptable contamination by a biological, chemical, or physical agent at sufficient level to cause a food to be unsafe for human consumption. By far the most common agents are biological, mainly pathogenic bacteria, other microorganisms and parasites.

Biological hazards include: bacteria, bacterial toxins, viruses and parasitic organisms that could survive, grow, or contaminate food products/raw materials, and potentially cause foodborne illness. (See chart entitled: Selected Factors Influencing Growth of Common Foodborne Pathogens following Principle #7.)

Chemical hazards could result from a number of sources: agricultural chemicals, insecticides, fungicides, etc.; cleaning/sanitizing agents and chemicals, certain naturally- occurring toxins such as Scombrotoxin (histamine), Ciguatoxin, mycotoxins from mold, shellfish toxins, etc. and misuse of food chemicals (preservatives, additives, etc.).

Physical hazards include: inadvertent field matter (stones, wood, metal fragments, etc.); inadvertent processing residues (glass, metal fragments, etc.); intentional materials (employee sabotage) and miscellaneous particulates and fragments.

Principal 2: Identify Critical Control Points

A Critical Control Point (CCP) means a point or procedure, in a specific food system, where loss of control may result in an unacceptable health risk.

CCP(s) are not limited to those processes or operations which eliminate hazards. CCPs can also be identified where hazard prevention or reduction can occur (e.g., ingredient or raw material specifications, sanitation programs, etc.).

Identification of CCP(s) is an important and painstaking process and provides the backbone of HACCP. In addition to the element of hazard control at a CCP, it is equally important that such control can be monitored and adequately verified (see Principles 4 and 7).

Principle 3: Establish Critical Limits

A **Critical Limit (CL)** is a safe limit or tolerance that must be met for each identified CCP. These are the boundaries of safety for the microbiological, chemical and physical hazards. Exceeding these boundaries indicates that a health hazard may exist or could develop.

The most obvious examples of such limits are specific temperature/time relationships for either processing or storage that are necessary to prevent, eliminate or reduce microbial hazards. Food composition information such as acidity may also be used.

Principle 4: Establish Monitoring/Inspection Required

Monitoring is a scheduled observation or measurement of a CCP and its limits. The purpose of monitoring is two-fold: to assess whether a CCP is under control and to generate data that will be used to produce an accurate record for future verification. Monitoring procedures should be accurate and done at appropriately established frequency

Principle 5: Establish Corrective Actions

A **Corrective Action** is a procedure followed when a deviation occurs. Corrective actions must be taken whenever monitoring indicates that limits or tolerances are not met. Such action must be immediate to assure that the situation is rectified. Action will vary with the process being monitored and the type of monitoring indicated. Based upon the severity of hazard and the individually defined situation, corrective action may involve: notifying a supervisor, process line shut down, reprocessing, adjusting process temperature and times, rejecting raw materials or ingredients, and holding or recalling product in distribution. Corrective actions must be identified and documented in the HACCP plan and should specifically address each CCP. It is fundamentally important to specifically delineate responsibility and authority with regard to corrective action.

Principle 6: Establish Verification Procedures

A working HACCP system is dynamic and flexible, and allows for change. It should have provisions for verification of its effectiveness.

Verification is a process designed to:

- Review the HACCP plan
- Establish whether the CCPs and CLs are being adequately controlled and monitored.
- Determine if the procedures for product deviations and record keeping are being followed correctly

Verification involves actual observation of procedures and a thorough review of records. The verification team should be clearly identified and empowered. On-going verification should be on a well-defined and established frequency (i.e., once per shift, daily, weekly, etc.). However, a comprehensive HACCP system verification should be conducted at least annually or whenever there is a change in the HACCP system. If the results of that comprehensive verification identify deficiencies, the HACCP plan must be modified, as necessary, to ensure the HACCP plan is controlling the hazards.

Principle 7: Establish a Record Keeping System

An **adequate record keeping system** is the heart of a HACCP program. Records are the documentation needed to verify effectiveness of the HACCP plan. They are the only reference available to trace the production history of a finished product. If questions arise concerning the product, a review of the records may be the only way to ascertain or prove that the product was prepared and handled in a safe manner in accordance with all the HACCP principles outlined in the establishment's HACCP plan.

In order to assure product safety and to document processes and procedures, HACCP records must contain the following information:

- ☐ Title and date of record
- ☐ Product identification
- ☐ Materials and equipment used
- ☐ Operations performed
- ☐ Critical criteria and limits
- ☐ Corrective action to be taken and by whom
- ☐ Operator identification
- ☐ Monitoring data
- ☐ Reviewer's initials and date of review

Key Terms

a_w
A measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature

Control Point
Any point in a specific food system at which loss of control does not lead to an unacceptable health risk.

Critical Control Point
A point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

Critical Limit
The maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize risk that the identified food safety hazard may occur.

Deviation
Failure to meet a required critical limit for a critical control point.

Good Retail Practices (GRPs)
Preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the Food Code interventions or risk factors.

Hazard Analysis Critical Control Point (HACCP)
A prevention-based food safety system that identifies and monitors specific food safety hazards that can adversely affect the safety of food products.

HACCP Plan
A written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by the National Advisory Committee for the Microbiological Criteria for Foods.

HACCP System
The result of implementing the HACCP principles in an operation that has foundational comprehensive, prerequisite programs in place. A HACCP system includes the HACCP plan and all prerequisite programs.

Hazard
A biological, chemical, or physical property that may cause an unacceptable consumer health risk.

Hazard Analysis
The process of collecting and evaluating information about hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Monitoring
A planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an interrupted record of data.

pH
The symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

Prerequisites for HACCP
Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety, as described in Codex Alimentarius Commission's Principles of Food Hygiene and other Codes of Practice.

Preventive Measure
An action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.

Reassessment of the HACCP Plan
Purpose is to determine whether the HACCP System, as designed and executed, is still adequate.

Risk
The likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

Risk Factor
One of the factors identified by the Centers for Disease Control and Prevention (CDC) as a contributor to the foodborne outbreaks that have been investigated and confirmed. The factors are unsafe sources, inadequate cooking, improper holding, contaminated equipment and poor personal hygiene.

Severity
The seriousness of the effect(s) of a hazard.

Standard Operating Procedure (SOP)
A detailed set of instructions, steps or procedures that control the operational conditions within a food establishment allowing for environmental conditions that are favorable to the production of safe food. These written procedures are often equivalent to prerequisite programs of HACCP. The extent to which operators employ various SOPs will determine which critical control points need to be controlled.

Time/Temperature Control for Safety Food (formerly "potentially hazardous food" (PHF).

(1) "Time/temperature control for safety food" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.
(2) "Time/temperature control for safety food" includes:

(a) An animal food that is raw or heat-treated; a plant food that is heat- treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and

(b) Except as specified in Subparagraph (3)(d) of this definition, a food that because of the interaction of its awand PH values is designated as Product Assessment Required (PA) in Table A or B of this definition.

Table A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently PACKAGED

A_w values	pH: 4.6 or less	pH: > 4.6 - 5.6	pH: > 5.6
≤0.92	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - 0.95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD ** PA means Product Assessment required

Table B. Interaction of PH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but NOT PACKAGED

A_w values	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	non-TCS food*	Non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD ** PA means Product Assessment required

(3) "Time/temperature control for safety food" does not include:

(a) An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;

(b) A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;

(c) A food that because of its pH or a_w value, or interaction of a_w and pH values, is designated as a non-TCS food in Table A or B of this definition;

(d) A food that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food Is precluded due to:

(i) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients,

(ii) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, or

(iii) A combination of intrinsic and extrinsic factors; or

(e) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the Subparagraphs (3)(a) - (3)(d) of this definition even though the FOOD may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury

Validation
Validation is that element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards (see Module 4 for further details).

Verification
Verification means those activities other than monitoring that determine the validity of the HACCP plan and that the system is operating according to the plan (see Module 4 for further details).

MODULE 3
SPECIALIZED PROCESSES & PROCEDURES REQUIRING A HACCP PLAN

The following guidelines do not provide detailed information on all individual steps that should be followed when conducting a specific process or operation. However, the references and resources available for review, and listed either within the document or at the end of this document will provide additional information to help evaluate the hazards and recommended control measures to ensure safety of specific specialized processes conducted in retail food establishments.

In addition, establishments not following existing validated methods may work with a process authority and/or conduct challenge studies to establish proper control measures to address identified hazards.

Acidification

Acidification/Adding Components to Render Food Non-TCS

Regulation: 3-502-11 (C) Specialized Processes

Section ¶3-502.11(C) of The Food Code stipulates that if food additives or other components are added to render a TCS food a non-TCS food, a variance is required. A request for such a variance must be accompanied by a HACCP plan in accordance with § 8-201.13 and § 8-201.14.

Public Health Rationale

Acids may be added to foods for flavor, but when acids are added to foods for the purpose of preservation (extending shelf life and/or rendering a product non-TCS) it is critical that the acidity level is carefully monitored to ensure harmful bacteria or the outgrowth of spores, such as Bacilleus cereus will be controlled.

Food is often acidified so it can be held without temperature control. The addition of rice wine vinegar to cooked rice, which is considered a TCS food, to lower its pH is a good example of acidification in a retail food establishment. This allows the cooked plant food to be handled or displayed at room temperature. If brown rice is used in place of regular white "sticky" rice, a separate validated study to determine the amount of vinegar is necessary because the brown husk on the rice kernel is more difficult for the vinegar to penetrate. Note also that any TCS ingredients added to the sushi rice, such as raw salmon, are unaffected by the vinegar and require refrigeration even if the rice is rendered a non-TCS food after acidification.

Beginning as a method of preserving fish centuries ago, sushi has evolved into an artful, unique dining experience. In its earliest form, dried fish was placed between two clumps of vinegar rice as a way of making it last. Seaweed was added later. Technically, the word "sushi" refers to a special kind of cooked sticky rice with sweetened rice wine vinegar, but commonly, the term is used to describe a finger-sized piece of raw fish or shellfish on or with a bed of vinegar rice or a layer of the rice rolled with other ingredients.

It is essential that the validated process and the HACCP plan be followed as written. Harmful bacteria may be inhibited by directly adding acid to food. Changes in pH are rapid if not immediate. Sufficient acid must be added to account for any neutralization or absorption of acid by the food.

Equilibrium pH is the pH of the food after the acid has been mixed in or has been in contact with the food for a specified time. Non-uniform sizes of particles in the mixture being acidified require a longer time for penetration (acidification) of the larger or more solid particles. The maximum equilibrium pH is the highest pH allowed for a specific retail process to provide a safe food. The target pH is the most desirable pH for the product and gives a large safety margin. If the pH of the food is not monitored or the pH fails to reach a pH of less than 4.2, the food must be kept refrigerated and the shelf life must be limited to no more than 7 days.

The preparation of acidified (adding vinegar) sushi rice may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

Key Terms

Equilibrium pH is the pH of the food after the acid has been mixed in or has been in contact with the food for a specified time.

Maximum equilibrium pH is the highest pH allowed for a specific retail process to provide a safe food.

Target pH is the most desirable pH for the product and gives a large safety margin. The target pH is lower than the equilibrium pH.

Controls and Guidelines

Example: Making sushi rice

The HACCP plan must include the following:

- There must be a written recipe or formulation for acidifying the rice.
- The recipe must contain the weights of rice and water needed prior to cooking and information regarding the vinegar mixture if the recipe does not use rice vinegar only.
- The recipe must be validated by a food laboratory to show that it results in a maximum pH of less than 4.2 (target pH of 4.1 from the laboratory).
- Any change in the recipe would require lab validation of the new recipe before it may be used. For example, switching to a new brand of vinegar could be a significant change if the % acid changes. This could necessitate revalidation of the recipe.
- Cooked rice must be mixed in such a way as to promote uniform acidification.
- One of the CCPs must be the pH of the cooked, acidified rice. The critical limit at the acidification step must be a pH of less than 4.2.
- A calibrated pH meter or pH test strips must be used, according to manufacturer's instructions, to monitor the pH of every batch of acidified rice.
- The pH meter must be calibrated against one or more buffer solutions for the first batch of rice each day. Manufacturer's recommendations must be followed when calibrating the meter.
- The pH strips must be able to detect 0.1 unit differences in pH. The target pH should be 4.1 but the maximum pH must be below 4.2.

- The results of the pH measurement of each batch of rice must be properly recorded, and the records must be retained for at least one month.

Guideline For Validating Acidified Rice HACCP Plans

Prerequisites and Standard Operating Procedure(s) (SOPs)

- ☐ Most recent inspection reports indicate compliance with all regulations. Any pre-existing violations, specifically those that may result in biological, physical or chemical contamination of this product, have been corrected.
- ☐ Obtain seafood and ingredients from an approved source.
- ☐ To control parasites, obtain letters of guarantee if purchasing non-parasitic species of fish, farm-raised fish (not fed live prey), or frozen fish. If fish is frozen on site to control parasites, written procedures must be available, and freezing times and temperatures must be recorded. All documents must be available at the time of inspection.
- ☐ Produce must be washed before preparation.
- ☐ Raw TCS foods will be held at or below 41°F.
- ☐ Separate bamboo mats and knives will be provided for raw and ready-to-eat products.
- ☐ Bamboo mats will be covered with plastic wrap and wrap will be changed at a maximum of every 4 hours.
- ☐ Knives will be cleaned and sanitized at a maximum of every 4 hours.
- ☐ If separate knives or utensils are not used, they must be cleaned and sanitized between uses.
- ☐ Wiping cloths, if used, will be handled in a sanitary manner.
- ☐ Manufacturer specifications and instructions for both pH meter or pH paper provided
- ☐ Buffer solution must be available and in use, based on manufacturer's recommendations (4.0, 7.0 and / or 10.0)
- ☐ Recipe and written instructions for preparing and acidifying rice to be provided
- ☐ HACCP plan and all relevant documents must be on site for review during inspections
- ☐ Distilled water provided for making rice slurry (if required by pH meter manufacturer's instructions)

Recipe/Formulation Provided

- ☐ Brand(s)/acid concentration of vinegar (%) identified
- ☐ Preparation steps identified

Hazard Analysis Included

- ☐ Outgrowth of *Bacillus cereus* and production of toxins identified

CCP Identified

- ☐ Acidification step (addition of vinegar to rice)

Critical Limit Identified

- ☐ pH of acidified rice must be less than 4.2 (if rice held overnight, lab tests must include 24 hour time period)

Monitoring Procedures Identified

- ☐ Calibrated pH meter or pH test paper used to measure each batch of acidified rice
- ☐ Person(s) identified for testing pH of rice

NOTE: If using pH test papers with increments of not more than 0.3 the results must indicate 4.0 or below otherwise results will show a deviation from the critical limit of less than 4.2)

Corrective Actions and Documentation Procedures Identified

- ☐ If rice has not been tested with the pH meter, do not use until it is tested
- ☐ If pH of rice is not less than 4.2:

  If rice was made within the hour, add additional vinegar and re-test pH

  Verify use of correct recipe and procedures

  Verify calibration and proper use of pH meter or pH test papers

  Discard rice if not made within the hour

Verification Process Identified (Short Term/Long Term)

- ☐ pH meter calibrated for the first batch of rice every day (if rice made daily, or if using a meter instead of pH test papers)
- ☐ pH test paper not more than 0.3 increments
- ☐ pH test papers and buffer solution(s) not expired
- ☐ Monitoring records reviewed on a weekly basis, or as needed, by PIC
- ☐ Recipe/formulation validated, signed and dated by a food laboratory (target pH from lab is </= to 4.1)
- ☐ Rice is retested at a laboratory when recipe is modified, or when daily pH levels are consistently higher than th laboratory validated pH measurement
- ☐ Signed and dated HACCP plan reviewed annually, or as needed by PIC

Records are Identified

- ☐ pH log for each batch of rice maintained for at least one month
- ☐ Calibration log maintained for pH meter for at least one month (may be included on pH log)
- ☐ Corrective actions recorded and maintained for at least one month (may be included on the pH log)
- ☐ Laboratory test results

Employee Training Plan Documented

- ☐ Pathogens of concern (particularly *Bacillus cereus*)
- ☐ Standard operating procedures
- ☐ Time and temperature controls
- ☐ Employee health and hygiene
- ☐ Prevention of cross-contamination
- ☐ Cleaning and sanitizing procedures
- ☐ Use of pH meter and/or pH papers
- ☐ Monitoring procedures
- ☐ Corrective actions
- ☐ Recordkeeping requirements (including pH measurements, meter calibration results, and corrective actions)

Reduced Oxygen Packaging (ROP)

Reduced Oxygen Packaging (ROP)

Regulation: 3-502.12

(A) Except for a food establishment that obtains a variance as specified under § 3-502.11, a food establishment that packages food using a ROP method and Clostridium botulinum is identified as a microbiological hazard in the final packaged form shall ensure that there are at least two barriers in place to control the growth and toxin formation of *Clostridium botulinum*.

(B) A food establishment that packages food using a ROP method and *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form shall have a HACCP plan that contains the information specified under ¶ 8-201.14(D) and that:

(1) Identifies the food to be packaged

(2) Limits the food packaged to a food that does not support the growth of *Clostridium botulinum* because it complies with one of the following:

(a) Has an awof 0.91 or less,

(b) Has a PH of 4.6 or less,

(c) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 318.7: Approval of substances for use in the preparation of products and 9 CFR 381.147: Restrictions on the use of substances in poultry products and is received in an intact package, or

(d) Is a food with a high level of competing organisms such as raw meat or raw poultry;

(3) Describes how the package shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(a) Maintain the food at 41°F (5°C) or below, and

(b) Discard food if within 30 calendar day of its packaging if not served for on-premises consumption, or consumed if served or sold for off-premises consumption;

(4) Limits the refrigerated shelf life to no more than 30 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(5) Includes operational procedures that:

(a) Prohibit contacting ready-to-eat food with bare hands as specified under ¶ 3-301.11(B),

(b) Identify a designated area and the method by which:

(i) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross-contamination

(ii) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, and

(c) Delineate cleaning and sanitization procedures for food contact surfaces and

(6) Describes the training program that ensures that the individual responsible for the ROP operation understands the:

(a) Concepts required for a safe operation,

(b) Equipment and facilities, and

(7) Is provided to the regulatory authority prior to implementation as specified under ¶ 8-201.13(B).

Fish

(C) Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method.

(D) Except as specified under ¶ (C) and ¶ (F) of this section, a food establishment that packages time/temperature control for safety food using a cook-chill or sous vide process shall:

(1) Provide to the regulatory authority prior to implementation, a HACCP plan that contains the information as specified under ¶¶ 8-201.14 (B) and (D);

(2) Ensure the food is:

(a) Prepared and consumed on the premises, or prepared and consumed off the premised but within the same business entity with no distribution or sale of the packaged product to another business entity or the consumer,

(b) Cooked to heat all parts of the food to a temperature and for a time as specified under ¶¶ 3-401.11 (A), (B), and (C),

(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4,

(d) Placed in a package with an oxygen barrier and sealed before cooking, or placed in a package and sealed immediately after cooking and before reaching a temperature below 135°F (57°C),

(e) Cooled to 41°F (5°C) in the sealed package or bag as specified under § 3-501.14 and:

(i) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C) and held at that temperature until consumed or discarded within 30 days after the date of packaging;

(ii) Held at 41°F (5°C) or less for no more than 7 days, at which time the food must be consumed or discarded; or

(iii) Held frozen with no shelf life restriction while frozen until consumed or used

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily,

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and

(h) Labeled with the product name and the date packaged; and

(3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan and:

(a) Make such records available to the regulatory authority upon request, and

(b) Hold such records for at least 6 months; and

(4) Implement written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section;

Cheese

(E) Except as specified under ¶ (F) of this section, a food establishment that packages cheese using a reduced oxygen packaging method shall:

(1) Limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semi Soft cheeses;

(2) Have a HACCP plan that contains the information specified under ¶¶ 8-201.14 (B) and (D) and as specified under ¶¶ (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;

Reduced Oxygen Packaging (ROP) - No Variance or HACCP Plan Required

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

Note: Some regulatory agencies may have regulations that require a variance to conduct any type of specialized process or may require prior approval of a HACCP plan that does not require a variance before conducting the operation.

Public Health Rationale

Increasingly, retail food establishments have expanded into food manufacturing/processing-type operations, often using sophisticated new technologies and equipment. Many are now choosing to package foods by using one or more reduced oxygen packaging (ROP) methods such as cook-chill, vacuum packaging, and sous vide.

Reduced oxygen packaging methods offer unique advantages and opportunities for the food industry including increased shelf-life, improved food consistency and quality, preservation of nutrient integrity and flavor, decreased product handling and chances of cross-contamination, and reduced operating costs by minimizing food waste through better portion control.

However, there are serious risk factors associated with the use of (ROP) for time/temperature control for safety foods (TCS) because ROP can create an anaerobic environment that inhibits the growth of aerobic spoilage organisms such as Pseudomonas spp. or aerobic yeast and molds. These aerobic organisms are responsible for off-odors, slime, and texture change, which provide the consumer with warning signs that the food may be spoiled.

The reduced oxygen atmosphere can also support the growth of anaerobic bacteria that do not require oxygen to grow. Anaerobic bacteria are of particular concern when using ROP. For example, *Clostridium botulinum* can grow in a low oxygen environment and subsequently release a deadly toxin into the packaged food. Therefore, strict adherence to temperature control and shelf life must be observed and documented by the facility using ROP.

Because of the serious public health risk associated with reduced oxygen packaging of TCS foods, current regulations mandate that retail establishments obtain a variance from the regulatory authority (§ 3-502.11) before TCS food is packaged using a ROP process, unless the growth and toxin formation of *Clostridium botulinum* and *Listeria monocytogenes* are controlled. However, as noted in § 3-502.12, when both of these pathogens are controlled, a variance is not required.

Questions often arise from both regulators and retailers when it comes to interpreting sections 3-502.11 and 3-502.12 of The Food Code. The following is this author's attempt to explain the difference.

There is broad range of processes that require a variance under § 3-502.11, including smoking (not for flavor enhancement only), curing, using food additives as a method of preservation or to render food so that it is not time/temperature control for food safety (TCS), operation of a molluscan shellfish tank utilized for human consumption, custom processing animals for personal use, sprouting seeds/beans, packaging TCS food using reduced oxygen packaging (ROP) methods that ***do not*** control the growth or toxin formation by *Clostridium botulinum* and growth of *Listeria monocytogenes*, or preparing food by another method that is determined to require a variance (like fermentation or drying).

These processes require a variance because they have one or more significant microorganisms of public health concern that must be controlled. The burden is on the retailer to prove to the regulatory authority that their process and methodology intended for use will control the microorganism(s) of concern.

Section 3-502.11 applies specifically to TCS foods packaged using an ROP method that ***can*** control the growth or toxin formation by *Clostridium botulinum* and growth of *Listeria monocytogenes,* by following the criteria outlined in § 3-502.12 ***exactly as written***. This is because the criteria listed in § 3-502.12 has already been approved under The Food Code. By submitting the HACCP plan, outlining the procedures you plan to follow, you are informing the regulatory authority that you plan to follow one or more of the criteria in that section as established by the FDA. If the process submitted does not meet the criteria outlined in this section, or the process deviates from the criteria listed in any way, a variance would be mandated.

The following is an example of a process using reduced oxygen packaging of a TCS food that ***would*** require a variance because it ***does not*** meet the ***specific*** criteria as shown in § 3-502.12.

An establishment cooks clam chowder in accordance with temperatures stated in The Food Code, chills the product following the two-stage cooling process required by The Food Code, then packages the food using an ROP method with a 14-day shelf life.

In this scenario, the retailer would be required to obtain a variance to conduct this process because they did not meet the criteria exactly as listed in ¶ 3-502.12(D)(2)(d). Specifically, they did not package the food at a temperature at or above 135°F.

They also did not meet the temperature requirements listed in ¶ 3-502.12(D)(2)(e), that would allow them to hold the food in the package longer than 7 days. Specifically, they were not able to hold the food at or below 34°F, nor were they willing to freeze the product, so shelf life would be restricted to 7 days.

In the end, this facility applied for a variance and hired a food safety professional who worked in conjunction with a certified laboratory to develop a HACCP plan to control identified hazards and determine an acceptable shelf-life for the finished product. They submitted their HACCP plan for approval prior to starting the process.

As a reminder, regardless of whether a variance is required to conduct one or more of these specialized processes, a HACCP plan is required when conducting all specialized processes, with this one exception: ¶ 3-502.12 (F) exempts refrigerated, ROP foods that are ***always*** removed from the package within 48 hours of packaging from the requirements in § 3-502.12. This exemption is allowed because the growth and toxin formation by anaerobic pathogens is not considered a significant hazard in that limited time frame.

Key Terms

Aerobic bacteria require oxygen for their basic survival, growth, and reproduction.

Anaerobic bacteria do not require oxygen for survival or growth.

Oxygen transmission rate (OTR) is the measurement of the amount of oxygen gas that passes through a substance over a given period. It is mostly carried out on non-porous materials, where the mode of transport is diffusion, but there are a growing number of applications where the transmission rate also depends on flow through apertures of some description. It relates to the permeation of oxygen through packaging to sensitive foods and pharmaceuticals.

Reduced oxygen packaging (ROP) is defined as any packaging procedure that results in a reduced oxygen level in a sealed package. The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gasses; or otherwise controlling the oxygen content to a level below that normally found in the surrounding, 21% oxygen atmosphere, and a ROP process that involves a food for which Clostridium botulinum is identified as a microbiological hazard in the final packaged form.

The term is often used because it is an inclusive term and can include other packaging options such as:

Cook-chill packaging is where the atmosphere of a package is hot filled into impermeable bags that have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotropic (cold-loving) pathogens.

Controlled atmosphere packaging (CAP) is an active system which continuously maintains the desired atmosphere within a package throughout the shelf-life of a product by the use of agents to bind or scavenge oxygen or a sachet containing compounds to emit a gas. Controlled Atmosphere Packaging (CAP) is defined as packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere using impermeable packaging material.

Modified atmosphere packaging (MAP) is a process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action. Modified Atmosphere Packaging (MAP) is defined as packaging of a product in an atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air, which normally contains 78.08% nitrogen, 20.96% oxygen, and 0.03% carbon dioxide.

Sous Vide packaging is where raw or partially cooked food is hot filled into impermeable bags that have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated (or frozen) at temperatures that inhibit the growth of psychotropic (cold loving) pathogens. The sous vide process is a pasteurization step that reduces the bacterial load but is not sufficient to make the food shelf-stable.

Vacuum packaging reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.

Reduced Oxygen Packaging

Reduced Oxygen Packaging (ROP) is considered a specialized process under The Food Code. It includes vacuum packaging, cook-chill, and sous vide processes. Essentially, any time that an operation places food in an impermeable ROP-type bag it is ROP. The main implication for ROP is that The Food Code requires operators to document and implement a HACCP-based food safety system.

When a food establishment intends to use ROP technology but does not use one of the secondary barriers defined in § 3-502.12 (Reduced Oxygen Packaging Without a Variance, Criteria), the operator must apply for a variance under § 3-502.11 providing evidence that the ROP methodology intended for use is safe. It is highly recommended that the operator and/or the regulatory authority consult a process authority to validate that the scientific evidence for the intended ROP methodology is safe.

NOTE: Non-TCS foods are exempt from the reduced oxygen packaging HACCP requirements of both § 3-502.11 and § 3-502.12 provided they are not modified in the operation after they are received in their original form, and that they are labeled as non-TCS foods.

Reduced Oxygen Packaging Without a Variance, Criteria

Certain foodborne pathogens that are anaerobes or facultative anaerobes can multiply under either aerobic or anaerobic conditions. Therefore, special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic C. botulinum and L. monocytogenes are able to multiply well below 5°C (41°F). For this reason, *C. botulinum* and *L. monocytogenes* are the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

The type of food, the production and packaging methods used, and the packaging material can impact the level of oxygen present within a package and within the food matrix. Combinations of some or all of these variables may result in an oxygen level within a package, or within a food matrix, that is less than 21%. While ROP may involve different foods and different packaging materials, each process is characterized by the deliberate removal of oxygen from or the reduction in the oxygen level in the package or the food matrix at the time of packaging.

This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging material that readily allow the transmission of oxygen is usually designated by an Oxygen Transfer Rate (OTR) of 10,000 cc/m^2/24 hours or greater with scientific evidence acceptable to the FDA that it maintains an aerobic atmosphere when shrink packaging raw seafood with no inclusions (marinades, oils, etc.). The packaging allows oxygen to pass permitting resident bacteria to spoil the seafood before the toxin of *C. botulinum* could develop.

This type of film is often referred to as 10K OTR film. While 10K OTR film has been approved for certain applications in food manufacturing and processing, use of 10K OTR film falls under ROP special processing requirements for retail food establishments. A variance and an approved HACCP plan with a validated process approved prior to starting the operation are needed to ROP with this film in retail food operations.

Evidence has been provided for this type of bag for only one type of use: raw fish. The FDA Fish & Fisheries Products Hazards & Controls Guidance 4th Ed. provides additional information on how 10K OTR films are used in the manufacturing and processing of raw fish (with no additives like oils or marinades).

NOTE: Raw fish received in 10K OTR film from a manufacturer or processor isn't considered a special process under food code and may be refrigerated as recommended by the supplier.

Time is also a factor that must be considered in ROP at retail. The use of date labels on VP, MAP, and CAP products and assuring those dates do not exceed the manufacturer's "sell by" or "use by" date is intended to limit the shelf life to a safe time period (based on a time in which growth will not occur or involves the presence of two barriers to growth). When these ROP products are frozen, there is no longer a restricted shelf life. The shelf-life limits for cook-chill and sous-vide foods are based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 1°C (34°F) or less for 30 days or 5°C (41°F) or less for 7 days after packaging, with stringent temperature monitoring and recording requirements.

The potential for *Clostridium botulinum* toxin to develop also exists when ROP is used after heat treatments such as pasteurization, or sous vide processing of foods which will not destroy the spores of *C. botulinum*. If the applied heat treatment does not produce commercial sterility, the food requires refrigeration below 3.3°C (38°F) to prevent spore germination and toxin formation and ensure product safety. For this reason, sous vide products are frequently frozen and held in frozen storage until use.

There is a further microbial concern with ROP at retail. Processed products such as meats and cheeses which have undergone an adequate cooking step to kill *L. monocytogenes* can be re-contaminated when opened, sliced, and repackaged at retail. Thus, a simple packaging or repackaging operation can present an opportunity for recontamination with pathogens if strict sanitary safeguards are not in place. Hard and semi-soft cheeses that meet the Standards of Identity for those cheeses in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese and 21 CFR 133.187 Semi-soft cheeses may be packaged using ROP without a variance. Refer to Annex 3 Public Health Reasons, § 3-501.17 and § 3-501.18 for a partial list of hard and semi-soft cheeses.

Listeria monocytogenes can grow at even lower temperatures; consequently, appropriate use-by dates must be established. Growth barriers are provided by hurdles such as low pH, a_w, or short shelf life, and constant monitoring of the product temperature. Any one hurdle, or a combination of several, may be used with refrigeration to control pathogenic outgrowth.

Finally, if foods are held long enough, even under proper refrigeration, extended shelf life may be a problem. A study on fresh vegetables inoculated with *L. monocytogenes*, conducted to determine the effect of MAP on shelf life, found that MAP lengthened the time that all vegetables were considered acceptable, but that populations of *L. monocytogenes* increased during that extended storage.

Reduced Oxygen Packaging with Two Barriers

When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of C. botulinum and L. monocytogenes without a variance. ¶ 3-502.12 (B) identifies an ROP method with secondary barriers that will control *C. botulinum* and *L. monocytogenes* when used in conjunction with a food storage temperature of 5°C (41°F) or less. These barriers are:

- a_w of 0.91 or less
- pH of 4.6 or less
- cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21
- high levels of competing microorganisms such as those found on raw meat or raw poultry or raw vegetables.

The barriers described above are effective controls for *C. botulinum* and *L. monocytogenes* in reduced oxygen packaged foods because:

- *C. botulinum* will not produce toxins below an a_w of 0.91, and the minimum a_w for growth of *L. monocytogenes* is 0.92.
- *C. botulinum* will not produce toxin when the pH is 4.6 or below and *L. monocytogenes* will generally not grow at this pH under refrigeration temperatures.
- Nitrite, used in meat and poultry curing, inhibits the outgrowth of *C. botulinum* spores.
- Most foodborne pathogens do not compete well with other microorganisms. Therefore, foods that have a high level of spoilage organisms or lactic acid bacteria that grow under ROP conditions can safely be packaged using ROP and held for up to 30 days at 5°C (41°F).

Other intrinsic or extrinsic factors can also control the growth and/or toxin production of botulinum and *L. monocytogenes.*

Reduced Oxygen Packaging with One Barrier (Cook-Chill and Sous Vide)

Some foods may not have secondary barriers to prevent the growth of *C. botulinum* and *L. monocytogenes,* such as pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses.

When these foods are packaged using a reduced oxygen packaging process, time/temperature becomes the critical controlling factor for the growth of *C. botulinum* and *L. monocytogenes.*

Non- proteolytic *C. botulinum* spores are able to germinate and produce toxins at temperatures down to 3ºC (38ºF). Therefore, holding ROP foods at 3ºC (38ºF) or less should prevent the formation of *C. botulinum* toxin. *L. monocytogenes* is able to grow, although very slowly, at temperatures down to 1°C (phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth.

Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential. Three separate options for cold storage temperatures are provided in ¶ 3-502.12 (D)(2)(e).

- Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C) and held at that temperature until consumed or discarded within 30 days after the date of packaging;
- Held at 41°F (5°C) or less for no more than 7 days, at which time the food must be consumed or discarded; or
- Held frozen with no shelf-life restriction while frozen until consumed or used

These time-temperature combinations will provide equivalent food safety protection without need for a variance. (*L. monocytogenes* will be eliminated by the cooking procedures specified in ¶¶3-401.11(A), (B) and (C) and recontamination will be prevented by filling the product into the bag while it is still hot (cook-chill) or by cooking in the sealed bag (sous vide). *C. botulinum* will not grow under the specified time- temperature combinations.)

Since there may not be other controlling factors for *C. botulinum* and *L. monocytogenes* in a cook-chill or sous vide packaged product, continuous monitoring of temperature control and visual examination to verify refrigeration temperatures is important. New technology makes it possible to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook-chill and sous vide products at 1°C (34°F) or 5°C (41°F) or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures that can be displayed using computer software. Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook-chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.

Reduced Oxygen Packaging with Cheese

Cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semi-soft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all the following:

- a lower pH;
- salt (NaCl) added during processing;
- low moisture content;
- added preservatives; and
- live competing cultures.

The extended shelf life for vacuum packaged hard and semi soft cheeses is based on the intrinsic factors in these cheeses plus the refrigeration temperature of 41°F (5°C) or less to maintain safety. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of *L. monocytogenes* under modified atmosphere conditions.

Reduced Oxygen Packaging with Fish

¶ 3-502.12(C) of The Food Code states that a retail establishment may only use an ROP method to package fish if the fish is frozen before, during, and after packaging, unless they apply for a variance, and submit a HACCP plan for pre-approval before starting the operation. This is because it is assumed that *Clostridium botulinum* spores are present in any raw fishery product. A key characteristic of *Clostridium botulinum* spores is their ability to withstand extreme conditions, such as high pressure, UV light, and heat treatments. They also germinate and produce toxins at low temperatures (*C. botulinum* (primarily type E) grows at 3°C (37-38°F).

Foods Which Require a Variance Under Code § 3-502.11 if Packaged in Reduced Oxygen Atmosphere

1. Unfrozen processed fish and smoked fish may not be packed by ROP unless retail food establishments have an approved variance application and a pre-approved HACCP plan to show *C. botulinum* spore germination and toxin production or *L. monocytogenes* growth will not occur. Establishments packaging such fish products must be licensed in accordance with applicable law. They must also be inspected by the regulatory authority.
2. Soft cheeses such as ricotta, cottage cheese, cheese spreads, and combinations of cheese with other ingredients such as vegetables, meat, or fish at retail must be approved for ROP through an approved variance application and a pre-approved HACCP plan. They must also be inspected by the regulatory authority.
3. Meat or poultry products that are cured at the retail establishment. Curing using nitrite or nitrate always requires a variance and a pre-approved HACCP plan.
4. Smoking (to extend shelf life) which meets the time/temperature parameters in § 3-401.11 does not require a variance, but requires a HACCP plan. Cold smoking where the temperature achieved by the product is greater than 41ºF requires a variance and a pre-approved HACCP plan.
5. ROP-packaged foods that do not meet the specific criteria listed under section § 3-502.12.

   When a food establishment intends to conduct ROP and hold the product for more than 48 hours without using one of the secondary barriers defined in § 3-502.12, it is important that an application for a variance provides evidence that the ROP methodology intended for use is safe.

Controls and Guidelines

Reduced Oxygen Packaging Without a Variance - Multiple Safety Barriers - ¶ 3-502.12 (B)

This section of the Food Code allows a food establishment to ROP foods without a variance, provided that they submit a HACCP plan to the regulatory authority that addresses the following:

1. Identifies the food to be packaged.
2. Indicates that the packaged food will be maintained at 5°C (41°F) or less and meet at least one of the following criteria:
   a) aw of 0.91 or less
   b) pH of 4.6 or less
   c) meat or poultry product cured at a USDA-regulated facility
   d) contains a high level of competing organisms (such as raw meat, raw poultry, or raw vegetables)
3. Describes how the package will contain a label on the principal display panel requiring the food to be maintained at 41°F (5°C) or below and to be either consumed or discarded within 30 calendar days. Opening the ROP package before the expiration date does not extend the shelf life beyond the allowed 30 days unless a variance is obtained.
4. Processed reduced oxygen foods that exceed the "use-by" date or manufacturer's "pull date" cannot be sold in any form and must be disposed of in a proper manner.
5. Describes training programs ensuring that employees responsible for ROP understand the concepts needed to conduct a safe operation.
6. Includes operational procedures, such as prohibiting bare-hand contact, minimizing cross-contamination, etc.

Other food safety issues to consider before approving one or more ROP HACCP plans include, but are not limited to the following:

HACCP Plan

- The HACCP plan is provided to the regulatory authority prior to implementation as specified under ¶ 8-201.13 (B).
- The HACCP plan using a MAP method of packaging foods must also include a listing and proportion of food-grade gasses used and a standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

Protection from Contamination

- All aspects of reduced oxygen packaging shall be conducted in an area specifically designated for this purpose.
- There shall be an effective separation to prevent cross contamination between raw and cooked foods.
- Cook-chill and sous-vide products should be protected from contamination before and after cooking.
- Some ROP procedures such as sous vide may require a "sanitary zone" or dedicated room with restricted access to prevent contamination.
- All equipment and food contact surfaces are cleaned and sanitized at a frequency dictated by The Food Code or as needed to prevent soil accumulation.

Time/Temperature Requirements

- Cook-chill and sous vide products meet the time/temperature standards set forth in section ¶¶ 3-401.11(A), (B), and (C) of The Food Code.
- Vacuum packaged raw meat and poultry products must be refrigerated at 41°F (5°C) or below and labeled with a “Use By” date that does not exceed 30 days from its packaging, and packages not consumed or sold within 30 days of packaging should be discarded.

- Refrigeration units storing cook-chill and sous vide products should be continuously monitored electronically and visually examined twice daily. If food products are transported to a satellite location, temperatures should be monitored during transportation using a verifiable electronic monitoring device. The food establishment should retain electronic monitoring records for at least 6 months. The electronic monitoring process should be examined two times each day. The personnel responsible for visually monitoring this process should be identified as well as the times the monitoring will take place.

Labeling - Refrigeration Statements

- All foods in ROP which rely on refrigeration as a barrier to microbial growth must bear the statement "Important - Must be kept refrigerated at 41°F" or “Must be kept frozen” in the case of foods which rely on freezing as a primary safety barrier.

- The statement must appear on the principal display panel in bold type on a contrasting background.

- Foods packaged using cook chill or sous vide processing methods must not be offered for retail sale in the package or sold to a different business entity. Because foods packaged using cook chill or sous vide processing cannot be offered for retail sale, a labeling statement regarding cold holding temperatures is not required.

Labeling - "Use-by date"

- Each container of food in ROP must bear a "use-by" date. Each package must be labeled. The label must contain a combination of a "sell-by" date and “use-by” instructions which makes it clear that the product must be consumed within the specified number of days specified by criteria set forth in The Food Code. .

- The date assigned by a re-packer may not extend beyond the manufacturer's recommended "pull date" for the food.

- The "use-by" date must be listed on the principal display panel in bold type on a contrasting background.

- Foods that are frozen, before or immediately after packaging, (and remain frozen until use) should bear a label statement, “Important, keep frozen until used, thaw under refrigeration immediately before use.

Disposition of Expired Product at Retail

- Opening an ROP package before the expiration date does not extend shelf life beyond the expiration date unless a variance is obtained.

Training

- Employees assigned to packaging of the foods must have documented proof that demonstrates familiarity with ROP guidelines and the potential hazards associated with these foods.
- At the discretion of the regulatory authority, a description of the training and course content, provided to the employees, must either be available for review or have prior approval by the regulatory authority.

Summary of Key Points

- HACCP plans and variances are only required for time/temperature control for safety foods packaged using an ROP method.
- ROP is NOT defined as packaging food items in a zipper/press and seal storage bag (because they are not considered impermeable).
- HACCP plans and variances are NOT required if sealing a product in a bag using ROP methods and the product is held in the bag for ***less than*** 48 hours (in accordance with § 3-502.12 (F)) because science supports that ROP foods held at or below 41°F (5°C) for short periods of time would not be considered a potential hazard for *Clostridium botulinum* or *Listeria monocytogenes,* thus allowing retail operators to conduct some of the following common processes.
    - Sous vide for immediate service (same day service).
    - Packaging foods for the purpose of rapid chilling because it is a good method to rapidly and effectively chill hot foods in an ice bath.
    - Packaging foods with spices or marinades to help quickly infuse the spice or marinade.
    - Packaging foods for any other purpose if food is removed from the bag within 48 hours.

- Cook-chill and sous vide are ROP processes. When cook-chill and sous vide processes are conducted in accordance with ¶ 3-502.12 (D), only a HACCP plan will be required.

  If either of these processes deviate in any way from ¶ 3-502.12 (D), a variance will also be required.

- Cook-chill and sous vide foods may be cooled to </= 41°F and held for up to 7 days.
- Cook-chill and sous vide foods held at or below 34°F (1°C) may be moved to 41°F (SC) or below and held for up to 7 days (not to exceed original 30 days shelf life at 34F or below).
- Fish may NOT be packaged using ROP unless it is frozen before, during, and after packaging (¶ 3-502.12 (C)).
- A variance is required if the fish ***is not*** frozen before, during, or after packaging.
- Food packaged using cook-chill or sous vide processing methods cannot be distributed outside of the food establishment doing the packaging. It cannot be donated, sold directly to customers, or distributed through a wholesale network, meaning to other retailers or processors.
- All products shall be cooked fully in accordance with ¶ 3-401.11 (A), (B), and (C), or a variance must be requested and a HACCP plan must be submitted and pre-approved prior to starting the process.
- Before engaging in ROP without a variance, a properly prepared HACCP plan must be submitted to the regulatory authority.

Note: Contact your inspector if clarification is needed prior to implementing an ROP packaging process.

Guideline For Validating Reduced Oxygen Packaging HACCP Plans

(For a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables)

Prerequisites and Standard Operating Procedure(s) (SOPs)

- ☐ Most recent inspection reports indicate compliance with all regulations Preexisting violations, which may result in biological/physical/chemical contamination of product, have been corrected.
- ☐ Designated area/physical barriers/methods of separation of raw foods and ready to eat foods identified
- ☐ Access to processing equipment limited to responsible, trained personnel
- ☐ Packaging materials protected from possible contamination
- ☐ Cleaning and sanitizing procedures for food contact surfaces delineated
- ☐ Good personal hygiene practices in place, including hand washing

Hazard Analysis Included

- ☐ Pathogenic growth, particularly *Clostridium botulinum* spores and *Listeria monocytogenes*

CCP(s) Identified

- ☐ Labeling
- ☐ Storage

Critical Limit(s) Identified

Labeling

- ☐ Packages prominently and conspicuously labeled with:
  - Product name
  - Date of packaging
  - "Use by" date
  - Ingredients (where necessary)
  - Warning statement - "Important - Must be kept refrigerated at or below 41°F" or “Important, keep frozen until used, thaw under refrigeration immediately before use”
  - Raw meat and poultry packaged using ROP methods must be labeled with safe handling instructions found in 9 CFR 317.2(l) and 9 CFR 381.125(b)
  - The “Use By” date does not exceed 30 days from the retail vacuum packaging date
  - Date assigned by the retailer does not exceed the manufacturer’s recommended “Pull Date”

Storage

- ☐ Maximum cooler temperature 41°F

Monitoring Procedures Identified

Labeling

- ☐ One finished product label from each batch visually inspected for appropriate “use by” date and label statement.

Storage

- ☐ Cooler air temperature measured on a daily basis, or as needed, by PIC
- ☐ Person(s) identified for monitoring temperature of cooler daily

Corrective Actions and Documentation Procedures Identified

Labeling

- ☐ Improperly labeled product segregated and relabeled
- ☐ Products not sold within the “use by” date discarded
- ☐ Corrective actions recorded in log (sample page included)
- ☐ Cause of deviation determined

Storage

- ☐ Products exceeding 41°F, held pending evaluation of time/temperature exposure
- ☐ Corrective actions recorded on log
- ☐ Determine cause of deviation

Verification Process Identified (Short Term/Long Term)

Labeling

- ☐ 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

Storage

- ☐ Thermometer calibrated monthly, or as needed or determined by the manufacturer

Records are Identified

Labeling

- ☐ Label check record

Storage

- ☐ Temperature logs
- ☐ Thermometer calibration Log
- ☐ Corrective action record

Employee Training Plan Documented (sample of training log provided)

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

Live Molluscan Shellfish Display Tanks

Molluscan Shellfish Tanks

Molluscan Shellfish Tanks

Regulation: § 4-204.110

(A) Except as specified under ¶ (B) of this section, molluscan shellfish life support system display tanks may not be used to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for display only.

(B) Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the regulatory authority as specified in § 8-103.10 and a HACCP plan that:

(1) Is submitted by the permit holder and approved as specified under § 8-103.11; and

(2) Ensures that:

(a) Water used with fish other than molluscan shellfish does not flow into the molluscan tank,

(b) The safety and quality of the shellfish as they were received are not compromised by the use of the tank, and

(c) The identity of the source of the shellstock is retained as specified under § 3-203.12.

Public Health Rationale

Molluscan shellfish is often held at retail food establishments in a holding tank to keep it live and fresh for sale or preparation. Molluscan shellfish are primarily filter feeders, allowing concentration of pathogenic microorganisms and toxins that may be present in the water where they are harvested to accumulate in a mollusk's tissue under certain conditions.

The commercial sale of molluscan shellfish is highly regulated because of the potential impact to human health. The growing, shipping, shucking, packing, and repacking of molluscan shellfish are regulated by states participating in the Interstate Shellfish Sanitation Conference through the *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish*, which serves as a Model Ordinance.

Molluscan shellfish are considered a time/temperature control for safety (TCS) food, often eaten raw by the consumer. This can lead to life threatening illness such as paralytic shellfish poisoning or vibriosis. Eating raw mollusks is even riskier for highly susceptible populations (HSP), which is why they cannot be offered on the menu in a food establishment that caters to HSPs.

Hazards associated with shellfish are unique to organisms found naturally in the marine environment, such as Vibrio parahaemolyticus, Vibrio vulnificus, and phytoplankton.

Certain species of phytoplankton can produce natural toxins that are concentrated by shellfish and cause these illnesses when consumed by humans:

- Paralytic Shellfish Poisoning (PSP)
- Diarrhetic Shellfish Poisoning (DSP)
- Neurotoxic Shellfish Poisoning (NSP)
- Amnesic Shellfish Poisoning (ASP)

However, these toxins cannot be introduced into shellfish in the holding tanks. They can only present a hazard if present in sufficient quantity at the time the shellfish is harvested. The National Syndromic Surveillance Program (NSSP) controls this hazard by only allowing shellfish harvested from areas unaffected by unacceptable levels of toxins.

Molluscan shellfish should be harvested from state-approved waters and properly tagged to allow traceback in case of a foodborne illness outbreak. Additionally, because live molluscan shellfish pose a high risk to consumers, the FDA Food Code requires a variance and pre-approved HACCP plan if they want to use molluscan shellfish life support system display tanks.

Key Terms

Molluscan Shellfish means Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

Interstate Certified Shellfish Shippers List (ICSSL) means an FDA publication of shellfish dealers, domestic or foreign, who have been certified by a state or foreign Authority as meeting the public health control measures specified in the National Shellfish Sanitation Program (NSSP). The list is updated monthly.

Controls and Guidelines

Operating Live Molluscan Shellfish Life Support System Display Tanks

Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria. Therefore, if shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place to eliminate, or minimize the potential for contamination. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

The design and operation of a live molluscan shellfish holding tanks can play a major role in the prevention of foodborne illness. Proper design will facilitate cleaning and sanitizing of the equipment. In addition, hydraulic design of the unit is important to assure an adequate quantity and quality of water for the intended purpose.

Inadequate flow or "dead spots" can lead to bacteriological growths and/or oxygen deficiency and fish mortality. Minimum turbulence will permit feces and other organic matter generated by active fish to settle out without being suspended and ingested. Use of food grade materials for all construction materials and additives will prevent possible adulteration by chemicals.

Handling Molluscan Shellfish

1. Cull out dead, cracked, and weak molluscan shellfish daily.
2. Before adding molluscan shellfish to the system, make sure they are cleaned thoroughly and that you cull out all dead, cracked, and weak animals
3. Never mix molluscan shellfish with other fish species.
4. If the tank is ever used for crab, lobster, etc. it must be sanitized before molluscan shellfish may be added. To sanitize the tank, follow the instructions for cleaning the UV bulb (adding bleach solution to tubes, etc.). At the end of the 30 minute soaking period do not open the drain. Fill the tank to normal operating level with fresh water and turn the system on for 30 minutes. Turn the system off and thoroughly flush out tubes, bio-mix, and tank sides. Make sure all bleach smell is gone before adding molluscan shellfish.
5. Never mix lots of molluscan shellfish which come from different shipping containers and are marked with different shipping tags. If molluscan shellfish are added to a tank which already has the same species, then the two lots must be kept separated with a non-absorbent, easily cleaned divider or by the use of non-toxic, single-use mesh bags. (These requirements are designed to facilitate a food poisoning investigation and/or food recall).
6. Every shipment, or portion thereof, should be visually inspected to ensure that shellfish is tagged with information as required under Section § 3-202.18: Shellstock Identification. In addition, shellstock tags are to be retained for 90 days from the date the container is emptied and filed in chronological order correlated to the date when, or dates during which, the shellstock are sold or served.

System Design

1. Equipment and utensils must be constructed with materials that are durable, non-absorbent, non-toxic, and easily cleanable.
2. Hold at least 100 gallons of water per 75 pounds of shellfish.
3. Recirculation systems should include:
   - A filtration system capable of maintaining a clean and healthy environment.
   - Refrigeration units that can maintain water temperatures between 40-60°F.
   - An accurate thermometer.
   - An adequately designed aeration system (see manufacturer's instructions)
   - Units which store bivalve mollusks require a UV disinfecting unit (or similarly approved device) capable of maintaining the water quality at a bacteriological count of 2 coliform/100 ml or less.
   - Water must be tested upon initial set-up and on a regular basis thereafter.
4. Dead-ended pipes or hoses that could fill with stagnant water should be avoided.
5. Systems should be equipped with back-flow prevention devices to protect potable water supplies.

System Operation

1. Operational and maintenance instructions plus a notice of public health concerns should be attached to each live holding unit.
2. Marine water used in a live holding system must not be taken from an area closed to bivalve harvesting or an area subject to contamination (i.e. sewer/storm drain out-falls, industrial areas) or within a 125 meter radius of any docks or wharves. If artificial sea water is prepared, the ingredients must be food grade materials and the water from an approved water system.
3. Defoamers, if used, must be of food grade quality.

4. The turbidity of the water should not exceed 20 NTU.
5. Product loading must not exceed the manufacturer's recommended limits.

Additional requirements for bivalve mollusks:

6. Prior to placement in tanks, all shellfish shall be washed and culled to remove dead, broken or weak animals and culled on a daily basis thereafter.
7. Bivalve mollusks must not be mixed with other fish species or share common water systems.
8. Bivalve mollusks from different suppliers, harvest areas or harvest dates must not be commingled. Vertical plastic dividers, mesh bags, etc., may be used to maintain the identity of the lot

Maintenance and Records

1. Designated employees should be responsible for maintenance.
2. Maintenance instructions, operating manuals and checklists should be made available.

Maintenance procedures should include:

(a) A weekly cleaning and servicing of the holding unit (draining not required) to include spray nozzles, filtration system, etc.

(b) Daily check to ensure the light is functioning, cleaning the Ultra-violet disinfection system every 6-8 weeks, and replacement of the UV bulbs every 9-10 months. (Spare UV bulbs should be readily available). (CCP)

3. Maintenance and operational logs (water quality, temperature, etc.) are to be complete and accurate and should be kept a minimum of one year.
4. Records of each lot of bivalves (indicating where purchased and at which plant they were processed) must be kept on site for a minimum of 1 year and made available upon request.

Maintenance Guidelines

Oysters, clams and mussels in a living state must be adequately protected to remain safe, wholesome and attractive to the consumer. Federal, state and local health codes usually have specific sanitary controls and record-keeping requirements that are to be applied to the shellfish by all wholesalers and retailers. These requirements usually specify that:

- Shellfish are to be stored and handled so as not to become contaminated
- Storage equipment is to be properly designed, constructed, and cleaned
- Different lots must be stored separately
- Health officials must be able to trace a lot of shellfish to the original shipper and harvest area of origin.

Proper use of holding tanks will ensure that these requirements are met or exceeded. Therefore, the following additional operating instructions must be followed to conform to federal and state requirements.

Care of the UV Unit

1. **Clean the bulb (every 6-8 weeks)**

   The UV Unit is a white tubular appliance that is connected to the water circulation hose lines. The unit contains an ultra-violet (UV) bulb which kills bacteria as they pass by. For this reason, clean the bulb every 6-8 weeks.

2. **Drain tank**

   Do not remove bio-mix. Mix 1/2 cup bleach with one gallon fresh water. Remove spray tops from riser tubes. Pour 1/2 of bleach solution down each riser tube using a funnel or container with a pour spout. Leave the tank drain closed and allow the solution to stand in tubes for 30 minutes. Open the tank drain and flush out the solution by running water from the hose down each riser tube. Flush system completely.

3. **Change the UV bulb (every 9-10 months)**

   Unplug unit! Remove protective end caps from the chamber. Disconnect bulb-pin plugs from both ends of the bulb. Remove "0" rings from each end and save for a new bulb. Remove the old bulb and replace with new. Replace "0" rings and reconnect plugs and end caps.

Additional System Procedures

Maintenance log

One of the welded panels on the system's base should contain a summary of critical instructions as well as a maintenance log. The log allows the establishment to track the frequency of critical maintenance procedures. The log should be filled out regularly.

Dividers

Removable dividers used in the tank to keep different lots of molluscan shellfish or different species separated must be smooth, non-toxic, non-absorbent, and easily cleaned. Dividers left in the system should be cleaned every time the system is cleaned and be washed, rinsed, and sanitized in an approved manner.

Cleaning Tank Interior

It is important that the tank interior be kept free of algae and slime build-up. To prevent this build-up, the tank interior should be wiped down with a clean rag or towel every time you clean the filter bed (at least once a week).

Troubleshooting Operational Problems

Proper maintenance is the key to the health and longevity of the aquatic animals within the tank. Routine maintenance such as dusting shelves or rotating stock needs to be done regularly. Proper cleaning of the filter system, cleaning and replacement of the ultraviolet lights and disinfection of the tank are major concerns.

Problems to look for are listed below:

1. Foam is caused by a build-up of organic proteins and other material in the water. Usual cause is from bleeding of an aquatic animal into the water.
   a) Remove foam by scraping off the surface with a fine mesh screen or siphon and vacuum.
   b) Look for the cause. Remove injured animals and check for missing body parts (i.e., fins, legs, cracked or broken shells, etc.).
2. Ammonia smell - foul odor indicates that organics have built up to a level that anaerobic bacteria have started to digest the matter.
   a) Clean tank
   b) Clean filters
   c) Remove organic solvents
   d) Change the water
   e) Check the ultraviolet light

3. Algae is normal when tanks are in areas with lots of natural light.
    a) Clean algae off with a clean soft cloth.
    b) Rinsing shellfish thoroughly with cold running water will remove the algae spores from their bodies.
    c) Do not use chemicals to remove the algae from tanks when animals are in the tanks
4. Cloudy or yellow hazy water indicates a build-up of organic proteins (will lead to foaming).
    a) Change the filter's activated carbon unit.
    b) Check for damaged or sick animals.
    c) Check for clogged filter units or clogged air stores.
    d) Install a properly designed filter system if one is not in place.
5. High mortality may be caused by several reasons such as:
    a) Animals damaged or suffering from temperature shock during transportation or transfer to tanks.
    b) Toxic substance added to tank, i.e. cleaning chemicals, insect spray, non-food grade glues, non-approved algaecides.

Guideline For Validating Molluscan Shellfish Tank 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 the product, have been corrected.
- ☐ SOPs that prohibit commingling molluscan shellfish with other species of seafood.
- ☐ SOPs for the separation of different lots of shellstock stored in the same tank.
- ☐ Personnel designated for system maintenance.
- ☐ Description of water source, treatment system and maintenance plan (equipment specifications/ manufacturer's instructions/operating manuals etc.).
- ☐ Shellstock tags to be retained for 90 days from the date the container is emptied and maintained in a manner that can facilitate tracebacks. (120 days if the state of origin labeling is different).
- ☐ Cleaning and sanitizing procedures provided. Disinfection or other water treatment activities cannot leave residues that are not Generally Recognized as Safe (GRAS)

Hazard Analysis Included

- ☐ Receiving
- ☐ Pathogens from the harvest area
- ☐ Culling & Ultraviolet disinfection unit
- ☐ Elevated bacterial counts

CCP(s) Identified

- ☐ Receiving
- ☐ Culling
- ☐ Ultraviolet disinfection unit

Critical Limit(s) Identified

Receiving

- ☐ Shellfish is tagged with information as required under § 3-202.18: Shellstock Identification

Storage

- ☐ Different lots of shellfish kept separated using flow-through dividers or mesh bags.
- ☐ No other species of seafood stored in molluscan wet storage tank.

Culling

- ☐ Dead or cracked shellfish discarded

UV Disinfection Unit

- ☐ Disinfected water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water.

Monitoring Procedures Identified

Receiving

- ☐ Every sack of shellstock is visually inspected for tags or labels by designated PIC
- ☐ Person(s) identified for receiving shellstock

Culling

- ☐ Tank visually inspected daily and/or when adding new shellfish, for open, cracked shells by tank operator

UV Disinfecting Unit

- ☐ Light is visually inspected daily, by tank operator, to ensure it is functioning properly
- ☐ For water that is disinfected by UV treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with Standard Method for the Examination of Water and Wastewater, APHA.

Corrective Actions and Documentation Procedures Identified

Receiving

- ☐ Untagged sacks rejected
- ☐ Corrective actions recorded in log (sample page included)
- ☐ Cause of deviation determined

Culling

- ☐ Culling operation initiated immediately
- ☐ Corrective actions recorded in log (sample page included)
- ☐ Cause of deviation determined

UV Disinfecting Unit

- ☐ Bulb replaced immediately
- ☐ Shellfish moved to cold storage if problem cannot be resolved immediately
- ☐ Shellfish held pending evaluation of time/temperature exposure
- ☐ Corrective action in accordance with MA Guideline for Obtaining a Permit for Onshore Wet Storage of Shellfish
- ☐ Corrective actions recorded in log (sample page included)
- ☐ Cause of deviation determined and recorded

Verification Process Identified (Short Term/Long Term)

Receiving

- ☐ If shellstock is received from out of state, Interstate Shellfish Shipper's List (ISSL) is reviewed to verify supplier as an approved source

Storage

- ☐ Thermometer calibrated monthly, or as needed

Receiving, Culling, Storage

- ☐ 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 Ultraviolet disinfection unit
- ☐ Coliform study conducted prior to final regulatory approval, when make-up water of more than 10 percent of the water volume is added, and whenever new UV bulbs are installed in accordance with the MA Guideline for Obtaining a Permit for Onshore Wet Storage of Shellfish (recirculating water systems).
- ☐ Weekly laboratory analysis of tank water negative for coliform.

Records are Identified

Labeling

- ☐ Label/tag check record or receiving log
- ☐ Corrective actions recorded in log (sample page included)

Storage

- ☐ Temperature logs (water 40-60°F)
- ☐ Corrective actions recorded in log (sample page included)

Water Testing

- ☐ All water testing reports and corrective action records retained for two years.

Employee Training Plan Documented (sample of training log provided)

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

Custom Processing Animals

Custom Processing Animals

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 and 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.)
- 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 a minimum of 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

Curing, Smoking, Fermenting, Drying

Curing, Smoking, Fermenting, Drying

Regulation: § 3-502-11 Specialized Processes

Background Information

There has been a notable increase in on site retail preparation of cured, smoked, and/or cured and dried meat products, especially in high-end restaurants and specialty shops. There are also an increasing number of restaurants producing specialty cured meats such as sausages and bacon. In addition, ethnic restaurants often produce cured or smoked meat products that may be unfamiliar. This has become so popular that chefs now specialize in "charcuterie," which is a style of cooking that focuses on prepared meats such as ham, bacon, sausage, and pâtés.

Meat and poultry are cured by the addition of salt alone or in combination with one or more ingredients such as sodium nitrite, sugar, curing accelerators, and spices. These are used for partial preservation, flavoring, color enhancement, tenderizing and improving yield of meat.

The process may include dry curing, immersion curing, direct addition, or injection of the curing ingredients. Curing mixtures are typically composed of salt (sodium chloride), sodium nitrite, and seasonings. The preparation of curing mixtures must be carefully controlled to avoid mistakes. A number of proprietary mixtures, which are uniform in composition, are available.

The maximum residual sodium nitrite in the finished product is limited to 200 ppm by the USDA Food Safety and Inspection Service (FSIS). A sodium nitrite concentration of 120 ppm is usually sufficient for most purposes. Specific requirements for added nitrite may be found in USDA regulations, 9 CFR 424. It is important to use curing methods that achieve uniform distribution of the curing mixture in the meat or poultry product.

Microbiological hazards involved with curing include vegetative pathogens such as *Salmonella*, *Listeria monocytogenes*, and *Escherichia coli* O157:H7; toxin production by *Staphylococcus aureus,* and spore formers such as *Clostridium botulinum*; and parasites such as *Trichinella spiralis*. Chemical hazards may include nitrite poisoning. Nitrite poisoning can occur from improper handling or inaccurate weighing.

Regardless of preparation method, cure ingredients must be distributed throughout the product. Cure ingredients may be introduced into sausage products during mixing or comminuting. Proper and thorough mixing is necessary whether the cure is added to the formulation in dry or solution form. Muscle cuts may be cured by immersion into a curing (pickle) solution. These methods depend on slow diffusion of the curing agents through the product. Products must be properly refrigerated during immersion curing.

Several methods may be used to shorten curing times. These include hot immersion curing greater than>120℉ (49℃), injection by arterial pumping (e.g., hams), and stitch pumping by a series of hollow needles. If the injection method is used, injection needles must be frequently monitored during processing to ensure that they are not clogged or soiled.

Tumbling or massaging may also be used as an aid to hasten curing. Proper sanitation must be observed to prevent contamination during this operation.

The dry curing method, a similar process, may also be used. In this case, curing ingredients are rubbed over cuts and surfaces of meat held under refrigeration. Precautions must include wearing sanitary gloves when meat is handled. Product temperature maintenance is critical.

Smoking is the process of exposing meat products to wood smoke. Depending on the method, some products may be cooked and smoked simultaneously, smoked and dried without cooking, or cooked without smoking. Smoke may be produced by burning wood chips or using an approved liquid smoke preparation. Liquid smoke preparations may also be substituted for smoke by addition directly onto the product during formulation in lieu of using a smokehouse or another type of smoking vessel.

As with curing operations, a standard operating procedure must be established to prevent contamination during the smoking process. Microbiological hazards involved with smoking include vegetative pathogens such as *Salmonella, Escherichia coli 0157:H7*, and *Listeria monocytogenes* as a post-processing contaminant.

Key control measures required to produce a safe smoked meat product include inspecting sources of meat and poultry from commercial vendors to minimize bacterial load and maintain a wholesome and safe product, and the materials used to generate smoke should be safe and intended for smoking meat, not for building purposes.

Fermentation of Sausages

Fermentation of sausages is a specialized process that requires multiple hurdles to produce safe products. The microbiological hazards are like those associated with cured and smoked meat. The process requires that several pathogens be inhibited or inactivated at various stages of the process. Failure with any one of these processes could have devastating effects for the consumer. To add to the complexity of the process, desirable organisms that positively contribute to the fermentation process must be provided with an optimal growing environment. It is critical that all processes related to fermentation be seriously and carefully designed with the public's safety in mind.

Meat may be fermented or dehydrated for preservation. The purpose of fermentation is to reduce the pH to below and inhibit bacteria harmful to health as well as bacteria which can cause spoilage. Meat products may also be cured and then dehydrated to prevent germination and growth of bacterial spores. Many fermented and dehydrated meats are made without a cooking step. Sanitary practices in the production of these products are extremely important because *Staphylococcus aureus* can be introduced. *Staphylococcus aureus* produces an enterotoxin that is heat stable and thus will not be inactivated by subsequent cooking.

Some hazards may survive the addition of additives or components. For example: during fermentation of sausages, *Staphylococcus aureus* may proliferate to high numbers and produce a toxin if the lactic acid fermenters do not rapidly produce a pH drop sufficient to inhibit the *Staphylococcus*. Also, if an acidifier is used when acid-resistant organisms such as *Salmonella* or *Escherichia coli 0157:H7* are present, like in salsa, these pathogens may not be affected.

In addition, some hazards may be present in additives or components. Starter cultures saved from a previous batch of fermented food or cultures from non-commercial sources may contain low levels of lactic acid bacteria or contaminating organisms. Desirable fermenters that give the rapid drop in pH may not be able to compete successfully. Wheat or milk in a flour or whey substrate to give a starter culture sufficient nutrients to begin growing could be an undeclared allergen unless appropriately labeled on packaged items. Nitrite or any other food additive with a specific limitation set in the CFR may be considered a hazard.

Meat must be from an approved source. Processed pork products require treatment to destroy *Trichinella spiralis.* At retail, this means that products that contain raw pork and ***are not*** subsequently cooked must be produced from certified trichina-free pork or treated to destroy trichinae. USDA regulations, 9 CFR 318.10(c)(3), establish various requirements for destroying trichinella in pork by heating, freezing, drying, or smoking. And since some fermented and dry cured products are processed without cooking. The labeling for these products should include instructions to the consumer to cook thoroughly before consumption.

Drying of Meat and Poultry

One well-known ready to eat (RTE) dried shelf-stable meat in the United States is jerky. People have successfully made jerky by drying meat for thousands of years. It's a simple way to preserve meat or poultry for long periods of time without refrigeration. To prepare meat or poultry jerky that is not hazardous to consumers, specific steps must be taken. The average consumer prefers jerky that is not too hard or tough and contains a pleasing flavor, which creates some challenges for jerky processors.

The microbiological hazards associated with jerky and other dried meat products are like those discussed for cured and smoked meat, with one exception. Since cooked shelf-stable meats are stored at room temperature and are stable for long periods of time, molds can be a problem because of their ability to grow at very low water activity (aw). Foodborne outbreaks reported to CDC associated with jerky involved Salmonella, Trichinella spiralis and nitrite poisoning.

Most dried meats are dried to a water activity level less than < 0.88 to control bacteria. This is not sufficient to control growth of mold such as the aflatoxin-producing fungus called *Aspergillus flavus*, however, since *Aspergillus flavus* is able to grow in a water activity level down to 0.70. If jerky becomes moldy, it should be disposed of with caution since the toxin is also present in the spores of the mold and can become airborne. Bacteria require relatively high levels of moisture for their growth, but many microorganisms such as bacterial endospores,

Staphylococcus aureus, *Trichinella spiralis*, and molds can survive drying. As stated, when discussing smoking and curing of meat and poultry, processed pork products require treatment to destroy *Trichinella spiralis*, a parasite that is easily destroyed by the drying process with temperatures greater than 137°F (58°C).

Depending on the temperature used in the drying process, however, it may not provide a sufficient lethality treatment to make a safe RTE product because the time/temperature standards shown in *FSIS Appendix A: Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products* (hereinafter referred to as Appendix A) or in The Food Code cooking recommendations must be carried out in the presence of high humidity.

One recommendation for the use of Appendix A not shown on the table itself is that the food must be held under 90% relative humidity for at least 25% of the lethality process. This is a problem in preparing a very dry meat product like jerky since it is difficult to dehydrate the jerky if the relative humidity is high. If the relative humidity is too low, a thick crust forms on the outside of the jerky that inhibits the transference of heat into the center of the food. The term used for this is "case hardening" and it is a common problem in the drying of food.

If the heat cannot be transferred effectively through the crust, pathogens inside the jerky can survive. Because it is difficult for many retail food establishments to maintain the required humidity, if a food establishment cannot meet the guidelines of Appendix A including relative humidity), an alternate process must be validated. This will require a variance petition with the HACCP submission.

Another hazard associated with these types of dried meats is that consumers often think they are ready-to-eat and fail to cook them. To add to the confusion, some chorizos, soujouk, and other typically not-RTE sausages are fully processed and made ready-to-eat. Proper labeling is crucial for consumer protection, as is a validated HACCP plan. Dried meat or poultry products that have not received a lethality treatment must contain a consumer advisory printed on the label of the packaged product or posted at the point of purchase.

As with all the special processes that require a lethality or kill step for safety, retailers have several options such as validated regulatory standards, a validated challenge study, or a published validated process. The American Association of Meat Processors (AAMP), for example, has published several validated processes for drying meat and poultry and provides additional references. The American Meat Institute (AMI) also provides information about drying.

A carefully developed challenge study can validate the safety of a proprietary process with the help of a process authority. FSIS provides regulatory guidance in its Appendix A for meeting Lethality Performance Standards for various types of meat and poultry, including smoked poultry. It has other advisory materials about drying and smoking on its website as well.

The following guidelines are taken from the *Association of Food and Drug Officials (AFDO) Meat and Poultry Processing Guidelines***,** 2011. AFDO has provided the following guidelines in response to requests from state and local governments to provide guidance for the processing of meat and poultry at retail. These guidelines provide sound scientific support to produce unique meat and poultry products such as cured and smoked meat and poultry and dry and semi-dry fermented sausage. They have been reviewed and approved by members of the AFDO Retail Food Committee, the AFDO Board of Directors and the U.S. Department of Agriculture. These guidelines represent best practice recommendations, based on the best scientific and practical considerations, and do not represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why those procedures are effective. It is important to note that this guideline represents current thinking on these topics and should be considered usable as of the issuance date (2011).

Curing and Smoking of Meat and Poultry

Key Terms

Acceptable Product List" means a list of meat or poultry products for which a HACCP Plan has been approved by a process authority.

Casings mean natural animal stomachs, intestines or bladders or manufactured casings of cellulose or collagen, which are used to contain comminuted meat, or poultry product mixtures for sausages.

Cold Smoking means a smoking process used to apply smoke or a smoke flavor at or near ambient temperature to food products not sufficiently darkened or flavored in the original cooking process.

Comminuted means reduced in size by methods including chopping, flaking, grinding, or mincing.

Curing is a process of preserving meat by the application of salt, nitrite and seasonings to meat and is characterized by the interaction of nitrite and meat pigments resulting in the development of a "cured" pink color.

Cure Accelerator means compounds such as ascorbic acid or erythorbic acid or their derivatives, sodium ascorbate and sodium erythorbate as defined for use in 9 CFR ¶ 318.7(c)(4), which shorten the time required for the distinctive pink color to develop in cured meat and poultry products.

Cured sausages may be categorized as: (1) raw, cured; (2) cooked, smoked; (3) cooked, unsmoked; and (4) dry, semi dry, or fermented.

Injection means the process of transferring a curing solution into a whole muscle meat using a needle or group of needles connected to a brine source.

Massaging means subjecting meat chunks to a mechanical treatment to facilitate protein extraction from muscle fibers. This process accelerates the even dispersal of cure solution and increases yield.

Process Authority is a person or organization with expert knowledge in meat or poultry production, process control and relevant regulations.

Sausages include both finely ground and coarse ground products. Finely ground sausages include bologna, frankfurters, luncheon meats and loaves, sandwich spreads, and viennas. Coarse ground sausages include chorizos, kielbasa, peperone, salame, and summer sausages.

Showering means a potable water spray with or without liquid smoke in the smoke house which, depending on when the water spray is applied, maintains humidity, flavors, decreases cooking time, promotes rapid cooling or reduces casing shrinkage.

Smoking is the process of exposing meat products to wood smoke. Depending on the method, some products may be cooked and smoked simultaneously, smoked and dried without cooking, or cooked without smoking.

Smokehouse means a piece of equipment or room sized enclosure used to conduct the smoking and cooking process which has a smoke source, adequate ventilation, heat and humidity source if necessary, approved plumbing and waste lines if necessary, support structures for the food products to be smoked and a method to determine internal product temperature.

Controls and Guidelines

A. Trained Employees

All employees engaged in the curing and smoking process shall receive training and demonstrate familiarity with the curing and smoking processes as well as the associated hazards.

B. HACCP Plan

Each retail food establishment that engages in the curing and smoking process must have a HACCP plan validated by a process authority. This HACCP plan must be made available to the regulatory authority for review and audit. The HACCP Plan must contain process flow charts for each category of product, recipe formulations for each product that is cured and/or smoked, identified hazards, critical control points, critical limits, monitoring procedures, corrective action and verification steps. It must include a list of acceptable products, which have received approval under the HACCP Plan. It shall also contain a description of the training course content for employees engaged in the curing and smoking operation.

C. Equipment and Materials

1. A calibrated automatic recording thermometer with internal product temperature probes or calibrated metal-stemmed thermometer shall be available and used when product is smoked.
2. Calibrated and certified scales shall be used to weigh any curing compound, cure accelerator or other additive, provided it has not already been pre-measured and weighed.
3. Tumble massagers facilitate the extraction of salt soluble proteins and accelerates the distribution of cure solution in chunks of meat. Massaging must be done under refrigeration, recommended at 33°F to 36°F (91.4°C - 96.8°C).
4. All equipment coming in contact with meat products must be fully cleaned by washing, rinsing and use of an approved sanitizer.
5. A smoke generator attached to a smokehouse may only use materials approved by USDA, FDA, or other regulatory agencies. These include non-resinous hardwoods, hardwood sawdust, redwood, mesquite wood, corncobs, and natural liquid smoke.
6. Natural or artificial casings for sausage, loaf or chub forming must be sanitary and may not be stripped for reuse with another batch or lot. The casings may be salted or unsalted, colored, or shirred, that is, pleated or compressed for easy application to the stuffing horn.
7. Curing or smoking may not be used to salvage meat or poultry that has excessive bacterial growth or spoilage.

D. Time-Temperature Control During Curing

1. The curing process using immersion and injection shall be done so that product temperature remains at 41°F (5°C) or less.
2. Meat and poultry products, as well as natural and artificial casings during soaking shall be stored at 41°F (5°C) or less.
3. The internal temperature of any smoked meat or poultry or smoked meat or poultry product shall comply with cooking requirements for that product, with the exception that:
    a. cold smoking is a smoking process used only to apply smoke color or flavor at ambient temperature to food products, and
    b. When a cold smoking process is used for cosmetic purposes, that is, to add smoke color or flavor to pre-cooked product, it must be of such duration that the internal product temperature remains at or below 41°F (5°C).

E. Curing Process

1. Use of curing agents, curing accelerators, and other additives shall be according to 9 CFR § 318.7, Approval of Substances for Use in the Preparation of Products, and 9 CFR § 381.147, Restrictions on the Use of Substances in Poultry Products.
2. The formulation and preparation procedure must be documented by lot.

F. Curing Methods

1. Dry curing means all surfaces of the meat are rubbed and covered with a dry cure mixture at intervals of sufficient frequency to assure cure penetration.
2. Dry salt curing is a modification of the dry curing method where the product may be injected with cure solution directly into the muscle in addition to dry curing.
3. Immersion curing means the product is immersed in a strong pickle or brine solution. Immersion curing solutions shall be discarded after each use except when they remain with the same batch or lot during the entire curing process.
4. Injection curing introduces the curing solution into the muscle meat through hollow needles.
    a. Stitch pumping injects the curing solution deep into the muscle with a single orifice needle.
    b. Spray pumping injects the curing solution using a needle with many orifices to allow more uniform distribution of the solution.
    c. Artery pumping injects the curing solution into the natural circulatory system of the meat.
    d. Machine pumping, like stitch pumping, injects the curing solution using 10 or more needles. Sometimes spring-loaded needles are used for bone-in products to prevent breaking the needles products to prevent breaking the needles.

G. Time-Temperature Control During the Smoking Process

1. The hot smoking process shall be considered equivalent to a cooking process and be required to meet all internal time-temperature cooking requirements. This information shall be documented for each lot.
2. Cold smoked meat and poultry products shall be processed at or near ambient temperature so that the internal product temperature does not rise above 41°F (5°C). The product and air temperature shall be monitored at all times.
3. Hot smoked meat and poultry products shall be cooled from 135°F to 70°F (57°C - 21°C) within 2 hours and to 41°F (5°C) or less within an additional 4 hours.
    a. If cold water showering is used to rapidly drop product temperature after smoking, it must be potable water, should contain a chlorine residual, may not be re-circulated unless by an approved method, and if reclaimed, must be discarded daily.
    b. Cooling times and temperatures must be documented for each lot, but in all cases, internal product temperature must cool from 135°F to 70°F (57°C - 21°C) within 2 hours and from 70°F to 41°F (21°C - 5°C) or below within an additional 4 hours.

H. Storage of Smoked Product

Ready-to-eat smoked products must be stored in a manner and location to prevent cross-contamination or adulteration.

Dry and Semi-Dry Fermented Sausage

Key Terms

Dry Fermented Sausage means a product made of chopped or ground meat products that, as a result of bacterial action, reaches a pH of 5.3 or less and is then dried to remove 25-50% of the moisture to have a moisture/protein ratio in compliance with USDA requirements. Dry fermented sausages include hard salami, Genoa salami, and pepperoni.

Semi-Dry Fermented Sausage means a product made of chopped or ground meat products that, as a result of bacterial action, reaches a pH of 5.3 or less and undergoes up to 15% removal of moisture during the fermentation/heating process. Semi-dry fermented sausages include summer sausage, thuringer, cervelat and Lebanon bologna.

Moisture-protein-ratio (MPR) expresses the percent moisture divided by the percent protein. MPR is commonly used in the U.S. to classify dried sausages and other meat products. Although MPR values indicate the degree of product drying, they are not necessarily indicative of microbial safety or product shelf-stability because they do not take into account availability of the water.

A. Validation of Processing Procedure for Dry and Semi-Dry Fermented Sausages

Due to foodborne illness outbreaks of *Escherichia coli* 0157:H7 linked to dry fermented ready-to-eat sausage products, all procedures for dry and semi-dry fermented sausages must be validated to show products achieve a 5-log reduction of *Escherichia coli* 0157:H7. Full documentation is required. This can be accomplished by using one or more of the following options:

1. Submit the processing procedure to a recognized process authority for validation.
2. Design and conduct validation studies utilizing a laboratory that is certified for testing pathogenic bacteria in meat and poultry products including any nonfood manufacturing biosafety level II facility.
3. Modify processing procedures to include a moist heating step after fermentation but prior to drying. The moist heating can be accomplished by using a sealed oven or steam injection to raise the relative humidity above 90% throughout the cooking process and meet one of the following time/temperature requirements:

Minimum Internal Temperature ° F	Minimum Holding Time at Temperature
130	121 minutes
131	97 minutes
132	77 minutes
133	62 minutes
134	47 minutes
135	37 minutes
136	32 minutes
137	24 minutes
138	19 minutes
139	15 minutes
140	12 minutes
141	10 minutes
142	8 minutes
143	6 minutes
144	5 minutes
145	4 minutes
146	182 minutes
147	144 minutes
148	115 minutes
149	91 minutes
150	72 minutes
151	58 minutes
152	46 minutes
153	37 minutes
154	29 minutes
155	23 minutes
156	19 minutes
157	15 minutes
158	0 minutes
159	0 minutes
160	0 minutes

4. **Examples of processes that yield a 5D or more reduction of E Coli O157:H7:** (from *"Dry Fermented Sausages and E. coli O157:H7"* 1997 by the Blue Ribbon Task Force of National Cattlemen's Beef Association.)

    a. Ferment at 32°C (90°F) to pH 5.3 and heat to 52°C (125°F) 7 hours, then dry for ≥7 days (large casing)

    b. Ferment at 32°C (90°F) to pH 4.6 and hold at 32°C (90°F) 7 hours, then dry for ≥6 days (small casing)

    c. Ferment at 32°C (90°F) to pH 4.6 and heat to 52°C (125°F) about 7 hours, (small and large casings)

    d. Ferment at 43°C (110°F) to pH 4.6 and hold at 43°C (110°F) for ≥4 days (small and large casings)

5. Implement a HACCP plan combined with Good Manufacturing Practices (GMPs) for fermented sausage, including raw batter testing and documentation of at least a 2 D lethality of *Escherichia coli O157:H*7 between stuffing and shipping.
    a. An acknowledged analytical method equivalent to that used by USDA/FSIS must be implemented in the raw batter testing.
    b. The sample size and composting procedure must ensure a detection level of 1 E. coli/gm. (15-25gm is recommended. samples be taken from across the lot. These could then be composited into 575gm analytical samples.)
    c. The definition of a "lot" for the purposes of sampling must be statistically sound.
    d. GMPs must be applied.
    e. The process must also address other hazards, e.g., *Trichinella and Staphylococcus*
    f. A procedure for dealing with lots from positive batter samples must be defined in the HACCP plan. At a minimum, all positive lots must be subjected to conditions that will provide a total 5 D process.

B. Fermentation Cultures

An active fermentation culture is necessary to produce lactic acid which lowers the meat pH and aids in inhibiting staphylococcal growth during the warm-temperature processing (fermentation) phase, contributes to the process' lethality toward bacterial hazards, contributes to the stability of the finished product, and aids in releasing moisture from the meat during the drying phase for dry sausages.

1. *Starter Culture* - If a commercially prepared fermentation culture is used, any special handling instructions specified by the manufacturer regarding frozen or refrigerated storage and other factors must be observed.
2. *Background Inoculation* - If a back inoculum from a previously fermented and controlled mother batch is used, the mother batch shall have attained a pH of 5.3 and shall be monitored on a regular basis for lactic producing bacteria and coagulase positive Staphylococci.
3. *Enrichment* - Reliable enrichment requires both time and control. USDA ARS scientists established that aging salted meat for at least 10 days at 40°F (4.4°C) was required. The added salt could be no more than 3.5% salt and no less than 2% salt. Since that research, many packers have implemented bactericidal treatments for carcasses. These treatments may affect the reliability of traditional enrichment procedures.

C. Fermentation Time-Temperature Control

Once the sausage pH reaches 5.3, during lactic acid bacterial fermentation, the potential for staphylococcal toxin formation is effectively controlled. Because staphylococcal growth is directly proportional to temperature, the time to reach pH 5.3 at higher temperatures must be shorter. In 1982, the AMI developed the following degree-hour strategy for controlling staphylococcal toxin formation, which has proven to be effective.

1. Degrees/Hours Defined (see **Note** on next page)

    a. Fewer than 1200 degree/hours when the highest fermentation temperature is <90°F.

    b. Fewer than 1000 degree/hours when the highest fermentation temperature is between 90°F and 100°F.

    c. Fewer than 900 degrees/hours when the highest fermentation temperature is >100°F.

Note: Degrees are measured as the excess over 60° F at which staphylococcal growth effectively begins. Degrees/hours are the product of time in hours at a particular temperature and the "degrees." Degree/hours are calculated for each temperature used in the process. The limitation of the number of degrees/hours indicated in a, b, and c depend upon the highest temperature in the fermentation process prior to the time that a pH of 5.3 or less is attained.

Processes exceeding 89°F prior to reaching a pH of 5.3 are limited to 1000 degree /hours; processes exceeding 100°F prior to reaching pH 5.3 are limited to 900 degree/hours.

2. Temperature measurements should be taken at the surface of the product. Where this is not possible, fermentation room temperatures should be utilized.
3. Constant Temperature Processes. The time temperature relationships for constant temperature processes, predicated on fermentation room temperatures, are as follows:

Degree/Hours	Temperatures ° F	Allowed Hours
1200	75	80
1200	80	60
1200	85	48
1000	90	33
1000	95	28
1000	100	25
900	105	20
900	110	18

Examples of Constant Temperature Processes

Process A

Constant 80° F temperature for 55 hrs. with pH decline to 5.3

Degrees: 80 - 60 = 20

Hours: 55

Degree/Hours:(20) x (55) = 1100 degree/hours

Process A Passes

Process B

Constant 90° F temperature for 40 hrs. with pH decline to 5.3

Degrees: 90 - 60 = 30

Hours: 40

Degree/Hours:(3b) x (40) = 1200 degree/hours

Process B Fails (Limit: 1000 degrees/hours)

4. Variable Temperature Processes. In testing each process, each step-up in the progression is analyzed for the number of degree/hours it contributes, with the highest temperature used in the fermentation process determining the degree/hour limitation as follows:

Process C

Hours	Temperature ° F	Critical Temp Adjustment	Degrees	Degree/Hours
10	75	75-60	15	150
10	85	85-60	25	250
16	95	95-60	35	560

pH=5.3 **Total=960**

Process C Passes

Process D

Hours	Temperature ° F	Critical Temp Adjustment	Degrees	Degree/Hours
10	75	75-60	15	150
10	85	85-60	25	250
18	98	98-60	38	684

pH=5.3 **Total=1084**

Process D Fails (The limit is set at 1000 degrees/hours for times and temperatures and it has taken 1084 degrees/hours to attain pH5.3.)

Introduction to Dried Meat and Poultry (Jerky)

The following information is taken from the *FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments* (2014). The document provides guidance to assist establishments in meeting FSIS regulations related to jerky processing. These guidelines represent best practice recommendations by FSIS, based on the best scientific and practical considerations, and do not represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why those procedures are effective.

Key Terms

Case hardening occurs if relative humidity is too low when drying meat. A thick crust forms on the outside of the jerky that inhibits the transference of heat into the center of the food. Pathogens inside the jerky can survive.

Critical operational parameters are those parameters of an intervention that must be met for the intervention to operate effectively and as intended. Such parameters include but are not limited to time, temperature, water activity, concentration, relative humidity, and type of equipment (to the extent that the use of different equipment would result in an inability to achieve the critical parameters of the study).

Jerky means a product made from animal flesh that has been cut into long slices or strips and dried.

The **dry bulb** temperature refers to the ambient air temperature. It is called “dry bulb” because the air temperature is indicated by a thermometer not affected by the moisture in the air or evaporative cooling that removes heat and moisture from the surface of the product. The dry bulb temperature is most commonly measured by jerky-makers. Jerky makers commonly measure the dry bulb temperature.

Formed jerky means a product made from animal flesh that has been shredded or ground and molded into its final shape before drying and may or may not contain extenders.

Extenders are any materials such as textured soy protein or cereals that are added to the ground or shredded animal flesh and must be properly declared in the labeling of the product.

The **lethality treatment** is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the thermal processing begins (e.g., the product is placed in the heated oven) until the point at which the product reaches the desired lethality time-temperature combination (also referred to as the “cooking time”).

Marinade means to soak meat in a sauce to enrich its flavor, to tenderize or enhance its shelf life.

Moisture-protein-ratio (MPR) expresses the percent moisture divided by the percent protein. MPR is commonly used in the U.S. to *classify* dried sausages and other meat products. Although MPR values indicate the degree of product drying, they are not necessarily indicative of microbial safety or product shelf-stability because they do not consider availability of the water.

Relative humidity is defined as the degree of saturation of the air by water (vapor), expressed as a percentage. Relative humidity describes the relation of the existing vapor pressure at a given temperature to the maximum vapor pressure at that temperature. Air at a given temperature can absorb vapor until its saturation (100%). The difference between the dry and wet bulb temperature is the relative humidity at that temperature. The following website: http://www.ringbell.co.uk/info/ humid.htm contains a function for calculating the relative humidity given the wet and dry bulb temperatures.

A **sealed oven** is generally defined as one in which the smokehouse doors and smokehouse oven dampers are closed to prevent moisture loss

Shelf-stable is the condition achieved when meat and poultry products can be stored under ambient temperature and humidity conditions; if the package integrity is maintained during storage, shipping, and display at retail and in the home; and the product will not spoil or become unsafe throughout the manufacturer's specified shelf-life.

Water activity, also referred to as aw is a measure of the concentration of moisture (i.e., water) and its availability in food. The amount of water available in a food depends on the total concentration of all dissolved substances in the product because they bind water. Thus, if ingredients such as salt or sugar are added to foods, they compete with the bacteria for available water. The wet bulb temperature is the temperature indicated by a moistened thermometer bulb exposed to the air flow. A wet bulb thermometer measures the extent of cooling that happened as moisture dries from a surface, a process also known as evaporative cooling. The wet bulb temperature is always lower than the dry bulb temperature except when there is 100% relative humidity, when they will be identical. Because evaporative cooling occurs on the surface of thin jerky strips, the t bulb temperature is a more accurate measure of product surface temperature.

The **wet bulb** temperature is the temperature indicated by a moistened thermometer bulb exposed to the air flow. A wet bulb thermometer measures the extent of cooling that happens as moisture dries from a surface, a process also known as evaporative cooling. The **wet bulb** temperature is always lower than the dry bulb temperature except when there is 100% relative humidity, when they will be identical. Because evaporative cooling occurs on the surface of thin jerky strips, the wet bulb temperature is a more accurate measure of product surface temperature.

Step by Step Guide for Jerky Processing

Jerky producers are required to control the food safety hazards in their products (9 CFR 417.4(a)) and to document that their Hazard Analysis and Critical Control Point (HACCP) systems work according to 9 CFR 417.5(a). Establishments producing RTE products need to achieve lethality of pathogens (e.g., *Salmonella*) in the product, and stabilize the product to inhibit the growth of spore-forming bacteria (e.g., *C. botulinum* and *C. perfringens*). In addition, jerky producers need to ensure the growth of toxigenic microorganisms, such as Staphylococcus aureus, is controlled during the process and prevented during the distribution and storage of the finished product. This guideline provides steps jerky processors can take to ensure that the jerky processes they employ effectively control these hazards. The guideline discusses each step in the jerky process in more detail below with key considerations related to pathogen reduction or control highlighted for each step. Each process is unique, so some processors may not use all eight steps. Some may perform the steps below in a different order, or some may use additional steps.

Step 1
Strip preparation: Whole muscle is sliced or ground; ground product is formed into strips (some jerky is formed).

It is critical for establishments to use source materials prepared under good manufacturing practices (GMPs) designed to minimize contamination and the presence and growth of pathogens of public health concern, so the initial pathogen load is not higher than what the process is designed to reduce. Establishments that choose to purchase source materials known to be contaminated with pathogens of public health concern, such as *Salmonella* or shiga toxin-producing *Escherichia coli* (E. coli) (STEC) organisms such as *E. coli* O157:H7 or *E. coli* O45, should pay special attention to the controls they put in place to ensure cross-contamination between raw and ready-to-eat (RTE) product does not occur.

Step 2
Marination: The strips are marinated in a solution that often contains salt, sugar, and flavoring ingredients.

Establishments should use non-meat ingredients for marinades and spice mixes that are prepared under GMPs designed to minimize contamination and the presence and growth of pathogens of public health concern, so the initial pathogen load is not higher than what the process is designed to reduce. FSIS recommends that establishments use a new liquid marinade solution or dry spice mix with each production batch to reduce chances of cross-contamination from one batch of production to another. If an establishment does reuse a marinade or spice mix, it should consider and address the potential hazards associated with cross-contamination from one batch of production to another.

Step 3

Interventions: Antimicrobial interventions before, during, and, after marinating the strips of raw product have been shown to increase the level of pathogen reduction beyond that achieved by heating alone.

Some heating processes may not deliver an adequate lethality and, thus, may require an additional intervention step to ensure product safety. Examples of interventions that may increase the lethality of the process are:

- Preheating the meat or poultry jerky strips in the marinade to a minimum internal temperature of 160°F will provide an immediate reduction of *Salmonella* (Harrison and Harrison, 1996). Heating in marinade may produce unacceptable flavors for some products; however, other liquids such as water could be used. The times and temperatures in *FSIS Appendix A: Compliance Guidelines for Meeting Lethality Performance Standards For Certain Meat and Poultry Products* (referred to throughout the document as Appendix A) could be used for preheating in the liquid, although the product internal temperature should be monitored to ensure adequate lethality is achieved).

Dipping the product in 5% acetic acid for 10 minutes before placing it in the marinade can augment the log reduction effects of drying but not enough to eliminate pathogens (Calicioglu, 2002 & 2003). This intervention may also result in an undesirable flavor.

- Dipping the product in 1:2 or 1:3 mixtures of calcium sulfate (Mionix Safe$_2$O™) and water for 30 seconds or dipping in acidified sodium chlorite (Keeper®) at concentrations between 500 and 1,200 ppm can reduce the level of *Salmonella*, *Listeria monocytogenes* (*Lm*), and *E. coli* O157:H7 compared with no pretreatment. These pretreatments were effective in both dehydrators and smokehouse processing (Harrison et al., 2006).

Step 4

Surface preparation: Strips are heated using a low temperature heat step which makes the surface tacky to aid in smoke adherence and improve product texture.

Humidity is often not introduced until the next step, the lethality treatment. The lack of humidity during the initial surface preparation step is generally not a food safety concern because the step is usually too short (30 minutes or less) to dry out the product to such a degree that the heat resistance of *Salmonella* would be increased. This step may include or be followed by a color setting step during which humidity is also not introduced. This color setting step plus the surface preparation step should be 30 minutes or less in total. If an establishment uses a preparation or color setting step that is longer than 30 minutes, it should provide support for why the lack of humidity does not result in the product drying out before the lethality treatment.

Step 5

Lethality treatment: The lethality treatment is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the product is placed in the heated oven (including surface preparation and color setting) until the point at which the product reaches the desired lethality time-temperature combination (also referred to as the "cooking time").

In order to achieve adequate lethality, the establishment's actual process needs to adhere to the following critical operational parameters in the scientific support:

- Product time-temperature combination
- Relative humidity

In recent years, several jerky products have been found to be adulterated with *Salmonella* or *E. coli* O157:H7. Often the contamination has been linked to inadequate lethality treatment. The lethality treatment of meat jerky should achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp. and at least a 5.0-log10 reduction for shiga toxin-producing *Escherichia coli* (*E. coli*) (STEC) for products containing beef as recommended in the *Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products*. The lethality treatment of poultry jerky should achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp. Although poultry jerky is considered to fall under the performance standard in 9 CFR 381.150 (i.e., a 7.0-$\log_{10}$ reduction of Salmonella spp.), the regulation allows for the use of an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product.

Research has supported that a 5.0- $\log_{10}$ reduction in *Salmonella* is sufficient for such shelf stable products. Indeed, the *FSIS Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products* found that there would not be a significant increase in the cases of salmonellosis if jerky and other shelf-stable products achieved a 5.0-$\log_{10}$ vs. 7.0-$\log_{10}$ lethality. In addition to *Salmonella* spp., the lethality treatment of meat and poultry jerky should achieve at least a 3.0-$\log_{10}$ reduction in *Lm,* although a 5.0-$\log_{10}$ reduction or greater is desirable for providing an even greater safety margin for ensuring that *Lm* does not grow to detectable levels during storage.

However, establishments are not required to validate that their process achieves reduction in *Lm* (or STEC for products containing beef) if it achieves sufficient reductions in *Salmonella* because *Salmonella* is more heat resistant than other pathogens and is, therefore, considered an indicator of lethality.

Establishments should make sound decisions in the hazard analysis that support that source materials were prepared using GMPs and other process controls as discussed in the previous steps of strip preparation and marination such that a 5.0-$\log_{10}$ reduction in *Salmonella* results in the production of a safe product. Official establishments choosing to use cooking to achieve lethality before drying may consider several different types of scientific documents to support the time-temperature-humidity combination used in the actual process.

Critical Operational Parameters during the Lethality Treatment

Regardless of the scientific support document(s) used, it is important that an establishment's actual process and procedures relate and adhere to the critical operational parameters in the scientific support in order to achieve adequate lethality. There are several critical operational parameters that are important for jerky processing that will be reviewed.

Product time-temperature combination

One of the critical operational parameters during the jerky process is the time-temperature combination the product achieves. Most often the temperatures used during the lethality treatment that are reported in scientific support documents, such as the Appendix A guidelines, are the temperatures that the product should reach. FSIS has found that establishments will use these same temperatures to set critical limits for the oven temperature. However, setting the oven temperature to the temperature in the support is not appropriate because it does not ensure that the product will reach the same internal temperature, which is critical to ensure adequate lethality is achieved.

For this reason, FSIS recommends that establishments monitor the internal product temperature. Product internal temperature can be measured by inserting a thermocouple probe into the center of a beef strip. Proper insertion may be difficult because the product is so thin; therefore, FSIS recommends that establishments slice one piece of jerky twice as thick as normal so that the probe can be inserted. If this thicker piece reaches the lethality temperature, the thinner pieces should as well. In addition, to accurately measure the product temperature, the establishment should understand factors that could affect the temperature of the product. These factors include cold spots in the oven, as well as variation in oven temperature during different seasons.

Although monitoring product temperature is strongly encouraged, establishments can use the oven or smokehouse temperature in place of the product temperature, provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support.

In addition to the product temperature, the amount of time the product is held at this temperature is also critical to ensuring that adequate lethality is achieved. It is important for the establishment to understand how the actual temperature of the product was taken, the time it takes the product to reach the target temperature (known as the come-up time or CUT), and the amount of time the product is held at the target temperature compared to the scientific support documentation. If the product is held at the target lethality treatment for less time than what was used in the scientific support, then adequate lethality may not be achieved.

Relative Humidity

In addition to the product time-temperature combination, the relative humidity (e.g., steam) in the oven is also critical to achieve adequate lethality in jerky. It is important that the establishment maintains humidity according to its scientific support. If relative humidity is not added or maintained by the process, the establishment should maintain scientific support demonstrating that humidity is not a critical operational parameter. Some jerky processors may be concerned that adding humidity will affect the ability to dry the meat or poultry and result in unacceptable product texture; however, the lethality treatment during which relative humidity is applied takes very little time. Adding humidity during the lethality treatment should accelerate subsequent drying and prevent case hardening, which may improve product texture

Relative humidity around a product during the lethality treatment promotes lethality in two ways:

- First, the humidity reduces surface evaporation and the energy or heat that evaporation removes from the product during heating. If sufficient relative humidity surrounding the product is not maintained during the lethality treatment, undesirable evaporative cooling at the surface will occur, and the product will not reach the desired temperature. Producing products under conditions of high humidity early in the cooking process reduces evaporative cooling allowing products to reach higher product surface temperatures which results in a greater reduction in microorganisms.
- Second, the humidity keeps the product surface (and any pathogens) moisture and prevents unwanted concentration of solutes (e.g., sugar and salt) because of drying. Research has demonstrated that bacteria can become more heat resistant as their moisture levels decrease, and increased concentrations of solutes, especially sugars, increase the heat resistance of bacteria. Therefore, the drying of the product surface before the pathogens are destroyed will increase pathogen heat resistance and allow them to survive the heating process. By incorporating humidity to minimize evaporation, the D values (time at a constant temperature necessary to destroy 90% or 1-$\log_{10}$ of the target organism) that are the basis for Appendix A and other scientific support documents remain valid (Goepfert, 1970; Goodfellow and Brown, 1978; Faith, N.G. et al. 1998).

Note: Without sufficient humidity the product surface may dry too quickly, and the bacteria may become more heat resistant.

For these reasons, it is crucial that the processor prevents drying of the product until a lethal time-temperature combination is attained. To be most effective, the humidity should be applied during the lethality treatment and before the drying step occurs. Although the lethality treatment includes the time when the product is placed in the heated oven until the product reaches the desired lethality time and temperature combination (the "cooking time"), establishments may not introduce relative humidity into the process until 15 to 30 minutes after the product is placed in the heated oven. The establishment would do so because of the previous step of surface preparation that is needed to set the surface to aid in the adherence of smoke. As discussed earlier, the lack of humidity during this initial step is not a food safety concern because of its short duration.

In addition to applying humidity early in the lethality treatment, FSIS also recommends that establishments treat the lethality and drying steps as separate stages to ensure that lethality is achieved before the product dries out. Therefore, the establishment should measure and verify the desired product temperature has been met before the drying stage. One way for an establishment to know that the product has not dried out before a lethal time-temperature combination is attained is to measure the water activity of the 12 products after the lethality treatment but before drying and again after drying.

Some published articles (for example, Buege et al., 2006a) report the water activity at these points in the process for comparison. Another approach is for the establishment to monitor the wet bulb temperature early in the process because it provides a good indication of product surface temperature, which strongly influences lethality (Buege, 2006a). Further explanation and directions for making a wet bulb thermometer were developed by G. Burnham, S.C. Ingham and B.H. Ingham, University of Wisconsin-Madison Center for Meat Process Validation, and can be found at Microsoft Word - Wet_Bulb.doc (wisc.edu). Although this information may be useful, establishments do not need such data to validate the process if they are able to demonstrate that their process can achieve the level of relative humidity in their scientific support.

Some simple and practical measures that can be used to aid in meeting the humidity level utilized in the scientific support documents include:

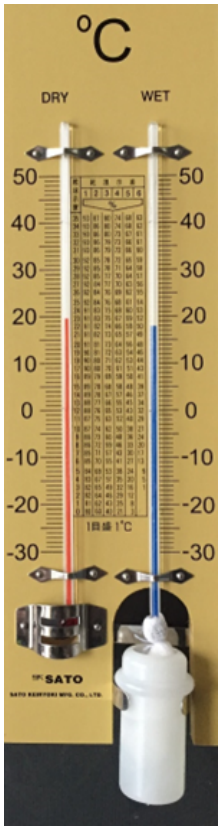
- Seal the oven: Close the smokehouse doors and oven dampers to provide a closed system and prevent moisture loss.

- Add humidity:
  - Place one or more shallow, wide pans of hot water in the oven to increase the humidity in the system. Conduct a test run to determine whether the water evaporates.
  - Injecting steam or a fine water mist into the oven can also add humidity.

The use of a humidity sensor or the use of wet bulb and dry bulb thermometers (to measure relative humidity) would enable the operator to determine whether adequate humidity is being applied for either measure

In order to ensure that adequate humidity is attained, the establishment should monitor the humidity throughout the lethality treatment. The process should be monitored using wet and dry bulb thermometers (used to determine relative humidity) or a humidity sensor.

A basic wet bulb thermometer can be prepared by fitting a wet, moisture-wicking cloth around a dry bulb thermometer. To maintain a wet cloth during the process, submerse an end of the cloth in a water supply. The cloth must remain wet during the entire lethality treatment especially if smoke is applied. The establishment should inspect the wet bulb sock prior to thermal processing, and the sock should be changed as necessary depending on its condition.



The use of a wet bulb thermometer is especially important for production at altitudes between 3,000 to 7,000 feet or areas of low humidity. Processing failures in the manufacture of jerky have occurred in establishments in New Mexico located between these altitudes (Eidson et al, 2000). Establishments located at higher altitudes will generally have a lower atmospheric pressure. This lower pressure leads to lower boiling points and faster evaporation from the product surface, which can lead to undesirable evaporative cooling and drying of the product surface. Furthermore, the relative humidity can be less at the higher altitude because of the lower air pressure (if the temperature at sea level and the high altitude is the same). As a result, at higher altitudes, the amount of moisture added to the smokehouse chamber necessary to achieve a given log reduction of bacteria may need to be increased to account for lower levels of humidity in the ambient (or room) air. Relative humidity in the ambient air will have an effect on the relative humidity in the smokehouse chamber, particularly when humidity is maintained by sealing the oven, because heat in the smokehouses is typically provided by heating ambient air that is passed over electrically heated or steam-heated coils.

For this reason, all establishments should also consider variability in relative humidity in the ambient air throughout different times of year.

Establishments will need to adjust the amount of humidity added to the smokehouse chamber to account for changes in humidity in the ambient air at high altitudes or during dry months. These adjustments should be made on a case-by-case basis as part of the initial design of the system to ensure that the humidity in the actual process matches the level in the scientific support.

FSIS recommends that establishments monitor relative humidity using wet and dry bulb thermometers or a humidity sensor with every lot or batch of product although FSIS does not require this monitoring frequency. Establishments have flexibility in how they address humidity in their HACCP systems. If relative humidity is addressed as part of a critical control point (CCP), the establishment is required to list the critical limits per 9 CFR 417.2(c)(3) and list and support the monitoring procedures and frequencies chosen for each CCP to ensure compliance with the critical limits per 9 CFR 417.2(c)(4) and 9 CFR 417.5(a)(2).

Furthermore, per 9 CFR 417.4(a)(2), establishments are required to calibrate process-monitoring instruments as part of ongoing verification activities and, per 417.5(a)(2), are required to support their verification procedures and frequencies of those procedures. If relative humidity is addressed in a prerequisite program, and the establishment determines that the implementation of that program results in potential hazards being not reasonably likely to occur, then it must have supported documentation for the decisions made in the hazard analysis per 9 CFR 417.5(a)(1).

NOTE: Accurate recordkeeping documenting the implementation of the critical operational parameters is critical to support the fact that safe products are produced. Inadequate or inaccurate recordkeeping (e.g., data entry error or unclear monitoring records) has contributed to jerky product recalls in the past, particularly when such records were associated with a lack of information regarding the implementation of all of the critical operational parameters for each batch or lot produced.

Often the owner's manual for humidity recorders recommends calibration on an annual basis. Establishments should follow the manual's instructions for calibration. Establishments may calibrate by comparing the temperature readouts from the microprocessor to the temperature and time plotted on the recorder charts to check for accuracy. For this procedure, FSIS recommends that the establishment calibrate the microprocessor controls before use and show that the calibration is accurate. This procedure can be performed "in-house" in a few simple steps:

1. The wet bulb and dry bulb probes can be placed in a bucket of hot water along with a National Institute of standards and Technology (NIST) reference thermometer. Some establishments use a small propane burner to maintain the water at a constant temperature.
2. The NIST thermometer represents the known temperature standard, and the establishment can compare the wet and dry bulb probe readings on the microprocessor to the NIST device to verify accuracy of the probes.
3. Once the probe readings are verified on the microprocessor as being accurate, the temperature reading on the microprocessor can be compared to the chart recorder temperature. The chart recorder is then adjusted (if needed) to the microprocessor reading.

These procedures for calibrating humidity recorders are provided as guidance to establishments; other procedures may be used, provided the establishment maintains support for the method chosen.

Step 6

Drying: is the process during which water (moisture) is removed from the product. After the lethality treatment, jerky is dried to meet a water activity level sufficient to prevent the growth of microorganisms, especially toxigenic microorganisms such as *Staphylococcus aureus*.

Jerky is a shelf-stable product (and consumers expect it to be shelf stable). After drying is complete, the establishment should monitor or verify the water activity to demonstrate that the product has attained shelf stability in accordance with the scientific support. FSIS does not have a standard of identity for jerky in its regulations. However, jerky has historically been dried to an MPR of 0.75:1 or below as described in the *FSIS Food Standards and Labeling Policy Book*. FSIS is aware that some manufacturers rely upon the MPR, rather than water activity, for determining whether their process adequately dries the jerky to produce a shelf stable product. ***MPR is an inappropriate indicator of shelf-stability***. ***Water activity (also referred to as a_w), measured by an instrument such as a water activity meter, is the more appropriate indicator to verify jerky is properly dried for food safety.*** This is because water activity is a better measure of available water (or water that is not bound by other components) for microbial growth than is MPR. Minimizing available water (e.g., achieving a sufficiently low water activity) is necessary to achieve shelf stability, provided measures are taken to address mold growth. Such measures to prevent mold growth may include using short inventory pull dates, low pH, antimycotics, coatings, packaging, or any combination of these measures.

Note: A product cannot be labeled as "jerky" just because it meets the MPR of 0.75:1. In order to label a product "jerky" it must be shelf stable. Establishments should use water activity to demonstrate that the product has attained the critical limit for shelf-stability.

To achieve a shelf-stable product, a water activity critical limit of 0.85 or lower should be targeted for products stored in an aerobic or oxygen containing environment such as in ambient air, provided the establishment takes steps to prevent mold growth on the finished product. If the product is vacuum packaged in an oxygen impervious packaging (creating an anaerobic environment where no oxygen is present), then the water activity critical limit can be 0.91 or lower. These limits are based on the growth limits for *Staphylococcus aureus* with and without oxygen present (ICMSF, 1996) and FSIS' definition of shelf-stability.

According to the International Commission on Microbiological Specifications for Foods (ICMSF), the water activity limit for *Staphylococcus aureus* growth is 0.83 under aerobic conditions and 0.90 under anaerobic conditions. However, as noted in one of the footnotes in the guidance document, this criterion is based on optimal conditions. FSIS recognizes that most jerky type products have other intrinsic factors, such as sodium nitrite, indigenous microflora, and salt concentration, that would also act as barriers to *Staphylococcus aureus* growth. By considering these factors, FSIS recommends an upper limit of 0.85 under aerobic conditions or 0.91 under anaerobic conditions.

Establishments that choose to use these limits as support for the shelf-stability of their product may cite this guideline as scientific support for these limits and are not required to provide additional scientific support. Establishments may be able to support other water activity critical limits, provided scientific support is available to support the decision-making. The establishment needs to achieve the water activity of the finished product identified in its scientific support.

NOTE: Vacuum packaged products with a water activity level > 0.85 and ≤ 0.91 should be kept refrigerated once the package is opened because the product would no longer be considered shelf-stable once it is exposed to oxygen.

Lack of shelf-stability once the product is exposed to oxygen is mainly a concern for products that would not be consumed within a single serving as these products are not likely to be vacuum packaged by the consumer between servings. Therefore, unless the establishment has support that the product is likely to be consumed in a single serving, vacuum packaged products with a water activity in the range of > 0.85 and ≤ 0.91 should be labeled with a statement such as "Refrigerate After Opening" (as described in 9 CFR 317.2(k)).

Finally, it should be noted that although the establishment may control the water activity level of a product to achieve shelf-stability, controlling water activity alone would not be sufficient to assure the safety of the product. Drying the product does not necessarily result in an adequate reduction of Salmonella organisms because the pathogen can be resistant to drying. For this reason, the establishment should use a validated lethality treatment, as described in **Step 5 – Lethality treatment.**

Step 7
Post-drying heat step: A post-drying heat step may be added to increase the level of pathogen reduction beyond that achieved by heating alone.

This step may be needed for processes that do not result in an adequate reduction of *Salmonella* through the initial heating process. Adding a post-drying heat step has the potential to reduce *Salmonella* levels by approximately 2-$\log_{10}$'s from the level of reduction achieved during the initial heat step. One example of a post-drying heat step that has been found to reduce *Salmonella* levels by approximately 2-$\log_{10}$'s is to heat the dried product in a 275°F oven for 10 minutes (Harrison et al., 2001).

Step 8
Handling: Product is often handled after the lethality and drying steps and prior to/during packaging.

Establishments should control their processes to prevent contamination of product with pathogens from handling after the lethality and drying steps. Such controls should include ensuring that cross-contamination of product is minimized before packaging and ensuring that the product is packaged in such a way that cross-contamination of product post-packaging is also minimized (e.g., with a good seal to maintain package integrity throughout storage, shipment, and display).

Preventing cross-contamination is important even if the product is dried to a water activity such that the product is considered shelf-stable. Pathogens may still be able to survive on the product if it becomes contaminated during handling.

Cross-contamination of product can occur from situations such as the following:

- Using the same equipment (e.g., preparation tables, scales, or packaging equipment) for both raw and cooked products without completely cleaning and sanitizing the equipment between production lots.
- Placing cooked product on the same surface (e.g., cutting table) as raw product without completely cleaning and sanitizing the surface before reuse.
- Using the same utensils or containers (e.g., scoops or buckets) for both raw and cooked product without completely cleaning and sanitizing the surface before reuse.
- Condensation, aerosolization, or dusting of dry ingredients into the processing environment.

Employee movement between raw and ready-to-eat areas without hand-washing or garment changing (as needed).

The establishment is required to maintain sanitation in the RTE area to ensure that food contact surfaces are free of contamination from *Lm* and other pathogens, such as *Salmonella,* in accordance with 9 CFR part 430. The establishment is required to develop and implement Sanitation SOPs (9 CFR 416) to ensure that contamination and adulteration of the product is prevented after the lethality treatment.

Further guidance on post-processing handling and sanitation for ready-to-eat products including jerky is in the *Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products* and the *Compliance Guidelines to Control Listeria monocytogenes in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products*.

Scientific Support Available for Jerky Processing

Establishments have numerous options for the types of scientific documents that can be used to support that the process achieves adequate lethality. Examples of the scientific support available to help develop a safe jerky process and product are discussed below, along with considerations for each type of support. Product sampling results, based on historical data alone, should not be used as scientific support for a jerky process because they do not provide information on the level of pathogen reduction that is achieved for the process.

Compliance Guidelines

FSIS has issued a number of different compliance guidelines that have application to jerky processing. It is important to note that, while FSIS considers these documents to be guidelines, if followed precisely, they are considered as validated process schedules because the guidelines contain processing methods already accepted by the Agency as effective in safely producing meat and poultry products. Some considerations for each of these compliance guidelines are outlined on the following pages.

- **FSIS Appendix A: Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat and Poultry Products**

For meat jerky, use of the product time-temperature combinations provided in Appendix A, including those temperatures above 158°F in which the time for the desired lethality is instantaneous, should help to ensure the safety of the product. These time temperature combinations are based on experiments that were done with products without added salt or sugar. Added salt, sugar, or other substances that reduce water activity will increase the heat resistance of bacteria in a product. However, time and experience have shown that the time-temperature combinations in the lethality compliance guidelines have been sufficient to produce safe products even with both salt and sugar added, but the humidity during heating is a critical factor.

The humidity options in Appendix A that are applicable to jerky processing are:

- Heating jerky to a minimum internal temperature of 145°F (62.8 °C) in an oven maintained at any temperature if the relative humidity of the oven is maintained either by continuously introducing steam for 50% of the cooking time or by use of a sealed oven for over 50% of the cooking time, or if the relative humidity of the oven is maintained at 90 percent or above for at least 25% of the total cooking time but in no case less than 1 hour; or

- Heating jerky in an oven maintained at any temperature that will satisfy the internal temperature and time combinations from the chart provided in Appendix A if the relative humidity of the oven is maintained at 90% or above for at least 25% of the total cooking time but in no case less than 1 hour. The relative humidity may be achieved by use of steam injection or sealed ovens capable of producing and maintaining the required relative humidity.

In order to introduce humidity by continuously introducing steam or sealing the oven, establishments should:

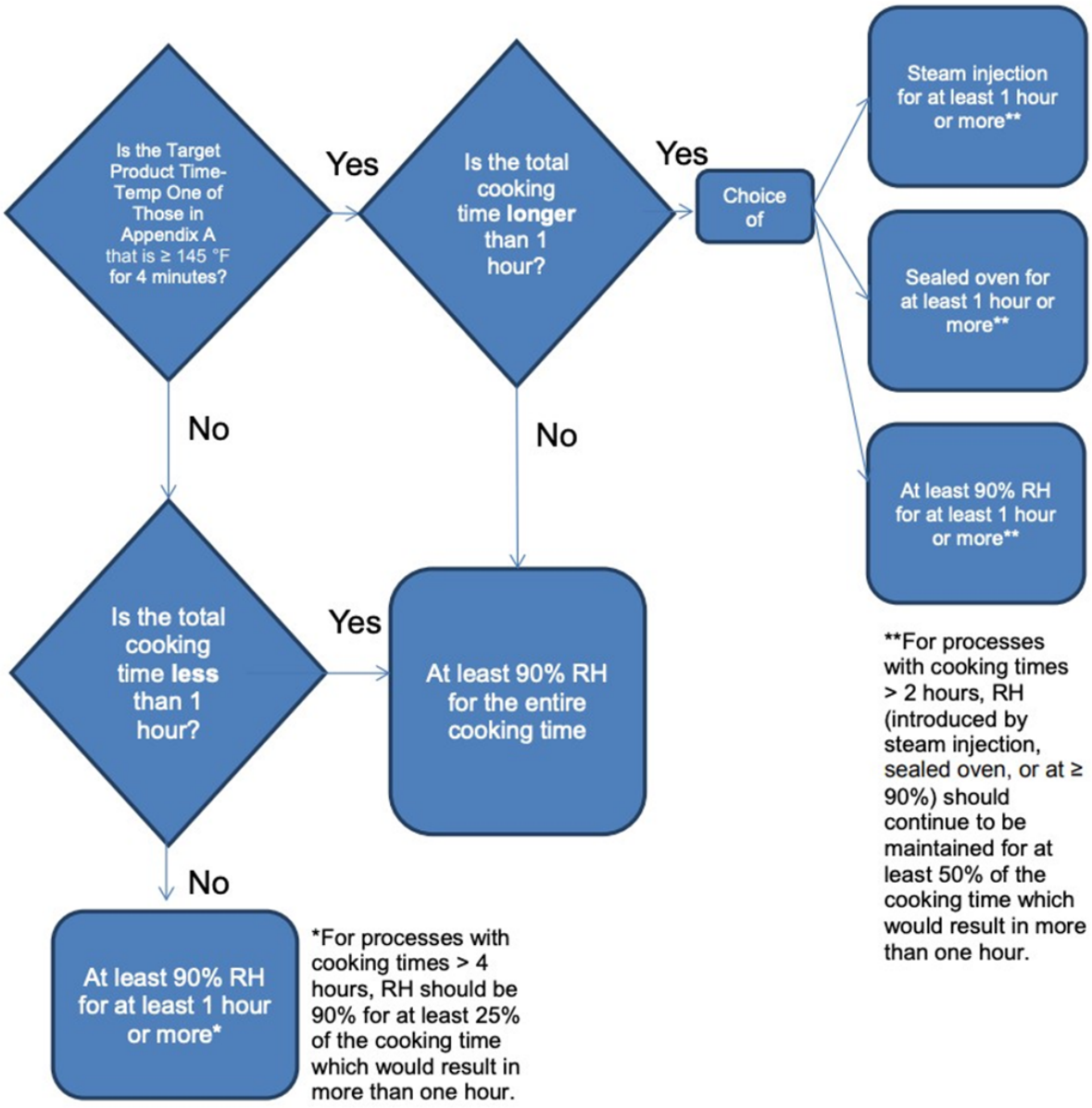
Cook the jerky product to an internal temperature-time combination of equal to or greater than 145°F for 4 minutes. It is important to note again that the temperature values in Appendix A correspond to product temperatures, not oven temperatures. If an establishment cooks its jerky product to an internal temperature-time combination of less than 145°F for 4 minutes, then the relative humidity should be maintained at 90% or above for at least one hour or 25% of the cooking time (whichever is longer).

AND

Cook the jerky product for at least one hour and in some cases longer. Cooking time should never be less than one hour. Appendix A states that the relative humidity of the oven should be maintained either by continuously introducing steam for 50% of the cooking time or by use of a sealed oven for over 50% of the cooking time, but in no case less than one hour. This means that these options should be applied for at least one hour or 50% of the cooking time - whichever is longer. If an establishment cannot apply these humidity options for equal to or more than one hour (for example because the lethality treatment takes less than one hour), then the humidity of the oven should be maintained at 90% or above throughout the lethality treatment (not just during the time and temperature combination in Appendix A) with the exception of a surface preparation step.

Establishments can use the flow chart on the next page to determine the humidity options when using the Appendix A guidelines as scientific support for a jerky process. The times listed in the chart do not include any surface preparation or color setting step where humidity is not introduced. So, if a process includes a 30-minute surface preparation or color setting step, the total cooking time would need to be 90 minutes in order to continuously introduce steam or seal the oven for at least 1 hour (or 50% or the cooking time, whichever is longer) as specified in Appendix A.

Flow Chart to Identify Humidity Options when Using the *Appendix A* Guidelines as Scientific Support For a Jerky Process



**For processes with cooking times > 2 hours, RH (introduced by steam injection, sealed oven, or at ≥ 90%) should continue to be maintained for at least 50% of the cooking time which would result in more than one hour.

*For processes with cooking times > 4 hours, RH should be 90% for at least 25% of the cooking time which would result in more than one hour.

Specific guidance for using sealed oven to introduce humidity

In order to support that the sealed oven option for introducing humidity is being implemented consistent with the Appendix A guidelines, establishments should:

1) **Maintain documentation that supports that the jerky product achieves an internal product time-temperature combination from Appendix A of equal to or greater than 145°F for 4 minutes.** Such documentation could include:

   a. Records of internal product temperature and time held at that temperature (if applicable); or
   b. Records of the oven or smokehouse temperature in place of product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support;

2) **Maintain documentation that supports that the oven dampers are closed for at least one hour or 50% of the cooking time - whichever is longer.** Such documentation could include:

   a. Records from a computerized system that contains the time at which the oven dampers were open and were closed; or
   b. Records of the times at which the oven dampers were open and closed made manually; or
   c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time - whichever is longer (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) with correlation data supporting a relationship between the relative humidity level in the oven and the time at which the oven dampers were open and closed (see page 91 for guidance on minimum levels of relative humidity/wet and dry bulb temperatures to achieve);

3) **Maintain documentation that supports that when the oven dampers are closed, humidity is maintained in the ovens.** Such documentation could include:

   a. Records demonstrating the relative humidity level in the ovens is maintained (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or
   b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while the dampers are closed; and

4) **Have an ongoing procedure for checking that the dampers are properly working along with a maintenance program to periodically monitor that the seals are intact and functional, and that when the oven dampers are closed, a tight seal is obtained.** A tight seal is one in which a significant loss of humidity is prevented. FSIS acknowledges that a small amount of smoke or vapors might be seen escaping the smokehouse even when a tight seal is obtained. Establishments should also consider whether there are other openings, particularly in older smokehouses, such as drain valves or air intake valves, that need to be closed in order to ensure that a seal is obtained. Finally, some older ovens may have a stack or other opening that cannot be closed. For those establishments with older ovens that cannot be completely closed, the sealed oven method should not be used. However, the establishment may choose to close what they are able to and add moisture in the system either by continuously introducing steam or another validated method.

Specific guidance for using continuously injecting steam to introduce humidity

In order to support that the continuously introducing steam option for introducing humidity is being implemented consistent with the Appendix A guidelines, establishments should:

1. **Maintain documentation that supports that the jerky product achieves an internal product time-temperature combination from Appendix A of equal to or greater than 145°F for 4 minutes.** Such documentation could include:
    a. Records of internal product temperature and time held at that temperature (if applicable); or
    b. Records of the oven or smokehouse temperature in place of product temperature provide that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support;

2. **Maintain documentation that supports that steam is continuously introduced for at least one hour or 50% of the cooking time - whichever is longer.** Such documentation could include:
    a. Records from a computerized system that contains the time at which the steam is turned on and off: or
    b. Records of the times at which the steam is turned on and off made manually; or
    c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time - whichever is longer (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) along with correlation data supporting a relationship between the relative humidity level in the oven and the time steam is turned on or a letter from the manufacturer stating that when the relative humidity is rising it is because of live steam injection (see page for guidance on minimum levels of relative humidity/wet and dry bulb temperatures to achieve);

3. **Maintain documentation that supports that when steam is injected, humidity is maintained in the ovens.** Such documentation could include:
    a. Records demonstrating the relative humidity level in the ovens is maintained (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or
    b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while steam is being injected.

NOTE: The "continuously introducing steam" option refers to the use of live steam, although it may also apply to establishments that spray water onto hot heating elements, which creates steam that in turn produces humidity in the smokehouse. "Continuous" does not mean that the steam is injected for at least one hour during one stage; rather, steam could be injected during stages or time intervals during the lethality (cooking) treatment if the total amount of time the steam is introduced adds up to at least one hour or 50% of the cooking time - whichever is longer. Furthermore, the establishment may turn the steam on and off throughout the cooking time when the target humidity is reached.

It is important that establishments maintain and monitor the humidity levels in the oven. Establishments using either the sealed oven or continuously introducing steam options for introducing humidity can support that humidity is being introduced consistent with Appendix A following the guidance on the previous two pages. Establishments do not need to achieve a specific humidity level in the oven if Appendix A is used as the scientific support.

However, FSIS recommends that establishments that monitor relative humidity try to achieve a wet bulb temperature of at least 125-130°F for 1 hour or more along with a corresponding dry bulb temperature needed to achieve at least 27-32% relative humidity or more. FSIS is making this recommendation based on expert opinion and a review of the literature that suggests that the wet bulb temperature should reach at least 125-130°F for an hour or more during the lethality process, and that at least 27-32% relative humidity should be present to ensure that adequate lethality is attained. Wet bulb temperature is generally a strong indicator of product surface temperature early in the process. Therefore, maintaining the wet bulb temperature at a high enough level to cause lethality (125-130°F) is recommended (Buege, 2006a; Harper, 2009).

Although establishments using either the sealed oven or continuously introducing steam option for introducing humidity are not required to achieve a specific humidity level, the values provided in this guidance document are listed so that establishments have further guidance concerning minimum levels to achieve as recommended by experts at FSIS. Establishments should be aware that achieving a low wet bulb temperature for a short time (i.e., below 125-130°F for less than one hour) or low relative humidity for a short time (below 27-32% for less than one hour) may indicate that the jerky process may not be achieving sufficient lethality at the product surface which could represent a vulnerability in the establishment's process to control food safety hazards of concern.

NOTE: Achieving a wet bulb temperature of at least 125-130°F and at least 27-32% relative humidity for 1 hour or more is not adequate on its own to support that the process is being implemented consistently with Appendix A. Rather, establishments should ensure that all critical operational parameters from Appendix A are met (i.e., product time-temperature combination and humidity). Guidance for introducing humidity for the options that require less than 90% relative humidity (continuously introducing steam or sealing the oven) is provided on the previous two pages.

➢ **FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks**

To support the safe production of meat jerky, establishments can use the time temperature combinations provided in *the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks*. Humidity should be considered when using this time-temperature table; therefore, the same options for humidity in Appendix A should be used with this guidance. In addition, the same recommendations regarding maintaining and monitoring humidity for Appendix A apply for establishments that use the *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks* for time-temperature combinations.

➢ **Time-Temperature Tables For Cooking Ready-To-Eat Poultry Products**

To support the safe production of poultry jerky, establishments can use the minimum internal temperatures listed in Appendix A of 160°F for uncured poultry or 155°F for cured and smoked poultry. Establishments should not use the time and temperature combinations provided in Appendix A for cooked beef, roast beef, and corned beef for poultry jerky.

NOTE: If highly pathogenic avian influenza (HPAI) virus H5N1 is identified as a hazard reasonably likely to occur, cured and smoked poultry should be cooked to at least 158°F or a time and temperature combination that achieves a 7-log10 reduction of *Salmonella.*

The required reduction of *Salmonella* can also be achieved by using one of the time temperature combinations listed in the *Time-Temperature Tables for Cooking Ready-to Eat Poultry Products* (Time-Temperature Tables). As stated in the Time-Temperature Tables guidance document, the tables reflect newer data on the temperatures needed to control *Salmonella* in poultry than the data used in developing Appendix A.

The Agency has not rescinded the guidance for poultry in Appendix A but an establishment needs to take into account the data in the Time-Temperature Tables regarding increased time at a specific temperature to achieve a given level of reduction of *Salmonella*. An establishment that utilizes Appendix A within its process should conduct on-going verification to confirm that the process is being effectively controlled. If an establishment is using Appendix A, and the Agency collects an RTE sample that is positive for *Salmonella*, the establishment would be required under 9 CFR 417.3(b), among other things, to support its decision within its hazard analysis.

Regardless of which time-temperature combinations an establishment uses, humidity during heating is a critical factor. As with meat jerky, the time-temperature combinations would be sufficient to produce safe products with both salt and sugar additives if the processor uses the humidity parameters applicable to beef as described in Appendix A. The same recommendations regarding maintaining and monitoring humidity for Appendix A apply for establishments that use the Time-Temperature Tables.

Validated Beef Jerky Process Example							
Step	**Type**	**Time Minutes**	**Dry Bulb**	**Wet Bulb**	**Humidity %**	**Damper**	**Smoke**
1	Reddening	30	49°C (120°F)	0°C (32°F)	0	Open	Off
2	Surface Prep	30	60°C (140°F)	0°C (32°F)	0	Open	Off
3	Cook	20	71°C (160°F)	69°C (156°F)	90	Open →Closed	Off
4	Smoke	30	54°C (130°F)	-4°C (25°F)	0	Open →Closed	On
5	Smoke/Cook	90	57°C (135°F)	10°C (50°F)	2	Open →Closed	On
6	Smoke/Cook	45	63°C (145°F)	49°C (120°F)	47	Open →Closed	On
7	Dry	30	68°C (155°F)	52°C (125°F)	42	Closed→Open	On

(Published by the American Association of Meat Processors. It takes into consideration an effective lethality step at high humidity before drying, use of wet and dry bulb readings for humidity control, and smoking for flavor after cooking, followed

Processes for which Appendix A is *not* appropriate as scientific support

Finally, although Appendix A is commonly used as scientific support for jerky processes, the time-temperature-humidity combinations cannot be applied in every scenario. For example, establishments should not use Appendix A:

- To support a process in which the drying step comes before the cooking step. Appendix A was not developed for such processes.
- To support a process that uses a home-style dehydrator. The humidity parameters in Appendix A cannot be maintained in a home-style dehydrator. Processes that can achieve an adequate reduction of *Salmonella* and *E. coli* O157:H7 using home-style dehydrators are described in studies by Borowski et al. (2009b), and Harrison et al. (2006).

Guideline For Validating Safe Curing of Meat & Poultry, Fermenting Sausages, Drying of Meat & Poultry

Prerequisites and Standard Operating Procedure(s) (SOPs)

- ☐ Most recent inspection reports indicate compliance with all regulations. Any pre-existing violations, which may result in biological, physical or chemical contamination of this product, have been corrected.
- ☐ A list of products approved by the regulatory authority, must be available on site at the retail establishment.
- ☐ All aspects of these operations must be conducted in an area specifically designated for this purpose. There must be an effective separation to prevent cross contamination between raw and cooked foods or cured and uncured foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in curing foods.
- ☐ If the same rooms and equipment are used for preparation and packaging, all process ware and food contact surfaces used for slicing of meat and poultry and placing in drying rooms or dehydrators shall be cleaned and sanitized before any finished product is packaged.
- ☐ The procedures for cleaning and sanitization must be accomplished according to parts 4-6 and 4-7 of the Food Code.
- ☐ Handling of products must be minimized and no bare hand contact with RTE foods.
- ☐ Employees assigned to conduct one or more of these specialized processes must demonstrate familiarity with these guidelines and the potential hazards associated with a specified process. A description of the training and course content provided to the employees must be available for review by the regulatory authority.

HACCP

- ☐ A HACCP plan and a variance are required for all of the following operations (curing, smoking (except for flavor only), fermenting, and drying). The following recommendations are provided to help process these foods safely. Reference and resource materials are available from local USDA extension offices, public libraries, college or university food or meat science departments, processing authorities, or other regulatory jurisdictions.
- ☐ The establishment shall facilitate the inspection and monitoring of the treatment process by providing appropriate time and temperature recording equipment.
- ☐ If cure mixes are blended on the premises instead of acquired pre-mixed, mixing must be carefully controlled by using calibrated weighing devices.
- ☐ The establishment shall record the time, temperature and other critical process parameters for each lot of product produced.
- ☐ The establishment shall have on file on site, a description of the current processing method for each product produced. The processing method description shall include a description of:
  a. Handling procedures for meat ingredients including maximum time and temperature exposures during thawing, trimming, curing, slicing, grinding, shredding, marinating, curing, and any other preparation steps or other applicable product factors;
  b. A procedure for identifying a product lot during processing, its lot identification codes, and how the finished product package codes can be identified with a specific production lot. The establishment shall divide production lots into one day time increments or less;
  c. Procedures used to comply with the treatment process; of the treated product; and
  d. The equipment and procedures used for measuring and recording time and temperature required by the treatment used by the establishment. The measuring devices shall be both readable and accurate within plus or minus 3°F and 1 minute.
  e. For shelf stable products, the procedures and control program to ensure the product meets the requirements for shelf stability.

Curing

- ☐ Purchase of prepared cure mixes; or
- ☐ If cure mixes are blended on the premises instead of acquired pre-mixed, mixing must be carefully controlled by using calibrated weighing devices.
- ☐ Cure ingredients must be stored in a dry location. Cure must be discarded if the package is wet or appears to have been wetted.
- ☐ Thawing must be monitored and controlled to ensure thoroughness and to prevent temperature abuse. Improperly thawed meat could cause insufficient cure penetration. Temperature abuse can cause spoilage or growth of pathogens.
- ☐ Meat and poultry must be fresh. Curing may not be used to salvage meat or poultry that has excessive bacterial growth or spoilage.
- ☐ A formulation and preparation procedure must be documented. All equipment and utensils must be cleaned and sanitized.
- ☐ Pieces must be prepared to uniform sizes to ensure uniform cure penetration. This is extremely critical for dry and immersion curing.
- ☐ Calibrated scales must be used to weigh ingredients.
- ☐ A schedule or recipe must be established for determining the exact amount of curing formulation to be used for a specified weight of meat or meat mixture.
- ☐ A schedule or recipe must be established for determining the exact amount of curing formulation to be used for a specified weight of meat or meat mixture.
- ☐ Methods and procedures must be strictly controlled to ensure uniform cure.
- ☐ Mixing of curing formulation with comminuted ingredients must be controlled and monitored.
- ☐ All surfaces of meat must be rotated and rubbed at intervals of sufficient frequency to ensure cure penetration when a dry curing method is used.
- ☐ Immersion curing requires periodic mixing of the batch to facilitate uniform curing.
- ☐ The application of salt during dry curing of muscle cuts requires that the temperature of the product be strictly controlled between 1.7°C (35°F) and 7.2°C (45°F). The lower temperature is set to limit microbial growth and the upper temperature is set for the purpose of ensuring cure penetration.
- ☐ Refer to USDA regulations 9 CFR 318.10(c)(3)(iv) for specific details on dry curing.
- ☐ Curing solutions must be discarded daily unless they remain with the same batch of product during its entire curing process.
- ☐ Injection needles must be inspected for plugging when stitch pumping or artery pumping of muscle cuts is performed.
- ☐ Sanitary casings must be provided for sausage, chub or loaf forming.
- ☐ Casings may not be stripped for reuse in forming additional chubs or sausages from batch to batch.
- ☐ Hot curing of bacon bellies, hams, or any other products must be performed at >49°C (120°F) as specified in 9 CFR 318.

Smoking

- ☐ When smokehouses are initially installed or structurally modified, calibration of product heating characteristics must be ascertained by competent food technologists. Tests should be run with a full range of anticipated product loading. Verification of even airflow and moisture should be recorded in operational records of the smokehouse for these various loads.
- ☐ Procedures for delivering the appropriate thermal treatment of cooked meats in conformance with The Food Code must be developed and used. (Also see 9 CFR § 318.17 and § 318.23 for USDA requirements for meat products.) A minimum of 165°F (73.9°C) should be used for cured poultry products.
- ☐ Cooking equipment that provides even temperature control of the heating medium must be used.

- ☐ Products must be adequately separated to prevent overlap in the cooking media whether immersed in hot water, sprayed with hot water, steamed, or oven heated.
- ☐ Calibrated temperature measuring devices must be used for determining internal product temperatures.
- ☐ Temperature measuring device probes must be sanitized to prevent contaminating products when internal temperatures are measured.
- ☐ Calibrated temperature measuring devices must be used for measuring temperatures of the heating medium.
- ☐ Raw products must be separated from cooked products.
- ☐ Time/temperature parameters of the cooking process must be monitored and recorded. In some processes, the heating medium temperature should also be monitored.
- ☐ Cooling must be done in accordance with recommendations in the Food Code or under a variance. The USDA Cooling Guideline, FSIS Directive 7110.3 for special procedures for cured products provides specific guidance.
- ☐ Written cooling procedures must be established.
- ☐ Chill water used in water sprays or immersion chilling which is in direct contact with products in casings or products cooked in an impervious package must be properly chlorinated.
- ☐ Chill water temperature must be monitored and controlled.
- ☐ Chill water may not be reused until properly chlorinated. Reclaimed chill water must be discarded daily.
- ☐ Product must be placed in a manner that allows chilled water or air to uniformly contact the product for assurance of uniform cooling.
- ☐ Internal temperatures must be monitored during cooling by using calibrated temperature measuring devices.
- ☐ Adequate cooling medium circulation must be maintained and monitored.
- ☐ Temperatures of the cooling medium must be monitored and recorded in accordance with a written procedure.
- ☐ Handling of product must be minimized during cooling, peeling of casing, and packaging. Sanitary gloves must be used in these procedures.

Fermenting and Drying

- ☐ Temperature and time must be controlled and logs must be maintained that record the monitoring of this process.
- ☐ Humidity must be controlled by use of a humidistat. Monitoring of the process must be recorded in a written log.
- ☐ Product must be kept separated to allow adequate air circulation during the process.
- ☐ Use of an active and pure culture must be ensured to effect a rapid pH drop of the product. Use of commercially produced culture is necessary and the culture must be used according to the manufacturer's instructions.
- ☐ Determination of the pH of fermented sausages at the end of the fermentation cycle must be recorded.
- ☐ Handling of products must be minimized and only done with sanitary gloves or sanitized utensils.
- ☐ Dry (unfermented) products may not be hot smoked until the curing and drying procedures are completed.
- ☐ Semi-dry fermented sausage must be heated after fermentation to a time/temperature sufficient to control growth of pathogenic and spoilage organisms of concern.

Packaging Juice

Packaging Juice

Regulations

¶ 3-502-11 (G) Specialized Process – Other Methods

§ 3-404.11 Treating Packaged Juice

Juice packaged in a food establishment shall be:

(A) Treated under a HACCP plan as specified in ¶¶ 8-201.12(B) – (E) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; or

(B) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance:

(1) As specified under § 3-602.11, and

(2) As specified in 21 CFR ¶ 101.17(g) with the phrase, "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."

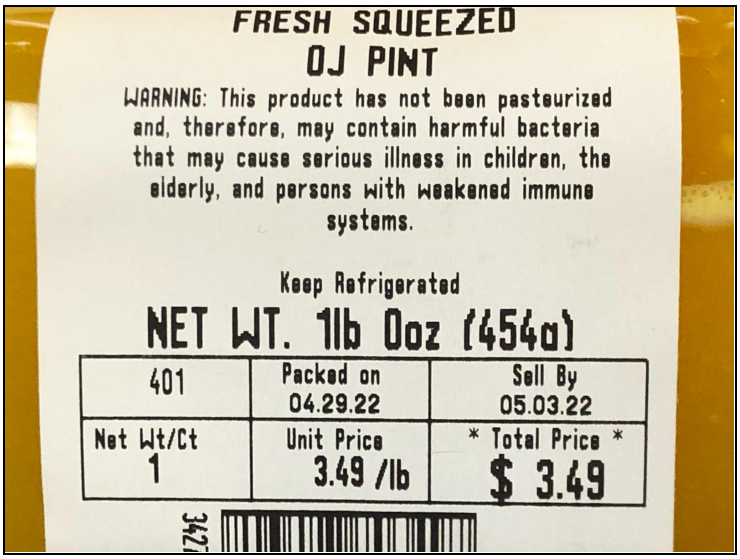
Juice – Prepackaged and Treated On-site - Variance and HACCP Plan Required

Juice packaged in a food establishment, treated to attain a 5-log reduction of the most resistant microorganism of public health significance that is likely to occur in the juice must obtain a variance and treatment must be conducted under an approved HACCP plan as specified in ¶¶ 8-201.14(B) - (E).

Juice - Prepackaged On-site – No Treatment – Warning Label Only

¶ 3-304.11 (B) If the retail establishment packages the unpasteurized juice on site but chooses to place a consumer warning label on the package in lieu of treating the juice to achieve a 5-log reduction of the most resistant microorganism of public health significance, neither a variance, nor a HACCP plan is required.

The package, as specified in 21 CFR 101.17(g) must be labeled with the phrase, "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."



Juice - Not Packaged, Fresh Squeezed On-site - No Variance, HACCP Plan, or Warning Label Required

Unpackaged juice that is squeezed freshly on site (e.g., by the glass or in small batches at juice bars) does not require a variance, a HACCP plan, a warning statement, or other consumer advisory.

Note: As explained in the 2017 FDA Food Code, Annex 3, Labeling for Juice: Unpackaged juice (glasses of juice prepared at a juice bar, for example) does not require the 5-log reduction, a warning statement, or other consumer advisory (juice is not an animal food and therefore not covered by section 3-603.11 when prepared and served at retail). Also, since the juice is usually served by the glass or in small batches, compared to a commercial juice processor the risk of using "drops" and damaged fruits or vegetables is less likely at retail because of buyer specifications that provide higher quality produce, meaning that fruits for juicing are less likely to be of a lower quality or damaged.

Unpasteurized Juice Not Allowed in Establishments that Cater to Highly Susceptible Populations

Under ¶¶ 3-801.11 (A) (2) prepackaged unpasteurized juice, may not be offered for consumption in an establishment that caters to highly susceptible populations (HSP), such as hospitals, nursing homes, preschools. In addition, under ¶¶ 3-801.11 (A) (3) unpackaged, fresh squeezed juice (e.g., by the glass) prepared on the premises may not be offered for sale. They may serve only pasteurized juice.

Note: According to the 2017 FDA Food Code, Annex 3, Labeling for Juice, *for juice only*, this population includes children who are age 9 or less and receive food in a school, day care setting, or similar facility that provides custodial care.

Public Health Rationale

The use of contaminated produce in the preparation of raw juices has been linked to a number of foodborne illness outbreaks. Acid juices have most commonly been implicated. Potentially hazardous pathogens for acidic juices (pH 4.6 or less) include enteric bacterial pathogens, such as E. coli O157:H7, various *Salmonella* species, and the protozoan parasite *Cryptosporidium parvum*. These microorganisms inhabit the intestinal tracts of animals and are excreted through manure or feces. When animals are located in an area near crops, produce can become contaminated through direct contact with feces or indirectly through contaminated irrigation water or runoff. Other possible contaminants of acidic juices are organisms that are ubiquitous in the environment, such as *Listeria monocytogene*s. Low acid juices, like vegetable juices, have the potential to cause foodborne illness too because they can produce toxins of non-proteolytic and proteolytic strains of *Clostridium botulinum*. Raw fruits and vegetables that are fresh-squeezed and packaged on-site in a retail establishment are subject to regulatory requirements because there is no pasteurization step to help with the destruction of these harmful microorganisms or their toxins.

Key Terms

Culled means separation of damaged fruit from undamaged fruit.

Fallen fruit means fruit that has fallen naturally from the tree to the ground in an orchard. It does not include mechanically harvested fruit, which is obtained by shaking the tree and collecting the fruit from the ground with appropriate mechanical machinery; also called grounders, windfall fruit, or drops.

Food processing plant means a commercial operation that manufactures, packages, labels, or stores food for human consumption, and provides FOOD for sale or distribution to other business entities such as food processing plants or food establishments. Food processing plant does not include a food establishment.

Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or purée. Juice does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as beverages or ingredients of beverages.

Packaged means bottled, canned, cartoned, bagged, or wrapped, whether packages in a food establishment or a food processing plant. Packaged **does not** include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.

Pasteurization means a heat treatment sufficient to destroy vegetative cells of pathogens.

Retail Establishment means an operation that provides juice directly to consumers and does not sell or distribute juice to other businesses. The term "provides" includes storing, preparing, packaging, serving, and selling juice.

Note: If a retail establishment produces their own juice and sells it at a roadside stand directly to the consumer, and also sells or distributes some of that juice to other businesses (to sell or resell), the establishment's juice must be processed under a HACCP system because they are not providing all of the juice directly to consumers. Also, if the retailer hires someone to make juice from their fruit and sell the juice at their roadside stand, the processor who makes the for the retailer is subject to the regulation because the processor is not selling the juice directly to consumers.

Turbidity is high cloudiness or haziness caused by individual particles in juice.

Controls and Guidelines

Retail establishments may squeeze and package unpasteurized juice on-site without a variance or a HACCP plan. However, if they choose to package unpasteurized, or untreated juice they must meet strict labeling requirements, which includes a consumer warning statement.

For retailers that choose to treat packaged juice using a method that will attain a 5-log reduction of the pathogen of most concern, they must submit a variance request to the regulatory authority. As part of that request, they must also submit a HACCP plan that includes a validated process for attaining the 5-log reduction.

There are several ways in which a 5-log reduction can be achieved:

1. **Pasteurization.**

   The time-temperature pasteurization process used in the 5-log reduction of the pathogen of concern must be from a process authority and validated as effective. Examples include:

   - Apple juice from fruit: 71°C [160°F] for 6 seconds for apple juice
   - Orange juice from fruit: 71°c [160°F] for 3 seconds

Although there are multiple methods for pasteurizing juice, two main methods are the Vat and the HTST (High Temperature/ Short Time) method. Under both methods the juice must reach certain temperatures and be held for a specific period of time in order to kill bacteria and harmful pathogens.

A. Vat or Batch (Low Temperature / Longer Time) Method of Pasteurizing Juice

1) Heat is applied to one large lot or batch.
2) The entire batch is held long enough to achieve 5-log reduction.
3) The juice is cooled after pasteurization.

The vat method of juice pasteurization is often used by small juice operators. With this pasteurization method, the product requires proper mixing and both the time and temperature of the juice treatment must be monitored to ensure that the process is achieving the 5-log pathogen reduction.

B. HTST (High Temperature/Short Time) Method of Pasteurizing Juice

1) The product flows over plate or tubular heat exchangers.
2) Heated product then flows through holding tubes.
3) The product is held for a specific time and temperature in the holding tubes.

With the HTST or continuous method of pasteurizing juice, large amounts of product can be heated and cooled quickly.

There are critical control points to monitor when pasteurizing juice. The following questions are recommended by the FDA when developing a HACCP plan. The following questions should be addressed when either Vat / Batch or HTST processes are being conducted:

1. Were the heating requirements met and continuously monitored during pasteurization?
2. Were the holding time requirements met and continuously monitored during pasteurization?
3. Are accurate charts and records kept?
4. Key questions to ask for HTST systems include:
5. Are visual checks of the timing pump periodically performed to ensure that it is delivering the proper flow rate?
6. Is the pasteurized juice discharged from the regenerator properly?
7. Is the holding tube properly constructed?

Pasteurized juices may be held at refrigerated temperatures to extend their shelf life, as not all spoilage organisms are destroyed.

2. **UV Treatment**

This method is expensive and may not be done at retail. The effectiveness of the UV treatment is affected by the turbidity of the juice. Juice that is high in color and solids transmits relatively little UV light.

3. **Surface Treatment (citrus fruits only)**

It is unlikely that pathogens will enter intact, sound fruit that is protected by the peel or rind. In the case of citrus fruits, surface treatments may be used to achieve the 5-log reduction. Citrus fruits are the only fruits that can use a surface treatment of the fruit rind to achieve the required 5-log reduction in pathogens of concern for packaged juice. The juice must be processed and packaged in one facility and certain other conditions must be met. The validated process often involves control measures such as washing the fruit in hot water, acid wash using roller brushes, application of chemical sanitizers, final potable rinse, and special extraction methods.

When implemented together, these control measures allowed specifically for citrus fruits have the cumulative effect of a 5-log reduction in the finished juice product.

Although there are many steps (control points) involved in the juice processing and packaging operation. The critical control points most often associated with packaged juice include, but are not limited to:

- Harvesting
- Culling
- Sorting
- Washing/brush washing
- Storage
- Filtration, screening
- Sanitizing
- Pasteurization/thermal process
- Storage after packaging (refrigeration)

Also, although there may be more critical limits associated with a given process, the main critical limits associated with packaged juice include, but are not limited to:

- Visual observations (for dirt, defects, foreign substances, mold, etc.).
- Pasteurization – time and temperature to attain a 5-log reduction
- Surface Disinfection – concentration(s) to attain a 5-log reduction
- Refrigeration – temperature

In addition, there are some general guidelines to follow that will help minimize the risk of contamination and spoilage of the finished product. They include, but are not limited to the following:

1. Manual harvesting of fruit involves contact with human hands, which increases the risk of foodborne illness. It is important that harvesters have access to hand washing facilities.
2. Using fruit that falls to the ground ("drops") increases the risk of microbial contamination. For example, if wild or domestic animals roam the area, fallen fruit may have contact with ground contaminated with fecal matter. Foreign materials such as twigs, leaves, stones, and insect and bird droppings can also increase the risk of contamination.
3. Transporting fruit in containers or boxes with mold, pieces of decayed fruit, or other foreign matter increases the risk of juice contamination.
4. Culling damaged produce is an extremely important step in preparing fruits and vegetables for juicing. It must be done to prevent contamination of the juice. Visually inspecting produce and removing foreign objects, washing, and culling blemished and damaged produce all increase the safety of the resulting juice. To prevent bacterial and fungal growth, it's critical to use only sound, mature fruit and vegetables for extracting juice and to use temperature control for extended storage.
5. Injured fruit whose outer protective epidermal barrier is damaged, bruised, or punctured allows entry of bacterial pathogens and fungi. Fluids released by injured fruit cells also provide nourishment to pathogens that can survive at refrigerated temperatures and multiply at non-refrigerated temperatures.
6. Sorting must be done carefully in juicing operations. Some establishments dump harvested fruit into the mill or juicer without sorting or culling. This increases the risk of bacterial and patulin contamination. Patulin is heat stable and not eliminated by pasteurization.
7. All surfaces that have contact with the fruit, including processing equipment, are potential sources of contamination. Food workers that handle the fruit and operate the equipment can also introduce contamination, especially fecal-oral route pathogens.
8. Failure to implement the time/temperature heating process or other control from the process authority will increase the risk of contamination.
9. Packaging materials used to hold juice are potential sources of contamination, so they must be stored and handled in a sanitary manner.
10. Juice is extracted and then filtered to remove extraneous materials (e.g., pulp and cloud) that detract from its appearance.
11. Extracted juice is treated to achieve a 5-log reduction of the most pertinent pathogen (optional).
12. The final step in the process is packaging and labeling of the juice (warning statement requiredif not subjected to a 5-log reduction process).
13. It may be necessary to consult with a process authority to establish control measures for achieving the 5-log reduction.

Fresh Juice Standard Operating Procedures

Since heat pasteurization is not used in the manufacture of these fresh-squeezed juice products, strict attention must be paid to sanitation principles throughout the operation. If processed and stored under appropriate conditions, good quality juice may achieve several days' shelf life prior to quality deterioration. Likewise, caution and care in production are necessary to assure microbiological safety of the product.

Prerequisites and Standard Operating Procedures (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 corrected
- ☐ Process overseen by trained personnel
- ☐ Employee health reporting procedures in place
- ☐ Employees practice good personal hygiene (guidelines that prohibit contacting food with bare hands provided)
- ☐ Written procedure for inspecting and culling fruit
- ☐ Designated area/physical barriers/methods of separation of raw foods and ready-to-eat foods identified
- ☐ Cleaning and sanitizing procedures for food contact surfaces delineated

Receiving

- ☐ All products, including fruits, vegetables and other juice components are obtained from identifiable, approved sources. (e.g. fruit is handpicked from the tree (no drops) and transported to the retail establishment)
- ☐ Inspect incoming products for condition, integrity of packaging, proper labeling, and temperature as necessary.
- ☐ Processed fruit is received at or below 41F

Food and Packaging Storage

- ☐ The storage area is clean and orderly:
- ☐ Products are contained and/or covered for protection.
- ☐ Bottles, caps and packaging materials are stored in a clean, dry, pest free area.
- ☐ Products are marked for identity and duration in storage {dated), as appropriate.
- ☐ Produce that is not immediately juiced is stored under refrigeration or in a cool, dry place.
- ☐ Products are stored above the floor (approx. 6 inches) and away from walls and the ceiling.
- ☐ Proper rotation practices are followed.
- ☐ Storage areas are free of insects and rodents and constructed to prevent the entrance and harborage of insects and rodents.
- ☐ Product is rotated to assure FIFO movement of product. Products exceeding the “sell-by” date will be discarded.

Preparation

- ☐ Defined schedule provided for bottling the fresh juice. The preparation schedule is arranged to minimize exposure of potentially hazardous foods to ambient room temperature conditions.
- ☐ Work area is cleaned and sanitized before and after production.
- ☐ Only whole fresh fruit and vegetables are used in production.
- ☐ All produce is washed prior to use, either on premise or at a commercial facility (e.g.pre-bagged greens).
- ☐ Integrity of packaging, quality of produce, and code dates are visually inspected prior to use.
- ☐ Employees handling produce maintain proper personal hygiene.
- ☐ Juicer and other food contact equipment have been properly cleaned and sanitized per manufacturer's guidelines and operate in a sanitary enclosed work area. Manuals are available on site.
- ☐ Food-contact surfaces of extraction equipment are impervious and cleanable, in good repair, and cleaned and sanitized at a regular frequency. Couplings, fittings, and other parts associated with extractors, pumps, and other equipment are disassembled for cleaning.
- ☐ Containers used for packaging must be food grade and maintained in clean condition.
- ☐ To ensure that juice is 41°F or below before placing it on display, the product is moved to the freezer for rapid chilling.

Cold Storage

- ☐ All finished products will be displayed for sale under refrigeration holding at or below 41°F.
- ☐ Refrigeration unit(s) function properly.
- ☐ Unit temperature measuring devices throughout the day; record temperatures at least
- ☐ twice a day (open and close). Monitor electronic records daily
- ☐ If internal temperature of juice exceeds 41°F (5°C):
- ☐ Adjust or repair refrigeration unit or
- ☐ Move product to another functioning refrigeration unit and,
- ☐ Hold product and evaluate based on time/temperature exposure and discard product if temperature exceeds 41°F (5°C) for 4 more hours
- ☐ Check temperature measuring device, or continuous monitoring device for accuracy and proper functioning. If deviation noted, calibrate device
- ☐ Determine what caused the deviation and correct the problem
- ☐ Calibrate thermometers and monitor unit gauges weekly

Product Labels/Dates

- ☐ Raw freshly pressed or squeezed juices are not heat treated and are described here as unpasteurized. These products have a short shelf life of a few days. They must be kept refrigerated and consumed by the best before date.
- ☐ All juice products sold for self-service will have proper labeling.
- ☐ All finished products will be given a 1-2 day shelf life depending on the product being juiced. A "use-by" date, not to exceed 2 days will be assigned to the label.

*The Consumer Advisory label will be prominently placed on each container prior to merchandising. "**WARNING**: This product has not been pasteurized and, therefore, may contain harmful bacteria which can cause serious illness in children, the elderly, and persons with weakened immune systems."*

Records

- ☐ Daily Operational Log
- ☐ Vegetable Sanitizer Log (includes corrective actions)
- ☐ Warewashing Sanitizer Log (includes corrective actions)
- ☐ Production Log (includes dates and lot codes)
- ☐ Refrigeration Log (includes thermometer calibration and corrective actions)

Note: Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC

Training

- ☐ Supervisory and Employee Training Plan Documented

Topics include, but may not be limited to the following:

Prerequisites

a. Employee Health and Hygiene
b. Protection from Contamination
c. Time/Temperature Controls
d. Proper Cleaning and Sanitizing Procedures

Sprouting

Photo credit: [William Keene]

Sprouting Seeds or Beans

Sprouting Seeds or Beans - Variance & HACCP Required

Regulation: ¶ 3-502-11(H)

Public Health Rationale

Sprouts are the germinated seeds of various herbaceous plants. There are many varieties of sprouts, including alfalfa, clover, sunflower, broccoli, mustard, radish, garlic, dill, pumpkin, mung kidney, pinto, navy, soybeans, and wheat berries (wheat grass). The entire germinated plant is sold for use in cooked foods, or as a ready-to-eat ingredient in salads and sandwiches. Sprouting is considered a form of food processing, rather than agricultural crop production; as such, it is regulated by the U. S. Food and Drug Administration (FDA).

Retail establishments, thinking about growing their own sprouts must carefully control the process because growing bean or seed sprouts has been designated a special process by the FDA due to their ability to support the growth of foodborne pathogens and the frequent recalls and outbreaks of foodborne illness associated with sprouts.

The FDA has cautioned children, pregnant women, the elderly, and immunocompromised individuals against eating raw sprouts of any kind. According to The Food Code, establishments serving highly susceptible populations (HSP) may not offer raw sprouts on the menu, and those retail establishments *not* serving highly susceptible populations are required to post a consumer advisory on packages, menus, or menu boards where raw sprouts are served. In addition, when sprouting is done in a retail food establishment, the establishment must obtain a variance from the regulatory authority, based on an approved HACCP plan.

The FDA recommends that everyone in the sprout supply chain (seed growers, conditioners, packers, holders, suppliers, and distributors) make an effort to become informed about the food safety practices, processes, and procedures followed by firms from the time they source their seeds until the time the sprouts reach the consumer. In order to provide recommendations to seed suppliers and sprout producers to reduce microbial food safety hazards common to the production of sprouts, the FDA developed several guidance documents over the years.

In October 1999, they released two of these guidance documents:

"Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds" identified the most important steps that should be implemented to reduce the risk of raw sprouts as a vehicle for foodborne illness.

"Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" provides sampling instructions and validated methods for testing sprout irrigation water to determine whether the pathogens are present.

In June 2019 they developed a third draft guidance document *"Reducing Microbial Food Safety Hazards in the Production of Seed Sprouting: Guidance for Industry"* to make the sprout seed industry aware of FDA's serious concern with the continuing outbreaks of raw and lightly cooked sprouts.

In November 2015, the FDA published in the Federal Register (80 FR 74353) a final rule entitled, *"Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption"* (The Produce Safety Rule). Subpart M of that Rule includes standards specific to sprout operations.

Each of these resources provides a great deal of useful information to assist those wishing to grow their own sprouts. However, because of the diversity of sprout production, practices, and types of sprouts, the recommendations found in each of these documents will be most effective when they are adapted for the specific practices, processes, and procedures at each individual operation.

The most common pathogens involved in foodborne diseases that have been traced back to sprouts are shiga-toxin producing *Eschericia coli (E. coli)*, *Salmonella spp*., and *Listeria monocytogenes (Lm)*. The likely source of these microorganisms is the contamination of seed prior to sprouting. Seeds are often produced without the knowledge that they are destined for the sprout market, thus precautions against contamination may not be taken. Bacterial contamination can occur when the seeds for sprout production come into contact with animal waste during production, harvest, transportation to the sprouting facility, or while in storage. Raw manure applied to the field, grazing animals, and irrigation water are some of the possible sources of contamination during seed production. Therefore, it is imperative that the supplier be able to produce documentation, proving that the seeds were produced with the intended purpose of sprouting. There should also be full traceback to the seed source.

The very nature of the seeds involved in sprouting, with their rough, pitted, and creviced surfaces, causes great difficulty in removing harmful bacteria or getting to the bacteria with adequate sanitizing or disinfecting solutions. Harmful microorganisms already on the seeds, or introduced during the sprouting process, grow quickly during the ideal conditions of germination and sprouting.

Sprouts are produced by placing the seed in a warm, humid environment for approximately 3-7 days for germination and growth. Depending on the type of seed chosen, seeds can take anywhere from 24 hours to 10 days to sprout. Seeds are easier to sanitize or disinfect than sprouts because contamination levels are lower, there is less debris present, and seeds are generally more resistant to treatments than the delicate sprouts. In addition, pathogens may be taken up into the tissue of the sprout from the roots, which makes the pathogens inaccessible to any sanitizer or disinfectants, making it impossible to kill the bacteria without a thorough heat treatment.

Based on levels of pathogenic bacteria found on seeds associated with foodborne outbreaks, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommends treatments that achieve a 5-log reduction in pathogen levels for food safety.

Routine use of approved seed disinfection treatments (such as 20,000 parts per million of calcium hypochlorite in water) is likely to reduce the level of contamination if present in or on seeds and, thereby reducing the risk of foodborne illness when consuming the sprouted seed. However, current approved treatments do not guarantee total elimination of pathogens. If even a few pathogens survive a seed disinfection treatment, they can grow to high levels during sprouting and contaminate the entire batch. Therefore, although seed disinfection treatment is recommended, microbial testing of spent irrigation water from each batch or production lot of sprouts should also be conducted to prevent contaminated products from entering the food supply.

Potable, drinking-quality water should be used for the sprouting and irrigation process. Irrigation water should be tested at 48 hours for S*almonella spp.*, and *E. coli* (STEC) as a means of verifying that seeds were effectively disinfected. The FDA recommends testing "spent irrigation water" that has flowed over and through the sprouts as it is a good indicator of the types of microorganisms in the sprouts. The water can be collected by qualified personnel at the sprouting facility; however, the actual water tests should be conducted by an independent laboratory. Sufficient time needs to be allowed so that testing results are returned prior to harvest. If the water tests positive for pathogens of public health significance, the entire batch of sprouts should be discarded.

In a 2004 publication on sprout safety (FDA Guidance Document *"Growing Sprouts in Retail Food Establishment - CFP Issues 02-III-01 and 04-III-012"* (December 2004), the FDA stressed the following: ***"There is no single treatment so far that has been shown to completely eliminate pathogens on seeds or sprouts that cause foodborne illness without affecting germination or yield."*** For this reason, the FDA recommends that everyone cook their sprouts thoroughly to reduce the risk of illness from possible contamination.

Without a kill step to destroy pathogens that may be present on sprouts, other controls must be in place to assure sprouts are safe to eat , every precautionary measure should be taken to prevent high levels of bacteria from growing on the seeds or sprouts. The following guidance is provided from the FDA to retail establishments wanting to grow their own sprouts.

Key Terms

Calcium Hypochlorite is the main active ingredient of commercial products called bleaching powder, chlorine powder, or chlorinated lime, used for water treatment and as a bleaching agent. This compound is relatively stable and has greater available chlorine than sodium hypochlorite. It is a white solid, although commercial samples appear yellow. It strongly smells of chlorine, owing to its slow decomposition in moist air.

Note: OSHA requires sprout processors and retailers to use personal protective equipment such as respirators and gloves when handling calcium hypochlorite.

Lot Number means the sprouts from a single lot of seeds that were planted at the same time in a single growing unit (single drum or rack of trays).

Pathogen is any microorganism that can cause disease.

Potable Water is water that is safe to be used as drinking water.

Production Batch of Sprouts means all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Spent irrigation water means water that has been used in the growing of sprouts.

Sprout means a seed that is germinated until it has formed a root or until it has developed its first set of leaves.

Sprouting is the natural process by which seeds or spores germinate and put out shoots, and already established plants produce new leaves or buds, or other structures experience further growth.

Note: Throughout this guidance document, everything that can be sprouted, including beans, is referred to as seeds.

Controls and Guidelines

All stages of sprout production should be conducted indoors in a sanitary environment, following good retail practices.

Purchasing

- ☐ Seeds purchased from a reputable supplier that follows good agricultural practices (GAPs) and good manufacturing practices (GMPs).
- ☐ Seeds must have been produced for the intended purpose of sprouting.
- ☐ Purchase seeds from a reputable supplier, one that is willing to provide a Certificate of Analysis (COA). The COA should contain negative test results for Shiga-toxin producing E. coli, Salmonella, and Listeria.

Receiving (seeds or sprouts)

- ☐ Examine seeds upon receipt for signs of contamination (e.g., tears, water damage, mold, etc.) Black lights should be used to detect pest contamination on seeds and bags.
- ☐ Containers should be labeled to maintain the identity of the seed lot (traceback) and whether the seeds have received prior treatment by the supplier.

Storage

- ☐ Store seeds off the ground and in covered containers to prevent contamination.

Processing

Initial Seed Rinse

- ☐ Rinse seeds in potable water before treatment to remove dirt, and to increase the efficiency of the treatment.

Seed Treatment

- ☐ Seeds treated at the establishment must be treated using science-based methods prior to sprouting.
- ☐ If the supplier is responsible for treatment of seeds, they must provide documentation, such as a Certificate or Statement of Conformance (COC) from the manufacturer stating that the prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance and the treated seeds were handled and packaged following the treatment in a manner that minimizes the potential for contamination. Documentation should include written control measures showing which approved treatment method or combination of methods were used to achieve a reduction in pathogens.
- ☐ Seed types can vary in sensitivity to antimicrobial agents and other types of treatments, which can affect treatment efficiency and how well the seeds germinate and grow after treatment. If a seed treatment described in scientific literature is implemented, the method should consider the parameters used in the study and determine whether they are compatible with how the treatment is applied in the establishment. For example, if the chosen treatment has only been tested on alfalfa seeds, then it can't be assumed that the treatment will be effective on mung beans.
- ☐ Methods used must be scientifically validated to achieve a 5-log reduction which may be difficult for smaller operations to achieve while maintaining seed viability. When reviewing the options available for seed treatment, especially if the seeds will be treated at the establishment (as opposed to, or in addition to, purchasing pre-treated seeds) consider the feasibility of correctly applying the treatment at that specific establishment.
- ☐ If applying a validated chemical seed treatment such as calcium hypochlorite at 20,000 ppm for 15 minutes, the treatment should be prepared correctly to ensure the chemical is present at the desired concentration. After mixing, the treatment solution concentration must be verified according to the label directions, since the concentration can impact treatment effectiveness.

Pre-germination Seed Soak

- ☐ Containers and other tools or equipment used for soaking must be cleaned and sanitized prior to contact with seeds used to grow sprouts.
- ☐ For both seed soaking and any additional rinses, conducted after soaking, potable water must be used.
- ☐ Soak seed in lukewarm water (see Note below)**.** Drain and rinse.
- ☐ Place in sprouting containers if different from the soaking container.

Note: *There are no time/temperature recommendations for pre-germination soaking. An example of best practice is to soak the seeds at 90-95°F (32-35°C) for 2-4 hours or at room temperature 68-73°F (20-22°C) overnight. This is to bring all the seed to a uniform moisture content, and to begin the germination processes in the seed.*

Germination and Growth

- ☐ Irrigation water must be from an approved potable source. Documentation must be provided showing how the irrigation water from each batch of germinating sprouts is tested.
- ☐ Growing units should be cleaned and sanitized before starting each new production batch.
- ☐ Sprouts must be protected from all sources of contamination (including overhead condensation).

Note: The FDA Food Code does not have temperature and frequency recommendations for irrigating sprouts. An example of best practice to control respiration rates and waste products is to flush the seeds with lukewarm water (ambient or 75°F (24°C) every 4-6 hours.

Harvest, Washing, Draining, and Cooling

- ☐ Sprouts are washed with cool water to remove hulls and to help lower the temperature of the sprouts.
- ☐ All wash water must be from an approved potable source.
- ☐ Once the sprouts are harvested, they must be cooled to 5°C (41°F) or below within 4 hours because harvested sprouts are considered TCS foods.
- ☐ Harvested sprouts must be handled in a manner that protects against contamination.
- ☐ Tools and equipment used in harvesting sprouts should be cleaned and sanitized at least daily, and before starting to harvest each new production batch of sprouts.
- ☐ Sprout spinning and/or drying equipment must be inspected, maintained, cleaned, and sanitized as frequently as reasonably necessary to protect against contamination and prior to contact with sprouts.

Packaging, Labeling, Storage, and Service

- ☐ Food-packing material must be adequate for its intended use.
- ☐ Proper personal hygiene practices must be practiced (e.g., hand washing, gloves, no ill personnel, etc.)
- ☐ Packaged seeds must be stored at or below 41°F (5°C) or below for a maximum of seven days.
- ☐ Packaged sprouts must be labeled with the discard date.

A consumer advisory must be posted on packages, the menu, or the menu board if served directly to the consumer.

Retail Sprouting Industry Best Practices		
PROCESS STEP	**SOURCE OF CONTAMINATION**	**CONTROL MEASURES**
Receiving (Seeds or Sprouts)	Bacterial contamination	•Approved source (purchase specifications - grown for human food, grown under Good •Agricultural Practices (GAPs) including manure management, labeled with lot number for traceback to source Stored and handled under sanitary conditions during distribution •Inspection for torn bags or containers, rodent evidence (feces, urine - fluoresces in UV light) •Product condition (not wet or moldy)
Seed Storage at Retail	Cross-contamination Rodent Infestation	• Stored in clean, sanitized bins/containers •Seeds protected after opening •Have SSOPs in place (cleaning & sanitizing, maintenance, pest control, etc.)
Seed Treatment (Soaking & Rinsing)	Unsafe water Physical contamination Bacterial contamination	•Use a public water supply or test private •well water on a regular basis •Screen for stones and other debris •Protect all seeds from contamination especially if scarification is done to change germination •Disinfection treatment
Germination (Sprouting)	Dirty equipment Unsafe water Unsafe soil (if used for sprouts) Airborne contamination Bacterial growth Ill employees with infections	•Hot & cold water available •Use potable irrigation water for sprouting seeds •Clean & sanitize all surfaces that irrigation water and sprouts contact •Wash hands before and after handling sprouts • No broken or cracked utensils or equipment • Building enclosed •Testing irrigation water for Salmonella and E. coli O157:H7
Post-Germination (Harvesting/ Packaging or Repackaging)	• Unsafe water • Ill employees with infections • Inadequate label information • Unsafe packaging materials	• Use potable water rinse • Adequate and accessible restrooms and hand washing facilities • No bare hand contact with sprouts • Exclusion or restriction of ill employees • Sprout package label contains sprouter's name, address & zip code, lot code and "Keep Refrigerated" instructions • Food grade packaging materials
Storage & Display	• Bacterial Growth • Cross-contamination	• Store/display at 41°/5°C or less • Protect sprouts from contamination

Reproduced from FDA guidance document "Growing Sprouts in Retail Food Establishment - CFP Issues 02-III-1 and 04-III-12", December 2004

Guideline For Validating Sprouting Seeds or Beans 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 the product, have been corrected.
- ☐ Process overseen by trained personnel
- ☐ Employee health reporting procedures in place
- ☐ Employees practice good personal hygiene (guidelines that prohibit contacting food with bare hands provided)
- ☐ Designated area/physical barriers/methods of separation of raw foods and ready-to-eat foods identified
- ☐ Cleaning and sanitizing procedures for food contact surfaces delineated

Hazard Analysis Included

- ☐ Pathogens of concern: Shiga toxin-producing Escherichia coli, Salmonella spp., Listeria monocytogenes

CCP(s) Identified

- ☐ Receiving
- ☐ Processing
- ☐ Cold Holding

Critical Limit(s) Identified

Receiving

- ☐ Sprouting seeds are purchased from an approved source.
- ☐ Supplier provides evidence that seeds are intended for the purpose of sprouting
- ☐ Seed containers are labeled to maintain identity of the seed lot (full traceback)

<u>If supplier treats the seeds:</u>

- ☐ Supplier provides documentation, such as a Certificate or Statement of Conformance (COC) from the manufacturer stating that the prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance and the treated seeds were handled and packaged following the treatment in a manner that minimizes the potential for contamination.
- ☐ Supplier provides a Certificate of Analysis (COA) as confirmation of negative results following seed treatment for pathogens of concern in seeds
- ☐ Supplier provides a Certificate of Analysis (COA) as confirmation of negative results following seed treatment for pathogens of concern in seeds

Processing

If the retail establishment is responsible for treating the seeds:

- ☐ Administer a fresh batch of calcium hypochlorite wash at 20,000 ppm (2%) for 15 minutes (or other scientifically validated seed treatment) on each batch of seeds immediately before sprouting. pH of prepared calcium hypochlorite solution should be between 6.2-6.8

Note: Water hardness affects results

- ☐ Test spent irrigation water for presence of pathogens of concern (E. coli 0157:H7, or Salmonella)

Storage after Processing

- ☐ Sprouts are stored or displayed at or below 41°F (5°C)

Monitoring Procedures Identified

Receiving

- ☐ Visual check for supplier documentation for each seed lot (seed receipts, Certificate of Compliance (COC), Certificate of Analysis (COA))
- ☐ Visual check that containers are labeled with identity of seed lot

Processing

- ☐ If seeds are treated at the establishment
- ☐ Test disinfectant concentration, record results along with process start and end times (frequency will depend in the HACCP plan, usually at least one lot per week)
- ☐ Sample spent irrigation water at 48 hours, and send to lab for testing (*Salmonella spp.* and *E. coli* O157:H7)

Storage after Processing

- ☐ Observe unit temperature measuring devices throughout the day; record temperatures at least twice a day (open and close). Monitor electronic records daily

Corrective Actions and Documentation Procedures Identified

Receiving

- ☐ If COA or COC not available, hold seeds until COA and COC are provided, or
- ☐ If containers are not labeled with lot identification, hold until information is provided, or
- ☐ Reject unlabeled lots, and
- ☐ Discontinue use of the supplier until problem is brought under control

Processing

- ☐ If test results for appropriate concentration of calcium hypochlorite is not achieved, rework product and retest, or
- ☐ Discard the batch, and
- ☐ Determine what caused the deviation and correct the problem
- ☐ If spent irrigation water testing results come back positive for one or more pathogens of concern, the seed lot used to produce the sprouts and any other sprout production lots made from the same seed lot may also be contaminated.
- ☐ Hold the lot and conduct confirmatory testing, or
- ☐ Discard the lot, and
- ☐ Determine what caused the positive test result(s) and correct the problem

Cold Holding

- ☐ If internal temperature of sprouts exceeds 41°F (5°C):
- ☐ Adjust or repair refrigeration unit or
- ☐ Move product to another functioning refrigeration unit, and
- ☐ Hold product and evaluate based on time/temperature exposure and discard product if temperature exceeds 41°F (5°C) for 4 more more hours
- ☐ Check temperature measuring device, or continuous monitoring device for accuracy and proper functioning. If deviation noted, calibrate device.
- ☐ Determine what caused the deviation and correct the problem

Verification Process Identified (Short Term/Long Term)

- ☐ Signed and dated HACCP plan reviewed and modified at least annually or as needed by PIC

Receiving

- ☐ Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC

Processing

- ☐ pH testing device is properly calibrated
- ☐ Scales are properly calibrated
- ☐ Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC

Storage after Processing

- ☐ Temperature measuring devices calibrated at a frequency based on the device and manufacturer's instructions
- ☐ Monitoring and corrective action records reviewed on a weekly basis, or as needed, by PIC
- ☐ Weekly laboratory analysis of tank water negative for coliform.

Records are Identified

Receiving

- ☐ Seed receipts (seeds were intended for sprouting, lot identification for traceback)
- ☐ Certificates of Analyses
- ☐ Certificates of Conformance

Processing

- ☐ Seed Treatment Log
- ☐ Seed receipts (seeds were intended for sprouting, lot identification for traceback)
- ☐ Certificates of Analyses (COA) if product treated at establishment showing seed treatment was effective

Storage after Processing

- ☐ Refrigeration/Display Temperature Log
- ☐ Thermometer Calibration Log
- ☐ Certificate of Calibration (for continuous temperature recording device)
- ☐ Training Record

Training

- ☐ Supervisory and Employee Training Plan Documented

Topics include, but may not be limited to the following:

Prerequisites

- Employee Health and Hygiene
- Protection from Contamination
- Time/Temperature Controls
- Proper Cleaning and Sanitizing Procedures

Processing Controls

- ☐ Contents of the HACCP plan
- ☐ Indent Monitoring Procedures Meeting Critical Limits
- ☐ Corrective Actions
- ☐ Recordkeeping Requirements

Pasteurized Food & Prohibited Food
Whole Shell Eggs

Pasteurized Foods and Prohibited Food – Whole Shell Eggs

Special Requirements for Highly Susceptible Populations (HSP)

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

In 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 pre-approved HACCP plan that:

(d) Identifies the food to be prepared,
(e) Prohibits contacting ready-to-eat foods with bare hands,
(f) Includes specifications and practices that ensure:

(iii) *Salmonella Enteritidis* growth is controlled before and after cooking, and

(iv) *Salmonella Enteritidis* is destroyed by cooking the eggs according to the temperature and time specified in subparagraph ¶ 3-401.11 (A)(2),

(e) Contains the information specified under ¶ 8-201.14 (D) including procedures that:

(iii) Control cross contamination of ready-to-eat food with raw eggs, and

(iv) Delineate cleaning and sanitization procedures for food contact surfaces, and

(f) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

Public Health Rationale

Recipes in which more than one egg is combined carry an increased risk of illness and possible serious consequences for certain people. This practice, often called “pooling” refers to the practice of breaking eggs into containers and using the combined eggs to make multiple servings of egg dishes or for use in multiple recipes. Pooling is a common practice in some food establishments to save time and to control portion size.

Fresh eggs may contain a bacteria called *Salmonella enteritidis* that can cause intestinal infections. Most healthy people recover from these infections within 4-7 days, but they can lead to severe and even fatal illness, especially for those most vulnerable to foodborne disease — young children, the elderly, or persons who live in a facility that provides custodial care, and persons with immune systems weakened by health problems.

Mixing eggs together can allow one or more infected eggs to contaminate a larger batch of eggs. The larger batch can then be a source for bacteria and can lead to multiple illnesses or contamination of other food. Storing uncooked eggs at improper temperatures can allow pathogens to grow to large numbers. Therefore, temperature control is very important.

It is due to this increased risk, and documented occurrences of foodborne illness and death among highly susceptible populations from temperature-abused raw shell eggs contaminated with *Salmonella enteritidis*, that combining eggs is not allowed in a facility that serves highly susceptible populations without a pre-approved HACCP plan.

Controls and Guidelines

Salmonella enteritidis often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

The food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to *Salmonella Enteritidis*.

Although it is recommended that pasteurized eggs or egg products be used in any recipe that calls for combining more than one egg and for any recipe, preparation or serving procedure that involves holding eggs or egg-containing foods before or after cooking, if permitted in a facility that serves highly susceptible populations under and approved HACCP plan, there are some safety measures that can be taken to minimize the microbial risk when combining eggs. These safety measures include, but are not limited to the following:

- Plan the production schedule ahead to avoid preparing pooled eggs too far in advance; pool eggs just prior to cooking as much as possible.
- Pooled eggs not for immediate service should be kept in covered containers under refrigeration and only take out small amounts as needed.
- Use all the eggs on the day they are pooled, and do not top them off with new eggs.
- If eggs are to be hot held, they must be held at or above 135°F at all times.
- Eggs should be held at 41°F or below prior to use.
- Follow good personal hygiene practices, avoid cross-contamination, and clean and sanitize all equipment and surfaces after use.

Note: If separating the egg yolks from the egg whites, use a clean egg separator instead of egg shells to minimize cross-contamination. *Salmonella*, if present on the surface of the shell, can be transferred to the contents of the egg.

Guidelines for Validating Whole Shell Eggs for 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 corrected.
- ☐ Instructions provided for combining raw eggs immediately before cooking
- ☐ Guidelines provided that prohibit cross contamination of ready to eat food with raw eggs / bare hands

Recipe/Formulation Provided

- ☐ Pooling Eggs Preparation steps identified

Hazard Analysis Included

- ☐ Pathogen survival – *Salmonella enteritidis*

CCP(s) Identified

- ☐ Cooking

Critical Limit(s) Identified

- ☐ Internal final product temperature of 155°F

Monitoring Procedures Identified

- ☐ Calibrated thermometer used to measure final internal product temperature
- ☐ Person(s) identified for measuring temperature of final product

Corrective Actions and Documentation Procedures Identified

- ☐ Process extended, or temperature elevated until proper internal temperature is reached
- ☐ Corrective actions recorded in log (sample page included)
- ☐ Cause of deviation determined

Verification Process Identified (Short Term/Long Term)

- ☐ Thermometer calibrated weekly, or as needed, by PIC
- ☐ 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

- ☐ Cook log for each product (sample page included)
- ☐ Daily calibration log maintained for thermometer
- ☐ Corrective action record

Employee Training Plan Documented (sample of training log provided)

- ☐ Employee Health and Hygiene
- ☐ Cleaning and Sanitizing Procedures
- ☐ Cross contamination Prevention Procedures
- ☐ Monitoring Procedures
- ☐ Calibration of Thermometer(s)
- ☐ Corrective Actions
- ☐ Record keeping Requirements

Module 4
Validating & Verifying the HACCP Plan

Key Terms

Validation is that element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Verification means those activities other than monitoring that determine the validity of the HACCP plan and that the system is operating according to the plan.

HACCP Plan Review

The regulatory review of the written HACCP plan should be carried out by the regulatory authority (RA) to verify that each HACCP plan is complete. The model HACCP Plan Review Application found at the end of this module, which is to be completed and signed by the operator, can be used by the RA to facilitate the validation process.

In order for a documented HACCP plan to be considered complete, it must be dated and signed by the designated person in charge or HACCP coordinator. It must also meet all regulatory requirements and include all required components of a HACCP plan.

When any section of the written plan is found to be incomplete, the deficiencies should be described in the "Comments" section of the HACCP Plan Review Application. Reasons for noted deficiencies (i.e. regulations, laboratory results, scientific data, etc.) should also be included. When all the items on the HACCP plan have been evaluated, the overall assessment of the written plan is complete.

If the HACCP plan documentation package is found to require further information or modification, the components, which are not acceptable, should be returned to the establishment with a cover letter explaining the deficiencies.

The establishment is responsible for correcting all deficiencies and resubmitting the amended HACCP Plan to the RA for follow-up review.

When the regulator is satisfied that all deficiencies have been corrected, or that the initial plan is acceptable, and the operator has informed the RA of the implementation date, the HACCP plan validation process is complete.

When the RA is satisfied that all deficiencies have been corrected, or that the initial plan is acceptable, and the operator has informed the RA of the implementation date, the HACCP plan validation process is complete.

The Validation Process

HACCP plans should not be written once and then forgotten. They evolve through a developing knowledge and understanding of specific product and process food safety hazards, changes to regulations, changes within business operations, and the inclusion of new and emerging food safety hazards.

This is where the concepts of validation and verification become important to the integrity of the HACCP system. The terms validation and verification are often used interchangeably. However, they are distinctly different.

Validation is the process that confirms that the HACCP plan will provide safe food when implemented. This is achieved by obtaining evidence that a control measure or combination of control measures, if properly implemented, are capable of controlling the hazard to a specified outcome. Validation is completed before the HACCP plan is implemented, and as an ongoing activity to revalidate the entire HACCP plan; confirming the intended level of control is maintained.

In contrast, monitoring and verification activities confirm that the control measures have worked as intended and this occurs after the validation of the control measures. Monitoring is a real-time measurement, whereas verification is an ongoing activity that is used to assess if the control measures have been implemented and that they are working as intended

CODEX HACCP requires two validation activities to be completed by food businesses:

1) establishment of validated critical limits for each CCP

2) validation of the HACCP plan

The critical limits for each control measure or combination of control measures are required to be scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented. There are two components to this validation:

1. Confirmation that the selected critical limits are correct and evidence to demonstrate that the business can consistently achieve these limits.

2. Confirmation that the critical limits are correct are known as ‘theoretical validation’. This requires a food business to source reliable and scientifically proven information from regulatory requirements, industry codes of practice, published journal articles, suppliers of equipment and raw materials, advice from technical experts or results from in-house analytical product testing for microbiological and chemical criteria.

A critical limit from a regulatory requirement or industry code of practice does not require any further validation to confirm it is the correct critical limit because this work has been done by the regulatory authority or the representative industry body. Example: The chosen critical limit for the storage of TCS foods is a maximum product temperature of 41°F (5°C) as referenced in The Food Code.

The second part of critical limit validation is a ‘process capability’ where the food business demonstrates they are able to consistently achieve the critical limit, even when the likely worst-case scenario is applied.

Elements of the HACCP Plan Validation Process

A. Product Description

1. All individual products are identified by brand name and/or common name in the HACCP plan. (Like products are grouped in an acceptable manner.)
2. Characteristics of the product(s) which are important to ensure it's safety are listed (e.g., pH and a_w).The characteristics must be similar for all products covered by the HACCP plan(s).

   These characteristics are critical in controlling any common food safety concerns. Products with different characteristics cannot be grouped. For example, reduced oxygen packaged foods cannot be grouped under the same HACCP plan as sushi because the product characteristics are different.
3. Description of how the product is to be used (e.g., raw, ready to eat, ready to cook, etc.).
4. Packaging material and packaging conditions used for the product(s) are identified.
5. Anticipated shelf life of the product(s) listed under normal marketing conditions at given temperatures.

   If the determined shelf life of the product exceeds industry practices, laboratory data or scientific studies, the establishment must provide sufficient background data to support the safety of the chosen shelf life. In this case, any reference documents must be made available at the time of review.
6. Safe handling and usage information pertinent to the product is indicated (e.g., “keep refrigerated,” best “use by” date, etc.).
7. If applicable, the HACCP plan includes a description of any special controls required during shipping and storage, i.e. temperature requirements.
8. Labeling information for each product is available. The sample label is found to be consistent with: "Product Name", "Intended Use", "Safe Labeling Instructions" and "Special Distribution Control" on the HACCP plan.
9. When applicable, recipes are available upon request to determine if the formulation/method of preparation is consistent with those submitted with the HACCP plan.
10. When applicable, a floor plan, showing the layout of the preparation area.
11. When applicable, a brief description of the lot identification system.

B. Incoming Materials

1. All ingredients, incoming materials, and processing aids coming in contact with the product(s) or used in the preparation of the product(s) are listed.
2. Hazard analysis is one of the most important steps in developing a HACCP plan. A wrong or faulty hazard analysis will significantly jeopardize the effectiveness of the HACCP plan.

   The establishment should evaluate hazards of significance and preventative measures needed for each food product and process. All hazards associated with incoming materials and ingredients should be specifically identified as biological, chemical, or physical in the HACCP plan. The hazards must at least include those that are commonly associated with a specific product.

   It may be necessary to use a variety of sources to gather information. Some of those sources could include scientific literature, regulations and other regulatory guidelines, laboratory records, and product specifications.

C. Process Flow Chart and Facility Layout Diagram

The HACCP plan includes a complete step-by-step flow diagram of the process and layout of the facility, indicating all pertinent processing steps, including where ingredients, packaging materials, etc. enter the flow and any preparation

Any hazards associated with possible cross-contamination are to be identified. It should also include product flow and employee traffic patterns within the establishment for products covered by the HACCP plan. The location of hand wash facilities should also be noted.

D. Critical Control Point Identification

The proper identification of Critical Control Points (CCPs) is crucial to the ultimate effectiveness of a HACCP plan. The plan must specify where each identified hazard will be controlled.

Hazards that cannot be controlled by the operator must be identified on the HACCP plan. The plan must indicate how these hazards will be addressed outside the establishment (i.e. purchasing pre-frozen fish, where the supplier is responsible for the freezing requirements as specified by regulation).

Note: The evaluation for completeness of the written CCPs will ensure that all relevant information dealing with critical limits, monitoring, corrective actions, verification procedures and record keeping is specified for each identified hazard.

E. Critical Limits Established

Critical limits have to be established for all critical components associated with each hazard that is controlled by a CCP.

Critical Limits must meet or exceed relevant regulatory and program requirements. Some establishments set critical limits to exceed regulatory requirements. This is acceptable, but the establishment should be made aware that if these limits are the ones written into the HACCP plan, the inspection will be conducted against these more stringent limits.

Critical limits normally include measurements such as temperature, time, moisture level, pH, a_w, available chlorine, and sensory attributes. When applicable, compare the critical limits found in the establishment HACCP plan to those considered standard industry practice.

For critical limits without regulatory or program requirements, the company must validate that the critical limits in its plant specific HACCP plan are appropriate. This could include product sampling and laboratory analysis and should be relevant to the hazard being addressed.

F. Monitoring Procedures

Monitoring procedures exist for each critical limit at each CCP to ensure that the CCP is under control.

Monitoring procedures must be complete (Who, What, When and How). When applicable, these procedures must meet regulatory/program requirements.

G. Corrective Action Procedures

Corrective action procedures exist for each CCP.

Corrective action procedures must be complete (Who, What, When and How). When applicable, these procedures must meet regulatory/program requirements.

Corrective action procedures must state the corrective action to be followed in response to a deviation from a critical limit.

The HACCP plan must describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

1. The cause of the deviation is identified and eliminated
2. The CCP will be under control after the corrective action is taken
3. Measures to prevent recurrences are established
4. No product that could put the public at risk as a result of the deviation reaches the consumer

If a deviation, not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment must:

1. Segregate and hold the affected product, until an assessment is made to determine the acceptability of the affected product prior to sale
2. Take action, when necessary, with respect to the affected product to ensure that no product that could put the public at risk as a result of the deviation reaches the consumer
3. Perform or obtain reassessment by an individual trained in accordance with HACCP Plan requirements, to determine whether the deviation or other unforeseen hazard should be incorporated in the HACCP Plan

All corrective actions must be documented in records that are subject to verification, under record keeping procedures, during the field verification inspection.

H. Verification Procedures

1. Verification procedures must exist for each CCP.
2. Verification procedures must be complete (Who, What, When and How). This may include review of operations & records, and analytical testing.
3. Verification procedures must ensure that the CCP is valid and effective (i.e. critical limits, monitoring procedures, and corrective action procedures are appropriate to ensure food safety).

Examples of on-going verification activities include:

- Calibration of monitoring equipment (food thermometers, equipment temperature measuring devices, scales, pH meters, etc.)
- Direct observations of monitoring activities and corrective actions
- Record review

I. Record Keeping

The following should be identified in the written HACCP plan:

- Corrective actions
- Records (including name and location)
- Verification

The requirement to record events at CCPs on a regular basis ensures that preventive monitoring is occurring in a systematic way. Unusual occurrences must be corrected and recorded immediately with notation of the corrective action taken.

The level of sophistication of the record keeping necessary for the food establishment is dependent on the complexity of the food preparation operation.

For example: a sous-vidé process or cook-chill operation for a large institution would require more record keeping than a limited menu cook-serve operation. It is best to develop and implement the simplest, most effective record keeping system that lends itself well to integration within the existing operation.

HACCP Plan Revalidation

The operator is required to review the HACCP plan on a yearly basis to verify that it is effective over time. Whenever significant changes are made in any of the following areas, they must be incorporated into the HACCP plan and the HACCP plan must be revalidated.

- Products added
- Formulations changed
- Processes or packaging added or changed
- Menu items added
- Suppliers, customers, equipment, or facilities changed
- Regulatory requirements changed
- Introduction of new technologies that may impact food safety
- A failure in control measures resulting in a process deviation for which the is of failure is not yet known
- A non-compliance to monitoring or verification activities
- Control of a hazard that is not achieved due to an inadequate or incomplete hazard analysis

Review procedures must be written and include:

a. What is reviewed
b. The specified frequency for the review
c. Person responsible for the review
d. Person responsible for making necessary changes to the HACCP plan

Records must be kept to show that reviews are performed as written and to identify changes made to the HACCP plan. These records must include:

a. A description of the changes
b. Where the changes are located in the HACCP system
c. The date changes took place
d. Person responsible for verifying and, if necessary, validating the changes

Revalidation of the HACCP plan includes a documented on-site review and verification of all flow diagrams and CCPs in the HACCP plan.

Validation of New/Modified HACCP Plans

Where an establishment has added a new process, requiring an additional HACCP plan, or modification of the existing one, the HACCP plan will require a full validation review. The new/modified HACCP plan must be submitted to the responsible regulator in a timely manner.

NOTE: The Model HACCP Plan Validation Checklist, located at the end of this module is a tool that can be used by regulators when validating an establishment's HACCP plan**.**

The Verification Process

On-going field verification of the HACCP plan is conducted by the regulatory authority. Verification is necessary to ensure that the validated HACCP plan reflects current establishment conditions and that it is functioning effectively. The written HACCP plan must be validated and accepted as complete before the field verification inspection takes place. The model HACCP Field Verification Report Form, found at the end of this module can be used by the regulatory agency, in conjunction with the inspection report form, to facilitate the verification process. The form can be easily completed by the regulator while validating the plan. In addition, the HACCP plan must be in operation prior to the verification inspection. In some cases, the regulatory authority may feel it necessary to conduct a pre-operational inspection to verify physical facilities and equipment requirements.

Such verification activities may include:

a. Review of the HACCP plan
b. Record review
c. Review of corrective actions and their resolution
d. Review of critical limits to ensure adequacy for controlling hazards
e. Direct observation or measurement at a CCP
f. Sample collection and analysis to determine the product meets all safety standards
g. On-site observations of activities carried out by the responsible employees

Verification of the validated HACCP plan will be made for each CCP. This assessment is made after record review and on-site observations have been completed. The HACCP plan should not be accepted as final until the field inspector is confident that all requirements of the validated HACCP plan have been fulfilled. Failure to comply with the approved procedures must be documented on the inspection report form (§ 8-103.12 Conformance with Approved Procedures).

When any section of the validated HACCP plan does not comply with findings noted during the field inspection, the deficiencies should be noted on the HACCP Field Verification Report Form as well as on the inspection report form cover sheet. Deficiencies should also be described in the narrative section of the food establishment inspection report form, which serves as an order for correction (i.e. regulations, laboratory results, scientific data, etc.)

An emergency suspension of operations may need to be considered by the regulatory authority if significant non-compliance with monitoring of critical control points is noted.

When the regulator is satisfied that all deficiencies have been corrected, or that the components of the validated plan match findings noted during the field inspection, the HACCP plan approval process is complete. The HACCP Field Verification Report Form should be dated and signed by the reviewer for the record.

Elements of the HACCP Plan Verification Process

1. **Record Keeping Procedures**

   The first step in the verification process is to review the records. This is usually done in the food establishment's office. The approved HACCP Plan and associated records must be on file at the food establishment and available for review.

   Records must be kept to show that CCPs are properly controlled. The establishment's HACCP plan must specify which records are in place for monitoring, corrective action, and verification procedures for each CCP.

   Records documenting the monitoring of CCPs and their critical limits could include the recording of actual times, temperatures, or other quantifiable values, as described in the establishment's HACCP plan; the calibration of monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; and product code(s), product name or identity. Each of these records shall include the date the record was made.

   Monitoring records should be retained at the establishment for a minimum of one year or, for the extent of the shelf life of the product, if it exceeds one year, and are available upon request.

   Generally, the following are examples of documents that can be included in the total HACCP system:

   A. List of the HACCP team members and assigned responsibilities

   B. Description of the product and its intended use

      1. *Ingredients*
         Supplier certification and letters of guarantee documenting compliance with establishment and regulatory requirements.

      2. *Preparation*
         Records from all monitored CCPs.

      3. *Packaging*
         Records indicating compliance with specifications of packaging materials and sealing specifications.

      4. *Finished product*
         a. Sufficient data and records to establish the efficacy of barriers in maintaining product safety.
         b. Sufficient data and records establishing the safe shelf-life of the product; if age of product can affect safety.
         c. Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.

      5. *Storage and distribution*
         a. Temperature records.
         b. Records showing no product shipped after shelf life date on temperature-sensitive products.

C. Flow chart indicating CCPs

D. Hazards associated with each CCP and preventive measures

E. Critical limits and preventive measures

F. Monitoring records

All monitoring activities are recorded and signed by the person doing the monitoring on a timely basis. They are up-to-date and complete for each CCP. Records show that the monitoring procedures are carried out as described in the validated HACCP plan and that they are effective.

G. Corrective action plans for deviations from critical limits

Validation records and modification to the HACCP plan indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.

All deviations and the resulting corrective actions are recorded and initialed by the responsible person on a timely basis. They are up-to-date and complete for each CCP. Records show that the corrective action procedures are carried out as described in the validated HACCP plan and that they are effective.

H. Verification procedures

All verification activities are recorded and signed by the responsible person on a timely basis. They are up-to-date and complete for each CCP. Records show that the verification procedures are carried out as described in the validated HACCP plan and that they are effective.

I. Employee training

Records indicating that food employees responsible for implementation of the HACCP plan understand the hazards, controls, and procedures. These records should indicate the training courses completed by each employee.

2. Flow Chart and Facility Layout Diagram

On-site verification is performed to confirm that the flow chart is accurate in relation to hazard identification and conforms to all aspects of the validated HACCP plan. The facility layout diagram must also be accurate and complete in relation to hazards associated with cross-contamination from product flow and employee traffic patterns.

3. Recipes/Formulations/Method of Preparation

Assessment is made for completeness of the product description and to ensure that the establishment is following its written procedure. When possible, this review should take place while the product is being prepared.

Obtain the recipe/formulation/method of preparation that corresponds to the validated HACCP plan. If a deviation is found, stop and ask the company to review all its formulation/methods of preparation for this HACCP plan.

4. Incoming Materials

Compare actual ingredients and incoming materials to the establishment's HACCP plan. This will include raw materials, product ingredients, processing aids, and packaging materials.

5. **Labels**

   Randomly select one or more labels covered by the HACCP plan. Inspect the label(s) to ensure it matches the written product description.

   If a deviation is found, select at least one more label. If an additional deviation is found, stop and ask the company to review all its labels for this HACCP plan.

6. **Monitoring Procedures**

   Monitoring procedures must be defined for each critical limit at each CCP to make sure the CCP is under control. Individuals are interviewed and should be able to demonstrate that they have an understanding of the critical limits, reason & importance of the monitoring of this CCP and how to perform the related monitoring procedures, including record keeping.

   Monitoring procedures are to be ongoing at all times during processing and must be done in a location that accurately reflects the critical limit. In some cases, the frequency of monitoring reflects regulatory requirements (e.g., visual examination of packaging for proper vacuum seal).

   Results of monitoring procedures must be readily available and give information on a timely basis allowing a decision to be made on the acceptability of the product and conformance to the validated HACCP plan.

7. **Corrective Actions**

   A deviation occurs when a predetermined critical limit is exceeded, resulting in a potential impact on the health & safety of the product. In some cases, the corrective action procedures reflect regulatory requirements (e.g., proper temperature control, sufficient acidification, etc.). Corrective actions must include the course of action to be taken in order to deal with the deviations when they occur and they must match corrective action procedures listed in the validated HACCP plan.

   Individuals are interviewed and should be able to demonstrate that They can identify deviations and understand the required corrective action to be taken as specified in the validated HACCP plan.

8. **Verification Procedures**

   Verification procedures include the review of operations and records. They could also include analytical testing to determine if the CCP is valid and effective (e.g., the review of the corrective action records by the responsible person at a set frequency to determine if appropriate corrective action was taken when a deviation occurred). They are not intended to make a decision on the acceptability of the product. When applicable, compare actual verification procedures to those noted on the validated HACCP plan.

   Individuals are interviewed and should be able to demonstrate that they understand how to perform the verification procedures and can complete the required records.

9. **Record Maintenance**

   It is the operator's responsibility to establish a system for maintaining records. The HACCP Plan must be dated in order to identify the most current version. In addition, all modified pages of the HACCP plan must be signed by the HACCP coordinator or designated person to indicate management approval.

   Copies of the dated and signed pages must be distributed to all users as required.

   Only the most current version of a HACCP plan should be in use. All obsolete documents/pages should be removed.

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:

(C) 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

(D) 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

Non-compliant HACCP Systems

A HACCP system may be found inadequate if, during the field verification inspection, the regulator finds that actual procedures, corrective actions, records, critical limits, or verification procedures are not in compliance with regulations or the validated HACCP Plan. Some of these inadequacies may include:

- Aspects of the validated HACCP plan, do not match observations made during the inspection
- Changes have been made to the validated HACCP plan without prior review by the regulatory authority
- Establishment personnel are not performing tasks specified in the validated HACCP Plan
- The establishment fails to take corrective actions, as required by regulation, or as stated in the validated HACCP Plan
- HACCP records are not being maintained as required by regulation or as stated in the validated HACCP Plan
- Adulterated product is being produced or transported

Enforcement/ Corrective Action

During the field verification inspection, any finding, considered to have an immediate impact on public health and safety, must be assessed. When necessary, immediate corrective, or compliance action, must be taken to control the hazard and/or the product.

On-site corrective actions, or subsequent enforcement actions, should be appropriate to the type of violation and could include one or more of the following:

- Reheating when small deviations from hot holding have occurred
- Continued cooking when proper cooking temperatures have not been met
- Initiated use of gloves/tongs/utensils to prevent hand contact with ready-to-eat foods, or required hand washing when potential contamination was observed.
- Required hand washing when potential contamination is observed
- Restriction/Exclusions
- Modifications to the HACCP Plan
- Disposal of foods that have experienced extreme temperature abuse or do not comply with critical aspects of the HACCP Plan
- Embargo or disposal of foods from unapproved sources
- Warning letters
- Re-inspection
- Citations/Administrative fines
- Permit suspension
- Hearings
- Suspension
- Emergency closure

Follow-up Field Verification Inspections

It is recommended that follow-up verification inspections be conducted:

- Routinely or on an unannounced basis, to ensure that selected CCPs are under control
- When established criteria have not been met
- Patterns of non-compliance\non-conformance noted, indicating a systematic failure of management control
- When foods prepared at the establishment have been implicated as a vehicle of foodborne disease
- To verify that changes have been implemented correctly after a HACCP plan has been modified
- When requested on a consultative basis and resources allow accommodating the request

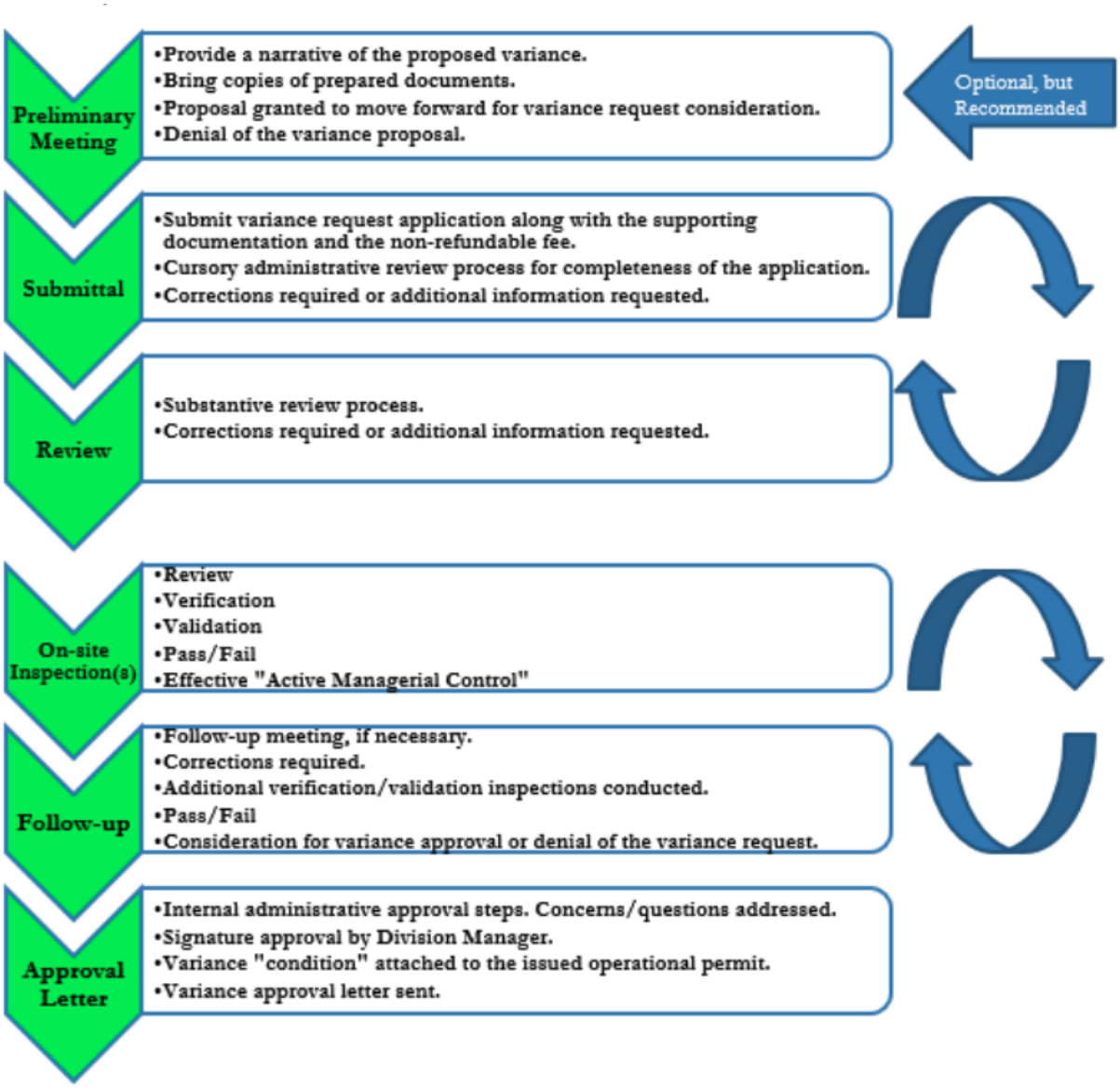
Review of changes to the initial HACCP plan should be carried out during a follow-up regulatory inspection. The establishment's records will form the basis to validate and verify the HACCP plan changes.

Prior to the follow-up inspection, the regulatory authority may wish to contact a regional expert for clarification or direction with regard to HACCP plan changes.

Following a successful inspection for changes to the HACCP Plan, the regulatory authority should issue an acceptance letter to the establishment.

Variance/HACCP Plan Approval Process

Approving a variance and a HACCP plan requires both validation and ongoing field verification by the regulatory authority. Each regulatory authority may have its own process. The following is an example of how the approval process may flow.



Reproduced from Maricopa County Environmental Services Department HACCP/Variance Guide

On the following pages you will find the Model Forms listed below. They have been added to assist those regulatory authorities that have not yet started a formal application process for specialized processes, or may wish to expand their current process..

1. Variance Request Form (Short Version)
2. Variance Request Decision from the Regulatory Authority (RA)
3. Variance Request Form (Detailed Version)
4. Model HACCP Plan Review Application
5. Model HACCP Plan Validation Checklist
6. Model HACCP Plan Field Verification Checklist

Variance Request Form (Short 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: _____

Variance Request Decision from the Regulatory Authority

For Official Use Only

Date of Hearing: _____

☐ Approved as submitted

☐ Approved with the following condition(s):

☐ Disapproved – Reason(s):

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

This variance is specific to the location and the current owner of the establishment set forth in the variance request application and is **NOT TRANSFERABLE**.

Any changes to the approved variance request as submitted will render this variance null and void.

REQUEST FOR A VARIANCE (Detailed Version)

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 [ ]**

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

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:**

    - o Ingredients, materials, and equipment used in the preparation of the food
    - o 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:**

    - o Each critical control point (CCP)
    - o The critical limits for each CCP
    - o The method and frequency for monitoring and controlling each CCP by the food employee designated by the person in charge (PIC)
    - o The method and frequency for the PIC to routinely verify that the food employee is following standard operating procedures and monitoring CCP's
    - o Action to be taken by the PIC if the critical limits for each CCP are not met
    - o 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:

[Please enter here the Regulatory Authority's name and address]

Please contact your local Regulatory Authority for assistance when completing and submitting the application.

Variances are intended for the allowance of specialized processes that will enhance operations with science based controls and monitoring. All supporting documentation must be submitted along with this completed application. Please contact your local Regulatory Authority (RA) for assistance in completing this application. Incomplete applications cannot be reviewed and will be returned to the applicant. You and the local RA will be notified upon the receipt of your application. After your application and supporting documentation have been reviewed, you will be contacted regarding the Request for Variance.

Approved Variance Requests and HACCP Plans are final and no changes or modifications may occur without prior review and approval by this Department. Compliance with approved variances will be reviewed during regulatory inspections. It is the responsibility of the establishment to follow the procedures approved by the regulatory authority and to notify the regulatory authority immediately if there is to be any change made in the approved process.

Variance Agreement

- Once the variance is approved by the regulatory authority, they will verify the plan is being followed as part of the ongoing inspection process. If the variance is not being followed, approval may be revoked by the NCVC and all operations associated with the variance shall cease. After the deficiencies have been corrected the permit holder may apply for another variance.
- If the RA determines that the variance is not being followed or if recurring deficiencies are observed a conference may be required. If deficiencies persist the case shall be forwarded to the Department for consideration of continued approval or revocation of the variance.
- Any adjustment or deviation from the approved variance will require resubmission of the variance request to the NCVC.
- Monitoring records must be maintained as specified in the variance approval and be available upon request from RA during routine inspections or any other time the request is made by the RA.
- A copy of the variance must be maintained on site and conveniently located, such that it is available for review by appropriate food employees and the RA during routine inspections or any other time the request is made by the RA.

Statement: I hereby certify the information provided within this application is accurate and I understand that any deviation without prior approval from the Department may nullify the variance approval. I understand this application will be returned to me if incomplete and will delay further processing. I have read and understand the Variance Agreement.

Signature: _____

Title: _____

Establishment Name: _____ Date: _____

Regulatory Authority use only:

Received: _____/_____/_____ First Application Submittal: _____ Resubmittal: _____

Notified: _____/_____/_____ Check one: Email_____ USPS_____ Other_____

Entered & Scanned to database: _____/_____/_____

Reviewed: _____/_____/_____ Contacted: _____/_____/_____Check one: Approved ___Denied___ Need more info___

Returned to Applicant

Notes:

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:

Model HACCP Plan Validation Checklist

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 the 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 the 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?
- ☐ Is there a statement regarding sending notification of changes in process or HACCP plan to the regulatory authority?

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**
Records available and accurate to address Critical Limits at each CCP. (Sample Logs Attached, i.e. Monitoring, Corrective Actions)	**In**	**Out**
Employee Training	**In**	**Out**
Evidence of Food employee training provided.		
Inspector:		
Date of Field Verification:		

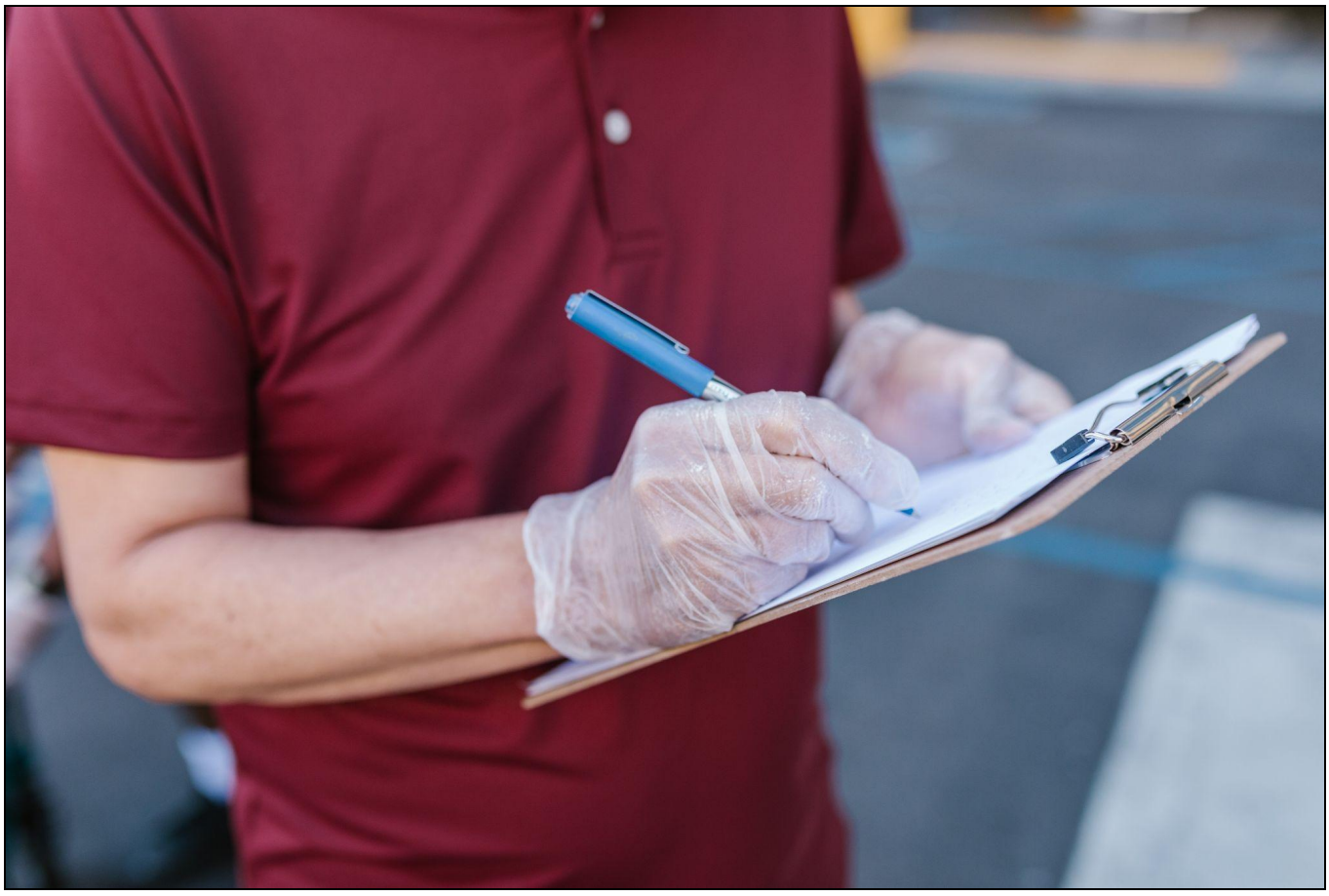
Corrective Action Taken?

- ☐ **NO** (Establishment is in compliance with approved procedures)
- ☐ **YES** (If **YES**, please indicate corrective action taken below)
  - ☐ Order for Correction Issued (Inspection Report Form or Letter)
  - ☐ Emergency Suspension or Operation
  - ☐ Embargo
  - ☐ Voluntary Disposal
  - ☐ Employee Restriction/Exclusion
  - ☐ Employee Training
  - ☐ Other

Appendix
Field Verification Checklists

The following Field Verification Checklists 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.

HACCP plans must be tailored to meet a specific operation. These checklists have been provided to assist you in developing a verification checklist to meet a specific HACCP plan that has been validated *prior to visiting the operation* to verify that the plan and practices match the HACCP plan as validated. These checklists are not required, and may need revisions in order to conform to a specific HACCP plan.



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:

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: _____

Adding Components or Food Additives HACCP Plan Validation Checklist

Hazard Analysis and Flow Chart

- ☐ Name of the food product and the special process for which the HACCP system 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
- ☐ Facility layout and information on whether a dedicated work space is provided to conduct the process
- ☐ Copy of labeling – Check for any required warnings such as consumer advisory for raw fish Hazard Analysis
- ☐ Intended Use of Product/Institutional use?/HSP?
- ☐ How it will be sold or served including package size
- ☐ Shelf-life – Date marking or Time as a Public Health Control
- ☐ A detailed flow chart showing the holding and preparation of the food product from receiving raw ingredients through packaging and any subsequent distribution. Flow charts 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.

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 flowchart that are designed to control hazards associated with the food
- ☐ Description of how the CCP will control the pertinent hazards and specific reference information

Establish Critical Limits

- ☐ A CL must be provided for each CCP Is the CL correct based on the Food Code?
- ☐ Can the CL be measured? How?
- ☐ Will this CL control the hazard(s)?

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, letter of guarantee for parasite destruction in raw fish, 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 the instrument calibrated?
- ☐ Is employee training documented?
- ☐ How will records for continuous monitoring be provided?

Establish Corrective Actions *The following should be provided:*

- ☐ Have a specific corrective action(s) 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?

Establish Record Keeping Procedures
The following should be provided:

- ☐ Where are the 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?

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?
- ☐ Is there a statement regarding sending notification of changes in process or HACCP system to the regulatory authority?

Sushi Rice Job Aid

The following must be included in a Sushi Rice HACCP Plan:

1. A recipe or formulation for the Sushi Rice HACCP Plan, which must include all of the following:
    - Type of rice (e.g. “short grain” sticky rice, brown rice)
    - The type, brand and concentration of the vinegar (e.g. 5 % Koyoto rice wine vinegar)
    - Methods of cooking rice, including the time and temperature
    - Methods of preparing mixture of vinegar, salt, and sugar
    - Method of cooling cooked rice, indicating time and temperature
    - Method of mixing rice and vinegar solution
    - Critical Control Points (e.g. adding vinegar to achieve pH of less than 4.2)
    - The pH of the sushi rice must be initially validated by an accredited laboratory to indicate the final target pH is less than 4.2
    - Laboratory results should be submitted with the plan
    - Methods of measuring and the frequency of monitoring the CCP (e.g. measuring the pH for each batch by using a calibrated pH meter or 4-color match pH test strip with an accuracy of 0.05 pH units)
    - Corrective actions are described (e.g. if the pH is not less than 4.2, the sushi rice will be discarded or more vinegar will be added)
    - Policy and procedures regarding storage of sushi rice should indicate holding time and temperature
2. A sample of sushi rice must be sent for pH testing to an accredited laboratory when:
    - Changing recipe or ingredients (for example: changing the type of rice or vinegar)
    - Annually, after the initial submission of the HACCP Plan
3. Describe policy regarding leftovers of the sushi rice.
4. Describe policy regarding record keeping, for example: keeping a record of all sushi rice HACCP plan related documents for at least 2 years.

This procedure was adapted from the California Retail Food Code (CAL CODE), Article 5. Section 114419 (3).

ROP HACCP Plan Validation Checklist

Hazard Analysis and Flow Chart

- ☐ Name of the food product and the special process for which the HACCP system 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 the 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 will it 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

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
- ☐ *Vegetative cells – Listeria monocytogenes
- ☐ *Spore formers – Clostridium botulinum
- ☐ Critical Control Points on the flowchart that are designed to control hazards associated with the food
- ☐ *Cooking (if applicable) – destroys vegetative cells
- ☐ *Cooling (if applicable) – prevents spore germination
- ☐ *Primary barrier (refrigeration or other required holding temperatures) *Secondary barrier(s)
- ☐ Description of how the CCP will control the pertinent hazards and specific reference information sources.

Establish Critical Limits

A CL must be provided for each CCP

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

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, a_w, equipment calibration, temperatures, recipe for 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?

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?

Establish Record Keeping Procedures The following should be provided:

- ☐ Where are the 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?

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?
- ☐ Is there a statement regarding sending notification of changes in process or HACCP system to the regulatory authority?

HACCP Field Verification Checklist Reduced Oxygen Packaging		
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:
YES	**NO**	**Establishment has Implemented Effective SOP and SSOP Prerequisites (Document violations on your Food Establishment Inspection Report)**
		Vendor certification programs and buyer specifications
		Food preparation complies with HACCP Plan
		Packaging (Seal is complete-no debris in seal; labels; no cross contamination)
		Hand washing and bare hand contact policies
		Dedicated work areas for raw and prepared foods
		Equipment specifications/Manufacturer's instructions and operational manual.
		Employee health policy (training and reporting requirements; exclusion and restriction requirements for il food employees)
		Storage and display temperature 5°C (41°F)/ 3°C (38°F)/ 1°C (34°F)
		Storage and display (shelf-life; expiration dates)
		Cook-chill/Sous vide (continuous electronic monitoring; visual examination two times per day)
		Cook chill/Sous vide products are not sold to any other business entity or to the public in bagged or packaged form
		Employee training
		Employee hygiene policy (clean clothing; hair restraints; prohibition of eating, smoking and drinking in work areas and of wearing jewelry)
		Thermometer calibration procedures and schedule
		Records
		First in and First out requirements and procedures
		Program to protect product from contamination--biological, chemical and physical
		Cleaning and sanitizing procedures
		Other
Comments:		

List Critical Control Points (CCPs) and Critical Limits identified by the establishment's verified HACCP plan

Food Item or Process e.g. receiving, cooler storage, dry storage	Critical Control Point	Critical Limits	Comments/ Problems Noted

What monitoring records are required by the establishment's verified HACCP plan?

Type of Record	Monitoring Frequency and Procedure	Record Location (Where kept?)

YES	NO	Accurate Description of Product/Process and Intended Uses
		Food flow, menu, packaging and formulation are consistent with flow chart and approved HACCP
		Temperature and other critical control points and critical limits are followed per HACCP plan
		ROP products not requiring a variance are packaged as prescribed by the Food Code Section 3.502.12
		Employee demonstrates calibration, temperature and CCP measurement for inspector
		Employee uses forms for recording recipe, calibration, temperature or other measurement during inspection
		An accurate description or list of products to be reduced oxygen packaged is provided in the HACCP plan
Comments:		

YES	NO	Hazards
		Establishment identifies individual(s) responsible for maintaining system and verification that required records are being completed and properly maintained
		Records for the present day accurate for the observed situation in the facility?
		Employee demonstrates knowledge of CCPs and critical limits for their retail process when asked
		Employee demonstrates understanding of importance of critical limit(s) when asked
		Routine calibrations are performed/ documented on the appropriate form according to the plan
		Monitoring actions are performed according to the HACCP plan
		Are there specific strengths or weaknesses with the current monitoring or record keeping regime? If yes, note in comments
		Expiration dates on packages, and items discarded beyond the appropriate expiration date
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 whom to contact to take corrective actions. Uses corrective action monitoring form
		Person-in-charge shows knowledge of corrective action and proper disposal of food unfit for consumption
		Corrective actions taken reflect the same actions described in the establishment's plan
Comments:		

YES	NO	Training
		The establishment has a training program to support the plan. If deficient, describe in comments
		When training is provided, is it documented and are the records available?
		Employee demonstrates calibration and pH, temperature or CCP measurement for inspector
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: _____

Cook-Chill and Sous Vide Time Temperature Standards

Cook-chill and sous vide products should be protected from contamination before and after cooking.

They should be placed in a package with an oxygen barrier and sealed prior to cooking or sealed immediately after cooking - before temperature drops below 57°C (135°F).

Cooked potentially hazardous food (time/temperature control for safety food) shall be cooled:

- Within 2 hours from 57°C (135°F) to 21°C (70°F); and
- Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less.

Cook-chill and sous vide products should be rapidly cooled to 5°C (41°F) in a sealed package or bag and subsequently cooled to the following:

- Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), and held at that temperature until consumed or discarded within 30 days after the date of packaging;
- Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours, at which time the food must be consumed or discarded;
- Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from packaging, at which time the food must be consumed or discarded;
- Held frozen with no shelf life restriction while frozen until consumed or used.

Note: Opening the ROP package before the expiration date does not extend the shelf life beyond the expiration date unless a variance is obtained.

Refrigeration units storing cook-chill and sous vide products must be continuously monitored electronically and visually examined twice daily. If food products are transported to a satellite location, temperatures must be monitored during transportation.

HACCP Field Verification Checklist Operating Molluscan Shellfish Life Support System Display Tanks at Retail		
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:		
YES	**NO**	**Establishment has Implemented Effective SOP and SSOP Pre-Requisites (Document violations on your Food Establishment Inspection Report)**
		Vendor Certification Programs and Buyer Specifications
		Equipment Specifications/Manufacturer's Instructions and Operational Manual
		Employee Health Policy (training and reporting requirements, exclusion and restriction requirements for ill food employees)
		Handwashing and Bare Hand Contact Policies
		Employee Hygiene Policy (clean clothing, hair restraints, prohibition of eating, smoking, and drinking in work areas and of wearing jewelry)
		Commingling Protocol (CRITICAL)
		Culling Procedures (dead and cracked shellfish discarded)
		Temperature Control Requirements
		Thermometer Calibration Procedures and Schedule
		Record System for Retention of Shellfish Tags (system to maintain the tags in chronological order for 90 days after the container is empty)
		First In and First Out Requirements and Procedures
		Program to Protect Product from Contamination--Biological, Chemical and Physical
		Equipment/System Maintenance Program (Tank and UV Disinfection System)
		Cleaning and Sanitizing Procedures
		Other
Comments:		

List Critical Control Points (CCPs) and Critical Limits identified by the establishment's verified HACCP plan.

Food Item or Process e.g. receiving, cooler storage, tank storage	Critical Control Point	Critical Limits	Comments/ Problems Noted

What monitoring records are required by the establishment's verified HACCP plan?

Type of Record	Monitoring Frequency and Procedure	Record Location (Where kept?)

YES	NO	Accurate Description of Product/Process and Intended Uses
		Food flow, shellfish, and packaging are consistent with flow chart and approved HACCP plan

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 limits for their retail process 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 regiment? 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 whom to contact to take corrective actions. Uses corrective action monitoring form
		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
		When training is provided, is it documented and are the records available?
		Employee demonstrates calibration and pH, temperature or CCP measurement for inspector
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: _____

Live Molluscan Shellfish Holding Tank HACCP Validation Checklist

Prerequisites Programs/Standard Operating Procedures

- ☐ Vendor Certification Programs and Buyer Specifications.
- ☐ Equipment Specifications/Manufacturer's Instructions and Operational Manual.
- ☐ Employee Health Policy (training and reporting requirements, exclusion and restriction requirements for ill food employees).
- ☐ Hand washing and Bare hand Contact Policies.
- ☐ Employee Hygiene Policy (clean clothing, hair restraints, prohibition of eating, smoking, and drinking in work areas and of wearing jewelry).
- ☐ Commingling Protocol (CRITICAL).
- ☐ Culling Procedures (dead and cracked shellfish discarded).
- ☐ Temperature Control Requirements
- ☐ Thermometer Calibration Procedures and schedule
- ☐ Record System for Retention of Shellfish Tags (system to maintain the tags in chronological order for 90 days after the container is empty).
- ☐ First In and First Out Requirements and Procedures.
- ☐ Program to Protect Product from Contamination--Biological, Chemical and Physical. Equipment/System Maintenance Program (Tank and UV Disinfection System).
- ☐ Cleaning and Sanitizing Procedures.
- ☐ Toxic Chemical and Cleaners Handling and Storage Requirements.

Hazard Analysis Included:

Control Points

- ☐ Receiving (Approved Source)
- ☐ Receiving (Temperature)
- ☐ Cooler Storage.
- ☐ Tank Storage - (Water Temperature).
- ☐ Tank Storage - (Water Quality/Total Coliform Testing).

Critical Limit Identified

- ☐ Receiving – Approved Source.
- ☐ Receiving Temperature, 10°C (50°F)
- ☐ Cooler Storage – Temperature, 10°C (50°F)
- ☐ Tank Storage – Water Temperature 5°C (41°F) Total Coliform Testing, (Maximum = 0 MPN).

Monitoring Procedures

- ☐ Receiving- Receiving temperature of every container should be checked and visually checked for shellfish certification tag to verify dealer on ICSSL by the designated employee for each shipment. Cooler Storage – Temperature check of cooler with thermometer two times (2X) a day by designated employee.
- ☐ Tank Storage – Temperature check of water with thermometer two times (2X) a day by designated employee.
- ☐ Tank Storage – Water sample taken once a week and sent to laboratory for testing by designated employee.

Corrective Actions When the Critical Limits are not Met

These are examples of corrective actions.

- ☐ Receiving – Approved Source- The shipment would be rejected and corrective actions documented on records.
- ☐ Cooler Storage – Add ice to product, move to another functioning cooler and make adjustments to the malfunctioning cooler, AND either destroy or hold the product until the time/temperature abuse can be evaluated. Corrective actions documented on records.
- ☐ Tank Storage (Water Temperature) – Add ice to water, move the product to a functioning cooler, AND hold the product until the time/temperature abuse can be evaluated or destroy the product. Corrective actions documented on records.
- ☐ Tank Storage (Total Coliform Testing) – A positive TC requires immediate re-sampling and a second positive TC requires the tank to be cleaned and sanitized and the product in the tank destroyed. Corrective actions documented on records.

Record Identified

- ☐ Receiving – Temperature and source records.
- ☐ Cooler Storage – Cooler temperature log and thermometer calibration log.
- ☐ Tank Storage – Water temperature log and thermometer calibration log.
- ☐ Tank Storage – Water sample, laboratory result logs and corrective actions documentation on records.

Verification Process Identified

- ☐ Receiving – Daily monitoring, weekly verification of temperature/source logs.
- ☐ Cooler Storage – Daily monitoring, weekly verification of records of cooler logs and monthly calibration of thermometers with quarterly record verification.
- ☐ Tank Storage (Water Temperature) – Daily monitoring, weekly verification of records. Monthly thermometer calibration with quarterly record verification.
- ☐ Tank Storage (Water Sample) –Weekly monitoring of lab results with any corrective actions documented. Weekly verification of records.

Employee Training Plan

- ☐ Employee Health
- ☐ Employee Hygiene
- ☐ Contamination Prevention Procedures
- ☐ Equipment Use and Maintenance
- ☐ Monitoring Procedures
- ☐ Corrective Action Procedures
- ☐ Recordkeeping Procedures

HACCP Plan Field Verification Checklist - Custom Processing of Meat for Personal Use		
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:		

YES	NO	Establishment has Implemented Effective SOP and SSOP Pre-Requisites (Document violations on your Food Establishment Inspection Report)
		Vendor Certification Programs and Buyer Specifications
		Equipment Specifications/Manufacturer's Instructions and Operational Manual
		Employee Health Policy (training and reporting requirements, exclusion and restriction requirements for ill food employees)
		Handwashing and Bare Hand Contact Policies
		Employee Hygiene Policy (clean clothing, hair restraints, prohibition of eating, smoking, and drinking in work areas and of wearing jewelry)
		Packaging (Seal is complete-no debris in seal; labels; no cross contamination)
		"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
		Separate storage areas in cold storage units for Custom Processes meat products
		Thermometer Calibration Procedures and Schedule
		Records (carcasses tags identified, written list, receiving log book and times when animals processed)
		Program to Protect Product from Contamination--Biological, Chemical and Physical
		Dedicated work areas for Custom Processed meat items that is separate from retail meat Items
		Cleaning and sanitizing all equipment used to process Custom Processed meat before domestic meat and retail products.
		Other
Comments:		

List Critical Control Points (CCPs) and Critical Limits identified by the establishment's verified HACCP plan.

Food Item or Process e.g. receiving, cooler storage, tank storage	Critical Control Point	Critical Limits	Comments/ Problems Noted

What monitoring records are required by the establishment's verified HACCP plan?

Type of Record	Monitoring Frequency and Procedure	Record Location (Where kept?)

YES	NO	Accurate Description of Product/Process and Intended Uses
		Food flow, shellfish, and packaging are consistent with flow chart and approved HACCP plan
		Temperature, pH and other critical control points and critical limits are followed per HACCP Plan
		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 limits for their retail process when asked
		Employee demonstrates understanding of the 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 regiment? 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 whom to contact to take corrective actions. Uses corrective action monitoring form
		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
		When training is provided, is it documented and are the records available?
		Employee demonstrates calibration and pH, temperature or CCP measurement for inspector
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: _____

HACCP Plan Field Verification Checklist - Curing and Smoking of Meat and Poultry		
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: Smoking to extend shelf life or for flavor?
Comments:		

YES	NO	Establishment has Implemented Effective SOP and SSOP Pre-Requisites (Document violations on your Food Establishment Inspection Report)
		Vendor Certification Programs and Buyer Specifications
		Approved vendor documentation and product labeled for traceability
		Equipment Specifications/Manufacturer's Instructions and Operational Manual
		Employee Health Policy (training and reporting requirements, exclusion and restriction requirements for ill food employees)
		Handwashing and Bare Hand Contact Policies
		Employee Hygiene Policy (clean clothing, hair restraints, prohibition of eating, smoking, and drinking in work areas and of wearing jewelry)
		Employee hygiene policy (clean clothing, hair restraints, prohibition of eating, smoking, and drinking in work areas and of wearing jewelry)
		Temperature, time and humidity meets Lethality Standards based on the product or have another approved validated process
		Time/Temperature Controls including cooling of product
		Water Activity and pH
		Thermometer calibration procedures and schedule available
		Dry curing
		Brine should be carried out under refrigeration for no longer than 4 hours.
		Brine should be monitored with a calibrated salinometer.
		Meat should be hung on smoking rods and allowed to dry for approximately 2 hours

		Program to protect product from contamination--biological, chemical and physical, especially post processing
		Records for temperatures during each part of the process should be documented on separate temperature logs
		Dedicated work areas for all processes.
		Cleaning and sanitizing all equipment used to process the cured, dried, smoked fish.
		Other
Comments:		

List Critical Control Points (CCPs) and Critical Limits identified by the establishment's verified HACCP plan.

Food Item or Process e.g. receiving, cooler storage, tank storage	Critical Control Point	Critical Limits	Comments/ Problems Noted

What monitoring records are required by the establishment's verified HACCP plan?

Type of Record	Monitoring Frequency and Procedure	Record Location (Where kept?)

YES	NO	Accurate Description of Product/Process and Intended Uses
		Food flow, shellfish, and packaging are consistent with flow chart and approved HACCP plan
		Temperature, pH and other critical control points and critical limits are followed per HACCP Plan
		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 limits for their retail process when asked.
		Employee demonstrates understanding of the importance of critical limit(s) when asked.
		Routine calibrations performed, and documented on the appropriate form according to the plan?
		Monitoring actions performed according to the HACCP plan?
		Are there specific strengths or weaknesses with the current monitoring or record keeping regime. 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 whom to contact to take corrective actions. Uses corrective action monitoring form
		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
		When training is provided, is it documented and are the records available?
		Employee demonstrates calibration and pH, temperature or CCP measurement for the inspector .
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: _____

HACCP Field Verification Checklist - Fermentation of Sausages		
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: Is jerky RTE? Does it contain beef?
Comments:		

YES	NO	Establishment has Implemented Effective SOP and SSOP Pre-Requisites (Document violations on your Food Establishment Inspection Report)
		Vendor Certification Programs and Buyer Specifications
		Approved vendor documentation and product labeled for traceability
		Equipment Specifications/Manufacturer's Instructions and Operational Manual
		Employee Health Policy (training and reporting requirements, exclusion and restriction requirements for ill food employees)
		Hand washing and bare hand contact policies
		Employee Hygiene Policy (clean clothing, hair restraints, prohibition of eating, smoking, and drinking in work areas and of wearing jewelry)
		Temperature, time and humidity meets Lethality Standards based on the product, or another approved validated process is available
		Proper time/temperature controls implemented, including degree hours, during fermentation
		Proper water activity and pH controls implemented
		Starter cultures used in curing process
		Thermometer calibration procedures and schedule available
		Proper drying and humidity temperature implemented
		Program to protect product from contamination--biological, chemical and physical
		Records for controls implemented during each part of the process documented
		Dedicated work areas for all processes
		Cleaning and sanitizing all equipment used to process the fermented sausages
		Other – Training, etc.
Comments:		

List Critical Control Points (CCPs) and Critical Limits identified by the establishment's verified HACCP plan.

Food Item or Process e.g. receiving, cooler storage, tank storage	Critical Control Point	Critical Limits	Comments/ Problems Noted
*Per FSIS Performance Standard			

What monitoring records are required by the establishment's verified HACCP plan?

Type of Record	Monitoring Frequency and Procedure	Record Location (Where kept?)

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
		Critical control points and critical limits are followed per HACCP Plan
		Employee demonstrates calibration and pH, temperature or CCP measurement for inspector
		Employee uses forms for recording formulation, calibration, and 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
		Records for the present day are accurate for the observed situation in the facility
		Employee demonstrates knowledge of CCPs and critical limit for their retail process when asked
		Routine calibrations are performed and documented on the appropriate form according to the plan
		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
		Shelf-stable fermented sausage meets required water activity or MPR requirements
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
		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
		When training is provided, is it documented and are the records available?
		Employee demonstrates calibration and CCP measurement for inspector
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: _____

HACCP Plan Field Verification Checklist - Jerky (Fully Cooked, Shelf Stable, RTE Meat and Poultry)		
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: Is jerky RTE? Does it contain beef?
Comments:		
YES	**NO**	**Establishment has Implemented Effective SOP and SSOP Pre-Requisites (Document violations on your Food Establishment Inspection Report)**
		Employee Health Policy (training and reporting requirements, exclusion and restriction requirements for ill food employees)
		Time/Temperature Controls \
		Cleaning and Sanitation
		Inspected and/or Reputable Suppliers of Meat and Ingredients
		Water Quality and Management
		Protection of Food/Ingredients from Chemicals/Contamination
		Recipe/Menu Production Standards
		Critical Equipment Operation/Calibration/Operation of Drying Ovens/Humidity Control
		Facilities/Equipment Maintenance
		Employee Education and training
		Packaging, Storage and/or Distribution (no rehydration)
		Other
Comments:		

List Critical Control Points (CCPs) and Critical Limits identified by the establishment's verified HACCP plan.

Food Item or Process e.g. receiving, cooler storage, tank storage	Critical Control Point	Critical Limits	Comments/ Problems Noted
Cooler Storage	*Temperature	<5°C (41°F)	
Heat Lethality	*Humidity and Temperature	>77°C (170°F) dry bulb in 30 min 52°C (125°F) – 61°C (142°F) wet bulb*	
Drying	*Water activity	<.88	

*Per FSIS Performance Standard
http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95033F_Appendix_A.htm

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
		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

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
		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 demonstrates calibration and pH, temperature or CCP measurement for inspector .
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: _____

HACCP Field Verification Checklist - Packaging of Juices		
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:
YES	NO	**Establishment has Implemented Effective SOP and SSOP Pre-Requisites (Document violations on your Food Establishment Inspection Report)**
		Employee health and hygiene
		Time/Temperature controls
		Cleaning and sanitation
		Approved food sources
		Fruit rejection standards
		Water quality and management
		Protection of food/ingredients from chemicals/contamination
		Recipe/Menu production standards
		Food protection management (including SOP for recording and monitoring specified items)
		Facilities/Equipment maintenance
		Employee education and training
		Storage
		Other
Comments:		

List Critical Control Points (CCPs) and Critical Limits identified by the establishment's verified HACCP plan.

Food Item or Process e.g. receiving, cooler storage, storage	Critical Control Point	Critical Limits

What monitoring records are required by the establishment's verified HACCP plan?

Type of Record	Monitoring Frequency and Procedure	Record Location (Where kept?)
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 and other critical control points and critical limits are followed per HACCP Plan
		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 the system and verification that required records are being completed and properly maintained is identified by the establishment.
		Are the records for the present day accurate for the observed situation in the facility?
		Employee demonstrates knowledge of CCPs and critical limits for their retail process when asked.
		Employee demonstrates understanding of the 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 regime. 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
		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.
		When training is provided, is it documented and are the records available?
		Employee demonstrates calibration and pH, temperature or CCP measurement for the inspector.
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: _____

HACCP Field Verification Checklist - Sprouting at Retail

Establishment Name:		
Address:		
Person(s) in Charge: Phone Email:		
Date Written Plan Validated:		
Food Product and Process:		
Inspection Type: ☐ **HACCP Plan Review** ☐ **Record Review** ☐ **OnSSite Verification**		
Inspector:		
YES	**NO**	**Validated HACCP Plan Available for Review**
		Comments:
YES	**NO**	**Establishment has Implemented Effective SOP and SSOP Prerequisites (Document violations on your Food Establishment Inspection Report)**
		Employee Health and Hygiene
		Time/Temperature Controls
		Cleaning and Sanitation
		Approved Seed Sources
		Water Quality and Management
		Protection of Food/Ingredients from Chemicals/Contamination
		Recipe/Menu Production Standards
		Food Protection Management (Including SOP for recording and monitoring specified items)
		Facilities/Equipment Maintenance
		Employee Education and Training
		Storage
		Other
Comments:		

List Critical Control Points (CCPs) and Critical Limits identified by the establishment's verified HACCP plan.

Food Item or Process e.g. receiving, cooler storage, storage	Critical Control Point	Critical Limits	Comments/ Problems Noted

What monitoring records are required by the establishment's verified HACCP plan?

Type of Record	Monitoring Frequency and Procedure	Record Location (Where kept?)

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 and other critical control points and critical limits are followed per HACCP Plan
		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
		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
		When training is provided, is it documented and are the records available?
		Employee demonstrates calibration and pH, temperature or CCP measurement for inspector

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: _____

Glossary

Terms	Definitions
Acceptable Product List	means a list of meat or poultry products for which a HACCP Plan has been approved by a process authority.
Active Managerial Control	The implementation and supervision of food safety practices to control risk factors by the person-in-charge.
Adequate Record Keeping System	An adequate record keeping system is the heart of a HACCP program. Records are the documentation needed to verify effectiveness of the HACCP plan. They are the only reference available to trace the production history of a finished product. If questions arise concerning the product, a review of the records may be the only way to ascertain or prove that the product was prepared and handled in a safe manner in accordance with all the HACCP principles outlined in the establishment's HACCP plan.
Aerobic bacteria	Requires oxygen for their basic survival, growth, and reproduction
Anaerobic bacteria	Does not require oxygen for survival or growth.
a_w	A measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature
Biological hazards	Biological hazards include: bacteria, bacterial toxins, viruses and parasitic organisms that could survive, grow, or contaminate food products/raw materials, and potentially cause foodborne illness. (See chart entitled: Selected Factors Influencing Growth of Common Foodborne Pathogens following Principle #7.)
Calcium Hypochlorite	is the main active ingredient of commercial products called bleaching powder, chlorine powder, or chlorinated lime, used for water treatment and as a bleaching agent. This compound is relatively stable and has greater available chlorine than sodium hypochlorite. It is a white solid, although commercial samples appear yellow. It strongly smells of chlorine, owing to its slow decomposition in moist air.
Case hardening	Case hardening occurs if relative humidity is too low when drying meat. A thick crust forms on the outside of the jerky that inhibits the transference of heat into the center of the food. Pathogens inside the jerky can survive.
Casings	mean natural animal stomachs, intestines or bladders or manufactured casings of cellulose or collagen, which are used to contain comminuted meat, or poultry product mixtures for sausages.
Chemical hazards	Chemical hazards could result from a number of sources: agricultural chemicals, insecticides, fungicides, cleaning/sanitizing agents, certain naturally- occurring toxins such as Scombrotoxin (histamine), Ciguatoxin, mycotoxins from mold, shellfish toxins, etc., and misuse of food chemicals (preservatives, additives, etc.).
Comminuted	means reduced in size by methods including chopping, flaking, grinding, or mincing.
Cold Smoking	means a smoking process used to apply smoke or a smoke flavor at or near ambient temperature to food products not sufficiently darkened or flavored in the original cooking process.
Control Point	Any point in a specific food system at which loss of control does not lead to an unacceptable health risk.

Controlled atmosphere packaging (CAP)	An active system which continuously maintains the desired atmosphere within a package throughout the shelf-life of a product by the use of agents to bind or scavenge oxygen or a sachet containing compounds to emit a gas. Controlled Atmosphere Packaging (CAP) is defined as packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere using impermeable packaging material.
Cook-chill packaging	When the atmosphere of a package is hot, it is filled into impermeable bags that have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotropic (cold-loving) pathogens.
Corrective Action	A procedure followed when a deviation occurs. Corrective actions must be taken whenever monitoring indicates that limits or tolerances are not met. Such action must be immediate to assure that the situation is rectified. Action will vary with the process being monitored and the type of monitoring indicated.
Critical Control Point	A point or procedure in a specific food system where loss of control may result in an unacceptable health risk.
Critical Operational Parameters	are those parameters of an intervention that must be met in order for the intervention to operate effectively and as intended. Such parameters include but are not limited to time, temperature, water activity, concentration, relative humidity, and type of equipment (to the extent that the use of different equipment would result in an inability to achieve the critical parameters of the study).
Critical Limit	The maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize risk that the identified food safety hazard may occur.
Culled	The separation of damaged fruit from undamaged fruit.
Cure Accelerator	means compounds such as ascorbic acid or erythorbic acid or their derivatives, sodium ascorbate and sodium erythorbate as defined for use in 9 CFR ¶ 318.7(c)(4), which shorten the time required for the distinctive pink color to develop in cured meat and poultry products.
Cured sausages	Cured sausages may be categorized as: (1) raw, cured; (2) cooked, smoked; (3) cooked, unsmoked; and (4) dry, semi dry, or fermented.
Curing	A process of preserving meat by the application of salt, nitrite and seasonings to meat and is characterized by the interaction of nitrite and meat pigments resulting in the development of a "cured" pink color.
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
Deviation	Failure to meet a required critical limit for a critical control point.
Dry Fermented Sausage	means a product made of chopped or ground meat products that, as a result of bacterial action, reaches a pH of 5.3 or less and is then dried to remove 25-50% of the moisture to have a moisture/protein ratio in compliance with USDA requirements. Dry fermented sausages include hard salami, Genoa salami, and pepperoni.

Drying	The process during which water (moisture) is removed from the product. After the lethality treatment, jerky is dried to meet a water activity level sufficient to prevent the growth of microorganisms, especially toxigenic microorganisms such as *Staphylococcus aureus.*
Dry bulb temperature	The dry bulb temperature refers to the ambient air temperature. It is called a "dry bulb" because the air temperature is indicated by a thermometer not affected by the moisture in the air or evaporative cooling that removes heat and moisture from the surface of the product.
Equilibrium pH	The pH of the food after the acid has been mixed in or has been in contact with the food for a specified time.
Extenders	are any materials such as textured soy protein or cereals that are added to the ground or shredded animal flesh and must be properly declared in the labeling of the product.
Fallen fruit	means fruit that has fallen naturally from the tree to the ground in an orchard. It does not include mechanically harvested fruit, which is obtained by shaking the tree and collecting the fruit from the ground with appropriate mechanical machinery; also called grounders, windfall fruit, or drops.
Field dressed	means that the body cavity has been opened and the internal organs removed.
Food hazard	is any unacceptable contamination by a biological, chemical, or physical agent at sufficient level to cause a food to be unsafe for human consumption. By far the most common agents are biological, mainly pathogenic bacteria, other microorganisms and parasites.
Food processing plant	means a commercial operation that manufactures, packages, labels, or stores food for human consumption, and provides FOOD for sale or distribution to other business entities such as food processing plants or food establishments. Food processing plant does not include a food establishment.
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.
Good Retail Practices (GRPs)	Preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the Food Code interventions or risk factors.
HACCP	An acronym for Hazard Analysis Critical Control Point.
HACCP Plan	A written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by the National Advisory Committee for the Microbiological Criteria for Foods.
HACCP System	The result of implementing the HACCP principles in an operation that has foundational comprehensive, prerequisite programs in place. A HACCP system includes the HACCP plan and all prerequisite programs.
Handling	A Product is often handled after the lethality and drying steps and prior to/during packaging.
Hazard	A biological, chemical, or physical property that may cause an unacceptable consumer health risk.

Hazard Analysis	The process of collecting and evaluating information about hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.
Hazard Analysis Critical Control Point (HACCP)	A prevention-based food safety system that identifies and monitors specific food safety hazards that can adversely affect the safety of food products.
Highly Susceptible Population	Persons who are more likely than other people in the general population to experience foodborne disease because they are immunocompromised; preschool age children, or older adults; and 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.
Identification of CCP(s)	is an important and painstaking process and provides the backbone of HACCP. In addition to the element of hazard control at a CCP, it is equally important that such control can be monitored and adequately verified (see Principles 4 and 7).
Injection	Injection means the process of transferring a curing solution into a whole muscle meat using a needle or group of needles connected to a brine source.
Interstate Certified Shellfish Shippers List (ICSSL)	FDA publication of shellfish dealers, domestic or foreign, who have been certified by a state or foreign Authority as meeting the public health control measures specified in the National Shellfish Sanitation Program (NSSP). The list is updated monthly.
Jerky	means a product made from animal flesh that has been cut into long slices or strips and dried.
Juice	means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or purée. Juice does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as beverages or ingredients of beverages.
Lethality treatment	is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the thermal processing begins (e.g., the product is placed in the heated oven) until the point at which the product reaches the desired lethality time-temperature combination (also referred to as the “cooking time”).
Lot Number (Sprouts)	Lot Number means the sprouts from a single lot of seeds that were planted at the same time in a single growing unit (single drum or rack of trays).
Marinade	Marinade means to soak meat in a sauce to enrich its flavor, to tenderize or enhance its shelf life.
Maximum equilibrium pH	The highest pH allowed for a specific retail process to provide safe food.
Modified atmosphere packaging	(MAP) is a process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action. Modified Atmosphere Packaging (MAP) is defined as packaging of a product in an atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air, which normally contains 78.08% nitrogen, 20.96% oxygen, and 0.03% carbon dioxide.
Moisture-protein-ratio (MPR)	expresses the percent moisture divided by the percent protein. MPR is commonly used in the U.S. to classify dried sausages and other meat products. **Although MPR values indicate the degree of product drying, they are not necessarily indicative of microbial safety or product shelf-stability because they do not take into account availability of the water.**

Molluscan Shellfish	Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.
Monitoring	A planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an interrupted record of data.
Oxygen Transmission Rate (OTR)	OTR is the measurement of the amount of oxygen gas that passes through a substance over a given period. It is mostly carried out on non-porous materials, where the mode of transport is diffusion, but there are a growing number of applications where the transmission rate also depends on flow through apertures of some description. It relates to the permeation of oxygen through packaging to sensitive foods and pharmaceuticals.
Packaged	means bottled, canned, cartoned, bagged, or wrapped, whether packages in a food establishment or a food processing plant. Packaged does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.
Pasteurization	means a heat treatment sufficient to destroy vegetative cells of pathogens.
Pathogen	Any microorganism that can cause disease.
Person in Charge (PIC)	The individual present at a food establishment who is responsible for the operation at the time of inspection.
pH	The symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.
Physical hazards	Physical hazards include: inadvertent field matter (stones, wood, metal fragments, etc.); inadvertent processing residues (glass, metal fragments, etc.); intentional materials (employee sabotage) and miscellaneous particulates and fragments.
Post-drying Heat Step	A post-drying heat step may be added to increase the level of pathogen reduction beyond that achieved by heating alone.
Potable Water	is water that is safe to be used as drinking water.
Prerequisites for HACCP	Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety, as described in Codex Alimentarius Commission's Principles of Food Hygiene and other Codes of Practice.
Preventive Measure	An action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.
Process Authority	is a person or organization with expert knowledge in meat or poultry production, process control and relevant regulations (see Resources for further information).
Production Batch (Sprouts)	means all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).
Reassessment of the HACCP Plan	Purpose is to determine whether the HACCP System, as designed and executed, is still adequate.

Reduced Oxygen Packaging	Any packaging procedure that results in a reduced oxygen level in a sealed package. The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gasses; or otherwise controlling the oxygen content to a level below that normally found in the surrounding, 21% oxygen atmosphere, and a ROP process that involves a food for which Clostridium botulinum is identified as a microbiological hazard in the final packaged form.
Relative Humidity	is defined as the degree of saturation of the air by water (vapor), expressed as a percentage. Relative humidity describes the relation of the existing vapor pressure at a given temperature to the maximum vapor pressure at that temperature. Air at a given temperature can absorb vapor until its saturation (100%). The difference between the dry and wet bulb temperature is the relative humidity at that temperature. The following website: http://www.ringbell.co.uk/info/ humid.htm.
Retail Establishment	means an operation that provides juice directly to consumers and does not sell or distribute juice to other businesses. The term "provides" includes storing, preparing, packaging, serving, and selling juice.
Risk	The likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.
Risk Factor	One of the factors identified by the Centers for Disease Control and Prevention (CDC) as a contributor to the foodborne outbreaks that have been investigated and confirmed. The factors are unsafe sources, inadequate cooking, improper holding, contaminated equipment and poor personal hygiene.
Sausages	include both finely ground and coarse ground products. Finely ground sausages include bologna, frankfurters, luncheon meats and loaves, sandwich spreads, and viennas. Coarse ground sausaged include chorizos, kielbasa, peperone, salame, and summer sausages.
Severity	The seriousness of the effect(s) of a hazard.
Sealed oven	A sealed oven is generally defined as one in which the smokehouse doors and smokehouse oven dampers are closed to prevent moisture loss.
Semi-Dry Fermented Sausage	means a product made of chopped or ground meat products that, as a result of bacterial action, reaches a pH of 5.3 or less and undergoes up to 15% removal of moisture during the fermentation/heating process. Semi-dry fermented sausages include summer sausage, thuringer, cervelat and Lebanon bologna.
Severity	The seriousness of the effect(s) of a hazard.
Shelf-stable	is the condition achieved when meat and poultry products can be stored under ambient temperature and humidity conditions; if the package integrity is maintained during storage, shipping, and display at retail and in the home; and the product will not spoil or become unsafe throughout the manufacturer's specified shelf-life.
Showering	means a potable water spray with or without liquid smoke in the smoke house which, depending on when the water spray is applied, maintains humidity, flavors, decreases cooking time, promotes rapid cooling or reduces casing shrinkage.
Smokehouse	means a piece of equipment or room sized enclosure used to conduct the smoking and cooking process which has a smoke source, adequate ventilation, heat and humidity source if necessary, approved plumbing and waste lines if necessary, support structures for the food products to be smoked and a method to determine internal product temperature.

Smoking	is the process of exposing meat products to wood smoke. Depending on the method, some products may be cooked and smoked simultaneously, smoked and dried without cooking, or cooked without smoking.
Sous Vide	Where raw or partially cooked food is hot filled into impermeable bags that have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated (or frozen) at temperatures that inhibit the growth of psychotropic (cold loving) pathogens. The sous vide process is a pasteurization step that reduces the bacterial load but is not sufficient to make the food shelf-stable.
Specialized Processes	Processes or procedures requiring specific food safety controls not otherwise addressed in the FDA Food Code.
Spent irrigation water	means water that has been used in the growing of sprouts.
Sprout	means a seed that is germinated until it has formed a root or until it has developed its first set of leaves.
Sprouting	is the natural process by which seeds or spores germinate and put out shoots, and already established plants produce new leaves or buds, or other structures experience further growth.
Standard Operating Procedure (SOP)	A detailed set of instructions, steps or procedures that control the operational conditions within a food establishment allowing for environmental conditions that are favorable to the production of safe food. These written procedures are often equivalent to prerequisite programs of HACCP. The extent to which operators employ various SOPs will determine which critical control points need to be controlled.
Target pH	is the most desirable pH for the product and gives a large safety margin. The target pH is lower than the equilibrium pH.
Turbidity	is high cloudiness or haziness caused by individual particles in juice.
Vacuum packaging	Reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.
Validation	is that element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.
Variance	A written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.
Water activity	also referred to as a_w, is a measure of the concentration of moisture (i.e., water) and its availability in a food. The amount of water available in a food depends on the total concentration of all dissolved substances in the product because they bind water. Thus, if ingredients such as salt or sugar are added to food, they compete with the bacteria for available water.
Wet bulb temperature	is the temperature indicated by a moistened thermometer bulb exposed to the air flow. It measures the extent of cooling that happens as moisture dries from a surface, a process also known as evaporative cooling.

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FSIS Compliance Guideline for Meat and Poultry Jerky Produces by Small and Very Small Establishments (FSIS Jerky Guideline)

FSIS Appendix A: Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products (hereinafter referred to as Appendix A)

FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A, June 2017

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Juice

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Guidance for Processing Fresh Juices in Retail Operations. AFDO, January 22, 2004, Florida Cooperative Extension Service / Institute of Food and Agricultural Sciences / University of Florida

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Produce Wash Water Sanitizers: Chlorine and PAA. UMass Food Science Extension, Kinchla, Issued 9/2015.

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Safer Juice - Part 1 - Introduction to Food Safety https://youtu.be/6KCHwDsJrXs
[Video] YouTube, PublicResourceOrg, (2010, June 20)

Safer Juice - Part 2 - Regulations, Requirements and Guidance
PublicResourceOrg https://youtu.be/unIJEXi9OU8

Safer Juice - Part 3 - Personnel Practices https://youtu.be/4YxnfP0NofY
[Video] YouTube, PublicResourceOrg, (2010, June 20)

Safer Juice - Part 4 - Cleaning and Sanitizing https://youtu.be/RFh_CyVu1U8
[Video] YouTube, PublicResourceOrg, (2010, June 20)

Safer Juice - Part 5 - Agriculture Practices and Raw Materials https://youtu.be/upgyxjq3TCY
[Video] YouTube, PublicResourceOrg, (2010, June 20)

Safer Juice - Part 6 - Processing Design and Packaging https://youtu.be/FOlixKyqIK8
[Video] YouTube, PublicResourceOrg, (2010, June 20)

Safer Juice - Part 7 - Performance Standards and Intervention https://youtu.be/8iDr70DTrhc
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Safer Juice - Part 8 - Wrap-Up https://youtu.be/ji51h02v23c
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Sprouts

Draft Guidance for Industry: Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations, FDA, CFSAN, January 2017

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Safer Sprouts – Part 1 Introduction to Food Safety https://youtu.be/RsRLtNVLhfc
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Safer Sprouts - Part 2 - Requirements and Guidelines for Sprout Processors https://youtu.be/kxfJV6fdWR0
[Video] YouTube, PublicResourceOrg, (2010, June 20)

Safer Sprouts - Part 3 - Growing, Harvesting, Milling, Transportation, and Storage https://youtu.be/d-NKL2m05kc
[Video] YouTube, PublicResourceOrg, (2010, June 20)

Safer Sprouts - Part 4 - Sprout Production https://youtu.be/0X5tobl11hI
[Video] YouTube, PublicResourceOrg , (2010, June 20)

Safer Sprouts - Part 5 - Seed Treatment https://youtu.be/XqP_7b1n2OM
[Video] YouTube, PublicResourceOrg , (2010, June 20)

Safer Sprouts - Part 6 - Sampling and Microbiological Testing https://youtu.be/uNyTDbkdgMQ
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Safer Sprouts - Part 7 - Cleaning and Sanitizing https://youtu.be/KGccyfGi_bQ
[Video] YouTube, PublicResourceOrg, (2010, June 20)

Safer Sprouts - Part 8 - Personnel Practices https://youtu.be/Zt8KJxaUq8A
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Juice HACCP Implementation

- Guidance for Industry: Juice HACCP Hazards and Controls Guidance - First Edition, 3/3/04
- Guidance for Industry: Questions & Answers for the Juice HACCP Regulation, 9/4/03
- Guidance for Industry: Juice HACCP Small Entity Compliance Guide, 4/4/03
- Adulteration with Patulin in Apple Juice and Apple Juice Concentrates

Process Authorities

The following is a list of process authorities that could provide a starting point for retail food establishments seeking assistance. This is not a complete list, nor does it act as an endorsement of one or more of the organizations included in this list.

Cornell Food Venture Center | CALS

Food Processing Authorities Directory – Association of Food and Drug Officials (afdo.org)

Food Processing: Guidance for Rhode Island State and Federal Regulatory Requirements (ri.gov)

foodsafety.wisc.edu/assets/Process Authorities by State.pdf

Food Testing Services - Cooperative Extension: Food & Health - University of Maine Cooperative Extension (umaine.edu)

Process Authority | Mérieux NutriSciences (merieuxnutrisciences.com)

Process Authority | Oklahoma State University (okstate.edu)

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Validation and Verification of HACCP Plans in Retail Food Establishments: A Course for Retail Food Regulators https://foodsafety.ces.ncsu.edu/retail-haccp/