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Guidance for Developing

HACCP Plans for Specialized Processes at Retail

Meeting the Recommended Requirements of the FDA Food Code in Relation to Specialized Processing Methods at Retail

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Jonathan Wheeler, SC Department of Health and Environmental Control

J. Joseph Corby, Association of Food and Drug Officials

Felissa Vazquez, Buncombe County HHS (NC)

Melissa Ham, Hoke County HHS (NC)

James Topie, Minnesota Department of Health

Dr. Dana Hanson, NC State University

Dr. Ellen Shumaker, NC State University

Dr. Benjamin Chapman, NC State University

Dr. Jonathan Campbell, Pennsylvania State University

Dr. Evelyn Watts, Louisiana State University

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FOREWORD

The Food Code is a model code that represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service. While the FDA Food Code is not a regulation, it is offered for adoption as regulation by local, state, and federal governmental jurisdictions that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations. The majority of the states have now adopted some version of the Food Code as regulation within their jurisdictions.

Specialized processes conducted at retail establishments are processes or procedures requiring specific food safety controls not otherwise addressed in the Food Code. These techniques often require specialized equipment, ingredients, procedures, or technology. Because of an increased potential health risk, specialized processes in retail food establishments must be conducted under strict operational procedures.

This guidance document is intended to provide regulators and retail food operators valuable information regarding the development and implementation of HACCP plans for specialized processes conducted in retail food establishments. These HACCP plans require preapproval by the regulatory authority. The authors have made every effort to present this information in as clear a format as possible. However, it is essential that retail operators fully understand the risks and the required control measures before engaging in these processes. This material is not intended for use by commercial food processors or manufacturers.

Additional guidance is provided for dry aging of beef and bottling of cold-pressed juices, which are not classified as specialized processes, but which are increasingly observed at retail and present challenges to state and local authorities.

This resource was developed in response to a survey of state retail regulatory agencies that indicated the need for more specific guidance addressing specialized processes at retail to benefit both regulators and the retail food industry.

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About HACCP

What is HACCP?

The ***H***azard ***A***nalysis ***C***ritical ***C***ontrol ***P***oint (**HACCP**) system is a preventive system for assuring the safe production of food products. It is based on a commonsense application of technical and scientific principles to a food production process.

The most basic concept underlying **HACCP** is that of prevention. The retail food processor/handler should have sufficient information concerning the food and the related procedures they are using in order to identify where and how a food safety problem may occur. If the 'where' and 'how' are known, prevention becomes easy and obvious, and finished product inspection and testing becomes needless. The **HACCP** program deals with the **control** of factors affecting the ingredients, product, and process. The objective is to make the product safely, and be able to prove that the product has been made safely. The where and how is the Hazard Analysis (HA) part of **HACCP**. The proof of the **control** of the processes and conditions is the **Critical Control Point** (CCP) part. Based on this premise, **HACCP** is simply a methodical and systematic application of the appropriate science and technology to plan, **control,** and document the safe production of foods.

HACCP is not the only way to ensure that safe food products are produced or processed. The plan will be successful when other procedures are in place such as sanitation standard operating procedures (SSOPs) and employee health and hygiene policies, and use of good retail practices (GRPs). These programs are fundamental in the development and operation of a successful **HACCP plan**. At retail, it needs to be understood that employee health and hygiene are of particular concern in handling food, especially when the process uses low-temperature cooking, or has no cook step. SSOPs should include personal hygiene practices as well as daily sanitation of the food contact surfaces and equipment. The SSOPs may also include routine inspection of processing equipment such as grinders, stuffers, and slicers as a **preventive measure** against potential foreign material being introduced when processing **meats** and other foods. Good sanitation practices are the foundation of safe food preparation.

HACCP is a management system in which food safety is addressed through the analysis and **control** of biological, chemical, and physical hazards from the first steps of raw material purchasing and receiving, through handling, production, distribution, and consumption of the finished product. For successful implementation of a **HACCP plan**, management must be strongly committed to the **HACCP** concept. A **food establishment** committed to **HACCP** by top management provides company employees with the sense of importance of producing safe food.

HACCP Requirements in the Food Code

The 2022 FDA Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service. Throughout this document, all citations referring to the Food Code will be specific to the 2022 version of that document, including its annexes. One requirement of the Food Code is for retail **food establishments** that conduct certain specialized food processes or operations to operate under a **HACCP plan** with the approval of the regulatory authority.

In addition, many of the specialized processes will require a **variance** authorizing a modification or waiver of one or more requirements of the Food Code if, in the opinion of the Regulatory Authority, a health hazard or nuisance will not result. In other words, a **variance** is required when a **control** specified by the Food Code is replaced with a **control** that is outside the Food Code. The **variance** grants permission for use of that substitution based on scientific evidence demonstrating that the new **control** provides a level of safety at least equal to that provided by the Food Code **control** that is to be replaced. Section 3-502.12 (Reduced Oxygen Packaging Processes, or ROP) prescribes the exact procedures that must be followed to conduct one of these processes without a **variance**. Any modification of those procedures must be supported by scientific evidence that the modification will provide the required level of safety. As an example, Section 3-502.12(F) allows exemption from the requirement for a **HACCP plan** for an ROP process in which the product is removed from the ROP package within 48 hours from the time of packaging. In this case, a written standard operating procedure must be approved by the regulatory authority, in which the instructions for this process are provided.

Retail Processes or Operations that Require a HACCP Plan and a variance: Food Code § 3-502.11

1. Smoking food for **preservation**, not for the purpose of imparting flavor only.

2. Curing **meats**, whether for **preservation**, or for flavor or color (all uses).

3. Using food additives or adding components, such as vinegar, as a method to preserve food (rather than to enhance its flavor) or change food into a non-**time/temperature control for safety** food. (See definitions on p. 7.)

4. Using a reduced oxygen method of packaging **time/temperature control for safety** food in which growth and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* are **controlled** by means other than as required in § 3-502.12.

5. Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption.

6. Custom processing animals that are for personal use as food and not for sale or service.

7. Sprouting seeds or beans.

8. Preparing food by another method that is determined by a regulatory authority to require a **variance**.

Retail Processes or Operations that Require a HACCP Plan without a Variance: § 3-502.12

1. Using a reduced oxygen method of packaging (**ROP**) **time/temperature control for safety** (**TCS**) food and **controlling** growth and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* as specified in § 3-502.12. Requirements for ROP packaging of **TCS** foods are covered in full detail in Section 4.

2. Sous vide cooking, or cooking foods in a reduced oxygen package.

3. Performing ROP cook-chill (foods cooked by traditional methods are then packaged in reduced oxygen packaging for storage).

4. Storing **fish** that is frozen before, during, and after reduced oxygen packaging and bearing a label indicating that it is to be kept frozen until time of use.

5. Using reduced oxygen packaging for storage of hard or certain semi-soft cheeses 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 semisoft cheeses.

Additional Requirements

While the process of developing a **HACCP plan** is a rather universal one, there are additional components that must be included as part of the retail establishment's **HACCP plan**. Section 4 provides details on the additional requirements such as standard operating procedures and "**prerequisite programs.**" The regulatory authority must grant final approval to the **HACCP plan**, even when a Process Authority has developed the plan, or has issued a process letter in support of the plan. The regulatory authority will provide reasonable opportunities for the retail **food establishment** to address any concerns identified during review. Once a **HACCP plan** is approved, with or without any required **variances**, the regulatory authority will issue written approval for the plan. Once approved, the retail **food establishment** cannot make changes without prior approval from the regulatory authority. This includes proposed changes to any foods, procedures, or equipment used in the process. Recommended requirements for the content of a **HACCP Plan** are found in § 8-201.14 of the 2022 FDA Food Code, and are discussed later in this manual.

Roles of Processing Authorities, Regulatory Authorities, and Retail Food Establishments

The ideal relationship of retail **food establishments** with processing authorities and the regulatory authority is best described as one of mutual reliance. Mutual reliance is a seamless partnership that allows the partnering groups to rely on, coordinate with, and leverage one another's work, data, and actions to meet the public health goal of reducing foodborne illnesses by improving food safety-related behaviors and practices. Each party in this relationship has specific expertise and specific responsibilities. The effectiveness of every **HACCP plan** depends on partners delivering fully on their responsibility to the plan.

Processing Authority

The FDA defines the **processing authority** as a "person who has expert knowledge of thermal processing requirements for low-acid foods packaged in hermetically sealed containers, or has expert knowledge in the acidification and processing of acidified foods" (21 CFR Parts 113.83 and 113.89). Similarly, the USDA definition in 9 CFR Part 431.1 describes the **processing authority** as "person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this part." As applied to retail **food establishments** conducting certain processes, the expertise of the **processing authority** fills two roles essential to **HACCP**:

- When critical elements of a process are not prescribed by the Food Code and state regulations, a **processing authority** can prescribe processing procedures and practices, oftentimes referred to as a "scheduled process" that meets requirements of applicable federal regulations. A **processing authority** is an individual recognized by their peers and by regulatory authorities as an expert on a subject who has experience, knowledge, and

achievements. In many cases, a **processing authority** may recommend specific process **controls** for a standard process based on published research – such as for canning of acidified vegetables or a pasteurization process. Processes for which the **processing authority** fills this role include canning of acidified foods (21 CFR Part 114) or low-acid foods (21 CFR Part 113); pasteurization of juices (21 CFR Part 120) and pasteurization of milk (21 CFR Part 1240.61.

- When a unique or novel process is proposed, the expertise and capabilities of the **processing authority** must be used to obtain scientific evidence supporting the effectiveness of the process. Types of testing required may include pH, water activity, or challenge studies to determine robustness of a product to resist growth of pathogenic bacteria. These data would be reported to the retail establishment, and must be provided by the establishment to the regulatory authority as **validation** of the proposed process. In this case, the expertise of the **processing authority** is needed to demonstrate that the final product of the proposed process meets applicable standards, such as for shelf stability or extended shelf life under specified conditions.

The Association of Food and Drug Officials maintains a list of Processing Authorities[1] across the country. You may also be able to find a Processing Authority at a college or university in your area.

Regulatory Authority

As the regulatory authority, the first responsibility of the government agency with jurisdiction over retail food sales is to ensure consumer safety by protecting the safety of foods produced at retail for sale or service. Regulators must maintain effective working relationships with the regulated community, and with processing authorities who provide the technical support necessary to regulating effectively. It is essential to recognize that **HACCP** requirements for special processes are a challenge for many in the retail food industry, requiring education and much guidance, if the program is to be successful for both industry and the regulatory agency. The regulatory authority must find the right balance between regulating and compliance assistance, recognizing the importance of understanding the needs of the regulated community. Regulatory reviewers need a solid understanding of both the science and how to apply the science to specific processes in determining whether appropriate **validation** has been provided. It is worthwhile to review the definitions of **validation** and **verification** provided below. Basic principles essential to the reviewing of **HACCP plans** for proposed processes and **variances** include:

- **Clear –** The reviewer, as an outside observer, must verify that the procedures provided in the **HACCP plan** are clearly stated so that a food worker could follow the instructions to correctly perform the process.

- **Complete –** The reviewer, working in partnership with the establishment and the inspector, must verify that the plan accurately represents the foods, ingredients, packaging, and process steps including any variations that may require coverage.

- **Concise –** The reviewer should ensure that the necessary procedures and instructions are provided without excessive or overbearing detail that does not contribute to the effectiveness of the plan.

- **Consistent –** The reviewer should verify that when repetition occurs in a **HACCP plan**, that the details provided are consistently the same from one location to the others in the plan.

[1] www.afdo.org/directories/fpa

Unnecessary repetition should be avoided, and adds to the possibility of confusion and problems.

- **Correct –** The reviewer must verify that the plan is supported properly by the required science-backed **controls** as identified by the establishment. In some cases, recommendations may be required from a **processing authority** to supply necessary **validation**, such as process step recommendations or testing.

When the criteria in these 5 C's have been met, the regulatory authority issues a written approval of the **HACCP plan**. The authority to approve **HACCP plans** and **variances** is assigned to the regulatory authority by the FDA in the Food Code, § 8-103.11, 8-103.12, 8-201.11, and 8-201.13.

Retail Food Establishment

The **HACCP Team** Leader, and the retail **food establishment** as a whole, bear full responsibility for accurately representing the process covered by the **HACCP plan**, for developing and seeking regulatory approval of required **HACCP plans**, and for fully implementing **HACCP plans** as approved by the regulatory authority. Inaccurate presentation of the process, the ingredients, and the end use of the products can result in an **uncontrolled** hazard. Those employed in the retail establishment will have the greatest in-depth knowledge of the process as it is conducted in the retail **food establishment**. For these reasons, regulators and processing authorities must rely on the establishment for the detailed knowledge of how the process is intended to be conducted. Likewise, the establishment must recognize the importance of relying on the expertise of processing authorities for processes that fall outside Food Code guidance, and the expertise of the regulatory authority for applying science-based **control**s, including the guidance of the **processing authority**, to the proposed process. When considering processes that go beyond standard preparation of foods for sale or service, the retail establishment should discuss such plans with its regulatory inspector to seek guidance. It is vital that retail operators recognize inspectors and regulatory staff as essential resources, and an important part of the establishment's food safety team. For the retail establishment, the goal in writing a **HACCP plan** should include satisfying the 5 C's, the same as listed above for regulatory reviewers.

Definitions

The following terms are used throughout this manual. These definitions establish the accepted meaning of each term for the sake of consistent understanding. Wherever these terms are used, they are bolded to refer to the definition, except in cases where the term is used as part of a title or proper name, definition, an example form or worked example, template document, or as part of a quoted regulatory citation. NOTE: Shellfish (mollusks) are included in the definition of "fish."

Approved: Acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

CCP Decision Tree: A sequence of questions to assist in determining whether a control point is a CCP.

Cold smoking: Smoke applied to product where the smokehouse temperature is low, generally below 90°F. The product is not cooked in a **cold smoking** process. May be used to apply smoke color and flavor to products not sufficiently darkened or flavored in the original cooking process.

Comminuting: Cutting, chopping, or grinding of meat into small particles.

Continuous monitoring: Uninterrupted collection and recording of data, such as temperature on a strip chart or a continuous recording thermometer.

Control: (a) To manage the conditions of an operation to maintain compliance with established criteria. (b) The state where correct procedures are being followed and criteria are being met.

Control measure: Any action or activity that can be used to prevent, eliminate, or reduce a significant hazard.

Control point: Any step at which biological, chemical, or physical factors can be controlled.

Corrective action: Procedures followed when a deviation occurs.

Criterion: A requirement on which a judgment or decision can be based.

Critical control point (CCP): A point, step, or procedure at which control can be applied and is essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level.

Critical defect: A deviation at a CCP that may result in a hazard.

Critical limit: A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard.

Deviation: Failure to meet a critical limit.

Fish: The FDA Food Code defines fish as (a) Fresh or saltwater finfish, crustaceans, and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, sea urchin, and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption. (b) An edible human food product derived in whole or in part from fish, including fish that have been processed in any manner.

Food allergy: Food allergies are the body's immune system's reaction to certain proteins in food. Food allergic reactions vary in severity from mild symptoms involving hives and lip swelling to wheezing, abdominal pain, diarrhea, nausea or vomiting, and dizziness or fainting. The most severe, life-threatening symptoms, often called anaphylaxis, may involve fatal respiratory problems and shock.

Food establishment: an operation that:

> (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides FOOD for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or FOOD bank; and
>
> (b) relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

The definition of food establishment includes:

(a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location *unless the vending or feeding location is permitted by the* REGULATORY AUTHORITY; and

(b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.

HACCP: A systematic approach to identification, evaluation, and control of food safety hazards.

HACCP Plan: The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of specific process or procedure.

HACCP System: The result of the implementation of the HACCP Plan procedures to be followed. Includes all records associated with implementation of the HACCP Plan.

HACCP Team: The group of people who are responsible for developing, implementing and maintaining the HACCP system.

Hazard: A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control, rendering a food unsafe for consumption.

Hazard analysis: The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan. The hazard analysis considers the food preparation process used, the handling of the food, the facility, and general characteristics of the food itself to consider the level of risk associated with each potential hazard and the severity of outcomes if the hazard should occur in order to determine the level of significance of the hazard.

Meat: The flesh of animals used as food including the dressed flesh of cattle, swine, sheep, goats, or other edible animals, except fish, poultry, and game animals as specified under Subparagraphs 3-201.17(A)(3) and (4) of the FDA Food Code.

Monitor: To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Poultry: The FDA Food Code defines poultry as

(a) Any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs), whether live or dead, as defined in 9 CFR 381.1, Poultry Products Inspection Regulations Definitions, Poultry; and

(b) Any migratory waterfowl or game bird, pheasant, partridge, quail, grouse, or pigeon, whether live or dead, as defined in 9 CFR 362.1, Voluntary Poultry Inspection Regulations, Definitions.

Preservation: Formulating, processing, or packaging a time/temperature control for safety food in a manner that either extends the shelf life of the ready-to-eat product beyond the 7 days allowed under § 3-501.17 of the Food Code, or that renders the final product shelf stable, or both. (NOTE: This is a working definition. As of the date of publication, the Food Code does not include an official definition.) The Food Code definition of time/temperature control for safety food provides more information.

Processing authority: An individual who has expert knowledge, experience, and achievement as well as recognition as an authority on one or more special processes.

Product assessment: A process by which a retail food establishment submits food to be tested at a laboratory approved by the regulatory authority to determine whether the food is TCS food, or non-TCS food. Testing shall include pH, water activity, inoculation studies, and other analyses required by the regulatory authority or the Processing Authority to provide validation that the product be held without time/temperature control.

Prerequisite programs: Procedures, including Good Retail Practices that address operational conditions providing the foundation for the HACCP system.

Preventive measure: Physical, chemical, or other factor that can be used to control an identified health hazard.

Ready to Eat (RTE): Food that

(a) Is in a form that is edible without additional preparation to achieve food safety, as specified under one of the following: Paragraphs 3-401.11(A) or (B), § 3-401.12, or § 3-402.11, or as specified in ¶ 3-401.11(C); or

(b) Is a raw or partially cooked animal food and the consumer is advised as specified in Subparagraphs 3-401.11(D)(1) and (3); or

(c) Is prepared in accordance with a variance that is granted as specified in Subparagraph 3-401.11(D)(4); and

(d) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

Risk: The likelihood of occurrence for a specified hazard.

Sausage – Shelf stable: Non-refrigerated, dry, shelf-stable sausages are those that:

- are fermented to a pH of 4.5 or lower (or pH may be as high as 4.6 if combined with product water activity no higher than 0.91)
- are in an intact form, or, if sliced, are vacuum packed
- have internal brine concentration of no less than 5%
- are cured with nitrite or nitrate
- may have been smoked with wood

Sensitive ingredient: An ingredient known to have been associated with a hazard for which there is a reason for concern. See the definition of food sensitivity, above.

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

Shelf stable: Products that have been sufficiently treated to destroy all viable forms of pathogenic organisms and nonpathogenic organisms capable of reproducing in the product under normal non-refrigerated conditions of storage and distribution.

Time/Temperature Control for Safety Food (formerly "potentially hazardous food," or PHF:

(1) 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)[2].

Validation: 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 the Food Code if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.

Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

Prerequisite Programs (Policies and Procedures) and Record Keeping

Prerequisite Programs (**PRPs**) are specific elements of "good retail practices" that provide the essential foundation for the **HACCP plan**. Without full implementation of these policies and procedures, the **HACCP system** is weaker and more subject to failure. Most PRPs are explicitly required by the FDA Food Code as elements of a **HACCP plan**. Other PRPs are required based on application of the principles of **HACCP** to the nature of a process, or the procedures or equipment used in a process. The standard operating procedure, the training plan for management and food workers, and management review of the **HACCP** program described in ¶ 8-201.14(D) are examples of **Prerequisite Programs** (**PRPs**) – policies and procedures that directly support the effective implementation of the **HACCP** plan. As an element of Principle Six (**Verification**), procedures for calibration of instruments and the associated testing or measurement procedures used to **monitor critical limits** must be included as part of the **HACCP plan**. The typical PRPs necessary in a retail **HACCP plan** for special processes are:

- **Standard Operating Procedure** for the process. Paragraphs 8-201.14 (C) and (D) of the Food Code include requirements to include the "methods and procedural **control measure**s" addressing the food safety issues of concern, and the "method and frequency for **monitoring** and **controlling** each **CRITICAL CONTROL POINT**." A clear and complete set of instructions for conducting the process from start to finish addresses this requirement. Special attention to detail is required in providing instructions at each CCP – identify each required **critical limit** and give instructions for **monitoring** each **critical limit** properly.

[2] www.fda.gov/media/164194/download?attachment#page=41

Include required **corrective actions** that are required if a **critical limit** is not met; identify the required records documenting **monitoring corrective actions** and identify the required **verification** measures including the responsible person and frequency. Keep in mind that a CCP may have several **critical Limits**, such as required cooking temperatures and times for different types of protein. Also remember that some **critical Limit** failures may require some investigation to determine appropriate **corrective actions**, and there may be more than one possible **corrective action** that depends on your investigation. For example, if a cooler is failing to meet 41°F. or lower and management was notified as soon as the failure was noted, the employee's initial action was correct. If product temperatures are then checked and found still at 41°F. or lower, immediate action might be to ice down product or move it to a different cooler, and call for maintenance on the cooler. However, if no employee notified management of the problem, the same actions might be appropriate, but retraining of employees would also be a required part of **corrective action**.

- **Approved Suppliers**: **Unapproved** sources have been reported to the Centers for Disease Control and Prevention (CDC) as a food safety risk factor in foodborne illness transmission at retail. In certain situations, a certification or approval policy may be required as a **preventive measure** to provide the level of safety required by the Food Code. Examples include:

    - Parasite destruction in **fish** that will not be fully cooked;

    - Temperature **control** for Scombroid species of **fish** along the supply chain;

    - Menu flexibility and ingredient lists that vary for reduced oxygen packaging processes; or

    - Assurance that raw materials are from a producer, supplier, or distributor operating in conformity with principles, practices, and generally recognized standards that protect public health, as established by the regulatory authority.

- When significant **hazards** associated with the raw commodity are to be **controlled** by the supplier and not in the retail **food establishment**'s process, these **hazards** must be recognized in the **hazard analysis** at the Receiving step. **Approved** Supplier should be cited as the Preventive **Control**. Documentation such as purchase agreements or a supplier Letter of Guaranty, or other documentation acceptable to the regulatory authority, must also be cited along with "**Approved** Supplier." This approach should be acceptable in the first two examples.

Seasonal menu variability, recipe flexibility, and local sourcing of ingredients are major concerns in numerous retail **food establishments**. These concerns present more of a challenge in how supplier approval must be handled. Here are several important points to consider in determining how best to address supplier approval:

- Simplify how you list the ingredients in describing your products and ingredients in the preliminary steps of writing the **HACCP plan**. For example, you could list "various cuts of beef steak and beef roasts with varied seasonings according to each recipe, all from recognized, **approved** distributors."

- For locally sourced products not from generally recognized producers, suppliers, or distributors, write a policy on how these entities will be **approved**. Possible criteria in your policy would include:

- Is the producer, supplier, or distributor inspected under a state regulatory authority such as the state **meat** inspection program, or the state Department of Agriculture?

- Has the producer, supplier, or distributor been audited and found in compliance with applicable food safety standards, such as USDA meat HACCP regulations (9 CFR Part 4173), the Produce Safety Rule[4] Good Agricultural Practices,[5] or other applicable standards?

Suppliers that cannot provide evidence of compliance with applicable food safety standards cannot be accepted as **approved** sources.

- **Employee health and hygienic practices** are considered by the Centers for Disease Control and Prevention (CDC) to be major contributing factors to foodborne illness transmission at retail. Hepatitis A Virus and Norovirus are two of the "Big Six" foodborne pathogens. The CDC has stated that heating foods to 185°F. for at least one minute[6] is necessary to destroy the Hepatitis A Virus, and that the Norovirus can survive temperatures as high as 145°F[7]. These viral pathogens are not **controlled** by other common methods used to **control** bacterial pathogens, such as salt content or acidic pH in the food. Viral pathogens should be recognized as process **hazards** at any step involving significant worker handling in processes with no cooking step, or only low-temperature cooking based on Food Code ¶ 3-401.11(B). Policies on employee health and hygienic practices should therefore be included as essential preventive **controls** in the **hazard analysis** at these process steps.

- **Sanitation Standard Operating Procedures (SSOPs)** *directly related to the process*: Inadequate or ineffective sanitation has also been reported to CDC as a major contributing factor to foodborne illness transmission at retail. (See FDA 2022 Food Code, Annex 7, Guide 3-B; B, Risk Factors and Interventions.) Processes using equipment with difficult to access components, or which must be disassembled for cleaning and sanitizing, tend to be more difficult to clean effectively. Examples include grinders, stuffers, slicers, and choppers. Use also produces wear on the metal components, which creates grooves, pockmarks, and nicks that can hold food residue, thereby providing potential harborage for pathogenic bacteria. Wear on metal components also can result in physical **hazards** such as metal filings or fragments, resulting in a potential physical **hazard** in the food. For this reason, sanitation standard operating procedures (SSOPs) should be included as preventive **controls** at relevant processing steps in these processes, and at steps involving handling of ready-to-eat food. Inspection of such equipment components should be included in the SSOP to ensure **control** of potential physical **hazards** from processing. For processes using grinders, stuffers, slicers, or choppers, the SSOP should be cited as an essential preventive **control** in the **hazard analysis** at relevant steps.

- **Calibration procedures** for instruments used to **monitor critical limits** are an element of Principle 6 (**Verification**):

  - **Thermometers** and other temperature sensing devices are specifically required by the FDA Food Code to be properly calibrated. Accuracy must be within 2.0°F. (1.0°C.) of the reference value. The ice point of water (32°F. or 0 °C.) is an appropriate reference point

[3] www.ldaf.state.la.us/wp-content/uploads/2019/05/417-HACCP.pdf
[4] www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety (FDA – FSMA)
[5] www.ams.usda.gov/services/auditing/gap-ghp
[6] www.cdc.gov/hepatitis/hav/afaq.htm
[7] www.cdc.gov/norovirus/about/prevention.html

for temperature sensing devices used to check low temperatures. The boiling point of water measured at a rolling boil (212°F. or 100°C.) should be used to verify accuracy of devices used to measure cooking temperatures. When required by the regulatory authority, correction for elevation above sea level should be used to correct for differences due to elevation. (A helpful calculator for determining the boiling point of water at different elevations above sea level is available[8].)

- **Sensitive scales** (reading to 1 or 2 decimal places in grams) used to measure gram amounts of curing salt are subject to calibration drift. They are of special concern because the dust of curing salt is corrosive, which can contribute to calibration error as it infiltrates instrument electronics. These scales should be checked on each day of use with a certified reference weight in the same weight range as the amount of cure that is typically weighed, such as 25 grams. Reference weights should read within +2.0% of their certified true weight.

- **All pH meters** must be calibrated on each day of use using two buffer solutions that bracket the **critical limit** value. Common **critical limit** values for pH in various processes are 4.2, 4.6, and 5.3, so calibration using 4.0 and 7.0 buffers is appropriate. After calibration, the 4.0 buffer should be read as a regular sample to verify the calibration is accurate; the reading should be between 3.9 and 4.1. Readings outside this range require re-calibration. This is an essential check, because over time the pH probe will respond more slowly, and readings will tend to drift with even the best possible maintenance. Always follow manufacturer recommendations for maintaining the pH probe.

- **Training plan** for management and food workers: The training plan must ensure that management is thoroughly familiar with the entire process, and that each food worker working under the **approved** plan is properly trained and competent for all parts of the process for which they are responsible (at the minimum). Beyond initial training, thought should be given to periodic refresher training, and training associated with process changes, plan updates, and **corrective actions** – especially those resulting from human error. Food worker and supervisory training must address the food safety issues of concern, as required by the Food Code ¶ 8-201.14(E) and as dictated by the process.

- **HACCP Maintenance Policy:** The standards set forth for **HACCP** by the National Advisory Council on Microbiological Criteria for Foods (NACMCF) require annual **reverification** of the **HACCP plan** as an element of Principle 6 (**Validation** and **Verification**). This is the mechanism for keeping the plan current with science and local regulations. This policy also should provide the mechanism for making revisions, in a properly **controlled** manner, to the **approved** plan based on changes of equipment, procedures, or foods used in the process, or based on **corrective actions** as warranted. **Uncontrolled** changes to a **HACCP plan** invalidate the approval status of the plan.

- **Record keeping** is required to demonstrate compliance with the **approved** plan, and to provide a means for identifying weaknesses in a plan that must be addressed. Regular review of these records on a scheduled frequency provides the information needed by management to properly maintain the **HACCP plan** and to address deficiencies in a timely manner. Example **monitoring** log forms are found in Section 6 for a wide variety of applications. For specific applications, some modification of certain forms may be appropriate – consult your regulatory authority for guidance for your particular process

[8] www.thermoworks.com/bpcalc/

needs. Electronic records are also acceptable, provided the required information is provided in a secure, tamperproof format with date- and time-stamping of all entries. Record retention schedules must meet local regulatory authority requirements. Electronic records must be backed up regularly to ensure continuous accessibility.

Templates are provided for PRPs later in this manual.

An Introduction to Preliminary Steps

The development of a **HACCP plan** is a logical step-by-step process. Each step builds on the information gathered from the previous step. It is necessary to complete these preliminary steps to properly perform the **hazard analysis** and remaining principles. You may wish to use the example forms located in Section 6, or you may want to create your own forms. In Section 2 we will discuss the preliminary steps in more complete detail.

1. Assemble the HACCP Team.

The first thing that must be done is to bring together individuals in your establishment who have a working knowledge of the various processing steps and operations in your establishment. This group will be your "**HACCP team**." It is understood that in some smaller establishments, the team may be very small and may even consist of one person - the owner/operator. Establishments may also utilize the services of food processing authorities or food safety consultants as part of their **HACCP team**. Once the **HACCP plan** has received regulatory approval, every member of the team must receive documented training on at least the portions of the process for which they will be responsible.

2. Identify products/foods/processes that must be covered by the HACCP plan.

Next, the **HACCP team** should write a categorization of the types of **TCS** foods that are to be covered by the plan. The foods listed should include the proteins and all other non-protein ingredients. Multiple foods with similar process steps or characteristics can be grouped together.

3. Develop a list of Ingredients, materials, equipment, and recipes/formulations.

The third step is for the team to thoroughly review each product and write down all of the ingredients, packaging, and equipment used in the preparation of a food and also to write down formulations or recipes that show methods and **control measures** that address the food safety concerns involved. Recipes and ingredient lists must include all ingredients or alternate process steps that may be used occasionally.

4. Develop a Process Flow Diagram.

At the fourth step, the **HACCP team** will draw a flow diagram that shows all the steps, including alternate steps, in the regulated **HACCP** process. A line list of steps is an acceptable alternative to the flow diagram. In general, **HACCP plans** in retail establishments cover every step from receiving through sale or service of the food produced under the **HACCP plan**. However, in **preservation** processes such as acidification of sushi rice, or production of certain cured **meats**, the **HACCP**-regulated process ends when the product is in its final form prior to another use in the establishment. Examples include use of acidified sushi rice in production of sushi; use of sprouts grown by the establishment in a salad; or use of an in-house produced dry sausage product as an

ingredient in another food. In these examples, the FDA Food Code does not require a **HACCP plan** for the final products.

*NOTE: Paragraph 8-201.12 of the Food Code requires that establishments submitting **HACCP plans** for specialized processes must include a proposed layout (e.g., kitchen diagram) demonstrating how cross contamination will be prevented.*

5. Verify the Process Flow Diagram.

The final step is to verify the accuracy of the flow diagram. The **HACCP team** can do this by having a second person familiar with the process do a walk-through of the entire production process, checking to see if there is anything missing from the diagram.

An Introduction to the 7 HACCP Principles

Principle 1: Conduct a Hazard Analysis

The **hazard analysis** looks at different factors that could affect the safety of your product. This analysis is done for each step in your production process, considering the foods, equipment, and operations at each step. It's important to remember that you are concerned with *safety*, not *quality* issues.

The **hazard analysis** is completed in two stages. The first stage identifies food safety **hazards** that are present in your process. The second stage evaluates these food safety **hazards** to determine the likelihood of occurrence, and the severity of consequences to consumers should the hazard not be effectively **controlled**. The likelihood and severity assigned to each hazard are used to determine whether the hazard must be considered significant, requiring control at some step in the process.

PROCESS-RELATED HAZARDS: As you evaluate the **hazards** in your process, don't forget about potential **hazards** related to the processing:

- Ingredient-related **hazards**. Everything that goes into your product must be evaluated. Ingredient and packaging specifications, provided by your supplier, should give you details on the materials/ingredients and packaging being sold, including statements that the materials/ingredients are of food grade and are free of harmful components.
- Process and equipment-related **hazards**. Processes that include steps for grinding, stuffing, injecting, or slicing foods may introduce the risk of hazards such as metal shavings or fragments, or other foreign material. Activities related to the process, especially those activities where there is a significant risk of cross contamination within the retail **food establishment**, should also be evaluated.
- Worker health-related **hazards**. Processes that use a low-temperature cooking step, or which have no cooking step, have no lethality measure to destroy viral pathogens such as Norovirus or Hepatitis A virus.

Principle 2: Identify Critical Control Points (CCPs)

A **critical control point** is defined as "*A point, step, or procedure at which **control** can be applied and is essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level*." This is the dividing line between safe and potentially unsafe food.

The **HACCP team** uses the list of food safety **hazards** and preventive measures they developed during the previous **hazard analysis** step to determine their **critical control points**. CCPs may include, but are not limited to:

- Chilling or freezing
- Cooking
- Certain processing procedures; smoking, curing, acidification
- Labeling (for allergens, required storage temperature and use-by dates, or safe handling instructions)

Steps that are CCPs in one retail establishment may or may not be CCPs in your own operation. When making a **HACCP plan**, the **HACCP Team** must look at the unique conditions present in that establishment. In certain cases, a prerequisite program used as a **preventive measure** must provide the same level of safety as required by the Food Code **controls** against a specific **hazard**. In those cases, a CCP may not be required, but documentation must support the proper use of that prerequisite program as the preventive **control**. Here are several examples:

- At an ROP packaging step in a retail establishment in which the food will only be used for in-house service, the step of applying a date mark is prescribed by the procedure. The most critical element is the expiration of the date mark, after which the product may no longer be safe. In this case, the application of the date-marked label may or may not be considered a CCP, but **monitoring** the *expiration* of the date mark is critical to safety. However, in a retail butcher shop where the product may be packaged and sold for consumers' home use, the application of the correct labeling is critical. In this situation, the establishment is obligated to provide the consumer the required information to properly **control** the potential **hazards** associated with expiration of the date mark, improper storage, and insufficient cooking of the product. In this situation, the application of a label that supplies all required information is critical because the establishment is passing **control** of critical process elements to the consumer.

- Use of game **meat** such as elk, bison, or wild boar, or of produce items from local small growers, may present **risk** of certain biological **hazards** such as parasites, pathogenic *E. coli* or *Salmonella* when not obtained from a source that is inspected and in compliance with federal regulations. A supplier approval prerequisite program may be cited in the **hazard analysis** as a preventive **control**, requiring an annual Letter of Guaranty attesting to the supplier's inspection status and compliance with applicable regulations regarding growing, agriculture, harvesting, processing, and transportation, as relevant. Supplier approval will be covered more fully in Section 2.

- Numerous species of wild-caught **fish** are known to be a **risk** for parasites that can infect humans upon consumption. These species include salmon, **flatfish** such as flounder, cod, **rockfish**, and certain species of tuna. (Consult your regulatory authority for more information.) If **fish** used in your process will be served raw or undercooked, such as in sushi, sashimi, or cooked to order rather than fully cooked, § 3-402.11 of the FDA Food Code requires either that the **fish** be frozen for parasite destruction, or farm raised and pellet-fed with parasite-free feed. A supplier approval prerequisite program may be cited in the **hazard analysis** as the preventive **control**, requiring an annual Letter of Guaranty attesting to the supplier's method of parasite **contro**l. If not **controlled** by the supplier, a

critical control point (freezing for parasite destruction) will be required in your **HACCP plan**, with the required records for this step as a CCP § (3-402.12).

Principle 3: Establish Critical Limits for Each CCP

A **critical limit** is defined as "*A maximum and/or minimum value to which a biological, chemical, or physical parameter must be **controlled** at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard*." **Critical limits** serve as minimum or maximum level for safety at each CCP. Often, they are a numerical value (whether that is temperature, pH, etc.) that must be reached to assure that a food safety **hazard** has been **controlled**.

*(A note about **critical limits**: When your **HACCP team** establishes **critical limits** for your specific establishment, remember that those limits may never be less strict than the current regulatory standards.)*

Principle 4: Establish CCP Monitoring Procedures

Monitoring is a fundamental part of any **HACCP system**. It consists of observations or measurements that check to see that your CCPs are operating under **control**. Observations must be conducted by a trained worker. Measurements must be made using properly calibrated and maintained equipment.

Monitoring Requires Precision

Monitoring a CCP is a big responsibility and employees must be properly trained and need to understand the reasons for careful monitoring procedures.

Specify in your monitoring procedures, every important detail about:

- Who will do the monitoring
- What is being monitored
- When it is done
- How it is done

For example, when taking the temperature of a piece of meat, be specific as to where you took the temperature. Remember that all records and documents associated with a CCPs monitoring should be dated and signed or initialed by the person doing the monitoring and the results recorded.

Monitoring serves three main purposes:

1. It tells you when there's a problem at a CCP, and **control** has been temporarily lost. This allows you to take **corrective actions** right away.

2. It tracks the system's operation and can help identify dangerous trends that could lead to a loss of **control**. This allows you to take preventive action to bring the process back into **control** before it goes beyond the **critical limits**.

3. It provides written documentation of your compliance with the **HACCP** regulation. This information can be used to confirm that your **HACCP plan** is in place and working right. For each CCP, the **HACCP team** will need to define the **monitoring** procedure and its frequency (hourly, daily, weekly, etc.) that best tracks that CCP. It's also important to thoroughly train the employee or employees that will be responsible for each **monitoring** procedure and frequency.

Principle 5: Establish Corrective Actions

Corrective actions are defined as *"Procedures followed when a **deviation** occurs."* A **deviation** is defined as a *"Failure to meet a **critical limit**."* **Corrective actions** are taken when **monitoring** shows that a **critical limit** was not met, potentially allowing a food safety **hazard** to go out of **control** at a CCP. **Corrective actions** should never be viewed as requiring punitive action against a worker. Instead, records of **corrective actions** provide the opportunity to improve the process and to regain **control** of the process.

The best way to handle **deviations** is to have a plan of action already in place. In general, **corrective action** plans are used for:

1. Determining the disposition of product affected by the **deviation**;

2. Bringing the process back into compliance with the **critical limit**;

3. Correcting the cause of the **deviation** to prevent a recurrence; and

4. Demonstrating that the CCP is once again under **control** (this means examining the process or product again at the CCP and getting results that are within the **critical limits**).

At least one specific **corrective** action procedure must be identified for each CCP as the plan is written. Remember that there may be more than one acceptable option for **corrective actions**.

Principle 6: Establish Validation and Verification Procedures

Regulatory review for approval. Before the regulatory authority can approve the proposed **HACCP plan**, an individual trained and knowledgeable in **HACCP** must review the plan and all supporting documents to determine if the **HACCP plan** as written, if properly implemented, will result in safe food. This review requires **verification** that each critical **control** is supported by published scientific information. For certain processes, testing or process recommendations from a recognized **processing authority** may be required to provide the required scientific support (**validation**).

As you are writing your **HACCP plan**, remember that as with the **monitoring** procedures, the **verification** procedures must specify each required **verification** activity, the individual responsible for that activity, and the frequency at which that activity must be conducted. Remember that **verification** activities are generally not the same as **monitoring** activities. **Verification** consists of methods, procedures, or tests *in addition to monitoring*, that determine if the **HACCP system** is being followed as intended and/or whether the **HACCP plan** needs modification and **revalidation**.

1. ***Ongoing verification activities.*** Ongoing **verification** activities include, but are not limited to:

    - The calibration of process-**monitoring** instruments
    - Direct observations of **monitoring** activities and **corrective actions**; and
    - The review of records.
    - In-house and regulatory **verification** audits

2. ***Reassessment of the HACCP plan.*** Every establishment should reassess the adequacy of the **HACCP plan** at least annually and whenever any change occurs that could ***affect*** the **hazard analysis** or alter the **HACCP plan**. Such changes may include, but are not limited to, changes in raw materials or source of raw materials; product formulation; processing methods or systems; production volume; personnel; packaging; product distribution systems; or, the intended use

or consumers of the finished product. Changes in the Food Code and local regulations, and new scientific information may also require reassessment of the plan. Reassessment should be performed by an individual trained in **HACCP** principles. The **HACCP plan** should be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of the Food Code.

3. ***Reassessment of the hazard analysis.*** During a reassessment of the **HACCP plan,** it may be necessary to reassess the **hazard analysis** when certain changes or conditions exist. In addition to the conditions above indicating need to reassess the **HACCP plan**, a known ***contamination*** event leading to a foodborne illness outbreak or a product recall will require reassessment of the **HACCP plan**, including the **hazard analysis**. Changes in the Food Code and local regulations, and new scientific information may also require reassessment of the **hazard analysis**.

Verification procedures help the HACCP plan work correctly.

Principle 7: Establish Record-Keeping Procedures

Record-keeping procedures are important in making and keeping a **HACCP system** effective. Every time **monitoring** procedures are done, or **corrective actions** are taken, a detailed record of that activity is made. These documents demonstrate compliance and facilitate maintenance of the **HACCP plan**.

Generally, the records kept in the total **HACCP system** include the following:

- The **HACCP plan** itself
- Supporting documentation, such as **product assessment**s, equipment, ingredient and packaging material specifications
- **Monitoring** logs
- **Corrective action** logs
- Instrument calibration and batch testing logs
- Training records
- Record of annual **HACCP plan** reviews and maintenance

SECTION 2: THE PRELIMINARY STEPS

Introduction

Developing a **HACCP plan** starts with the collection of important information describing the process and its products. This fact-finding process is known as the Preliminary Steps.

They are:

1. Assemble the **HACCP team**.
2. Identify products and processes.
3. Develop a complete list of ingredients, raw materials, equipment, recipes, and formulations.
4. Develop a process flow diagram that completely describes your process.
5. Verify the process flow diagram.

After the sections below discussing each of these preliminary steps, there is a template that exemplifies how to develop the information for each step.

Step 1: Assemble the HACCP Team

The **HACCP team** will begin by gathering details about the process, including the finished products, ingredients, packaging, and labeling; intended use and consumer; and the method of distribution – following the preliminary steps described below. They will also gather scientific data related to the process. Remember, the team isn't limited to internal resources. If needed, outside expertise may be available through regulatory agencies, cooperative Extension offices, trade or professional associations, and universities. **The HACCP team needs to be aware of the following:**

- Your product/process
- Any food safety programs you already have
- Food safety **hazards** of concern
- The seven principles of **HACCP**

In a very small establishment, perhaps only one individual is available to be on the **HACCP team**. This is perfectly acceptable; however, you can get help from as many people as you need to make the team function effectively.

The **HACCP team** will begin by collecting scientific data. Remember, the team isn't limited to internal resources. If needed, outside expertise may be available through regulatory agencies, cooperative Extension offices, trade or professional associations, and universities.

> However you decide to approach it, your **HACCP team** is ultimately responsible for building your **HACCP plan**.

Step 2: Identify Products/Processes to Be Covered

SECONDLY, make a complete listing of all the products that must be covered under this process and **HACCP plan**. Note that the requirements for reduced oxygen packaged foods limit the types of foods that can be packaged in this manner.

Step 3: Describe Ingredients, Materials, Packaging, Labeling, Equipment, Intended Consumer, and Distribution

THE THIRD STEP is for the team to thoroughly review all products of this process and write down all ingredients, materials, and equipment used in preparation, processing, and holding of each food. In the case of reduced oxygen packaging processes using recipes consisting of standard ingredients, the primary concern is that all ingredients are from **approved** sources. Many restaurants require menu flexibility, with changes occurring frequently. Local sourcing of ingredients is another concern for many restaurants, requiring more information on how **approved** sources will be identified. Use of game animal proteins, locally sourced ingredients, and frequent menu changes may require a "generic" listing of ingredients with a policy or procedure for identifying **approved** suppliers. The ingredients list may be as simple as a recipe format or may be more detailed, depending on the process and potentially other factors.

[If you use pre-packaged or pre-blended ingredients such as a seasoning mix, you can list it by blend (mix) name and staple that product information to the back of your Ingredients Form, or add a copy as an inserted photograph into the **HACCP** document.]

All HACCP plans must provide a listing of all ingredients or the recipes used in the process, for each product. It is recognized that retail **food establishments** often desire flexibility in their menus and recipes. For reduced oxygen packaging (ROP) processes, a list of all protein types and all ingredients that are or may be used is generally sufficient. Specific cuts of proteins such as beef, pork, **poultry** (e.g., chicken, turkey, duck) do not need to be listed exhaustively, but whole muscle products must be identified separately from non-whole-muscle items (e.g., mechanically tenderized by injection, Jaccarding, or grinding). Species of **fish** must be listed, as there are species-specific potential **hazards** (e.g., scombroid/histamine toxin, ciguatera toxin, parasites) that must be considered and addressed.

In processes such as smoking, curing, acidification, fermentation of foods for preservation, or making cheese, specific formulations and process steps are critical to the proper preservation and safety of the final product. Examples include use of curing salt in ratios that comply with 9 CFR Part 424.21, or canning vegetables with acidic brine in a ratio that consistently will result in the required target pH, followed by an **approved** thermal process. Curing and pickling processes may also be used in combination with ROP processes. For all such processes, the exact recipes are mandatory elements of the **HACCP plan**, and no **deviations** from the **approved** recipes are allowed without advance review and approval by the regulatory authority.

When chemical preservatives, curing salts, or starter cultures are used, the exact product must be identified by manufacturer and product name with the amount used per batch of product. Review may also be required by the **processing authority**, based on guidance from the regulatory authority.

Date marking requirements of the Food Code are covered in the sections "Specific HACCP Requirements for Reduced Oxygen Packaging" and "Date Marking of Special Process Products" later in this manual.

When recipes and process instructions from a published academic source such as the National Center for Home Food Preservation[9] followed exactly, those recipes and process instructions must still be provided along with the source of the information to validate that process and recipe.

In processes such as sprouting or the operation of molluscan shellfish tanks, the term *recipes* is not applicable. However, the types of seed for sprouting or species of molluscan **shellfish** must be disclosed in the **HACCP Plan**.

The method of packaging, intended use, and intended consumer of the product must be included. If the final product is to be packaged using a reduced oxygen packaging method (vacuum, or modified or **controlled** atmosphere), or canning with an acidification/thermal process, these packaging processes require regulatory authority approval. The intended use and distribution of the end product affect requirements for label content as well as potential requirements for temperature **control**, shelf stability, or other factors affecting formulation or processing. For example, the Food Code requires that the label for raw **meat** packaged at retail using reduced oxygen packaging must include instructions to refrigerate at 41°F. or below and to consume or discard within 30 days of the packaging date. However, if that same product is produced in a **meat** market for consumers' home use, additional, general labeling requirements found in § 3-201.11 and 3-602.11 also will apply. Some key questions to consider in describing the intended uses and distribution of the product include:

- Will the product be used only within my restaurant?
- Will the product be sold in packaged form from my **meat** market, grocery store, or other **food establishment**?
- Is the retail **food establishment** located in a facility that serves a highly susceptible population (elderly, preschool-age children, pregnant women, or persons with compromised immune systems), such as medical centers, adult or child care facilities, or senior centers?
- Do the ingredients of the product include one or more major food allergens recognized in the United States, i.e., milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame?

Step 4: Develop a Process Flow Diagram

AT STEPS 4 AND 5, the team will create a document that will be used repeatedly in the **HACCP plan** development process. The **HACCP team** needs to look closely at the production process and make a flow diagram that shows all the steps used to prepare the product. You don't need to include steps that are not directly under your **control**, such as distribution. The flow diagram could be a line list, or blocks and arrows. The flow diagram doesn't need to be complex. Looking at your establishment's floor plan can help you visualize the process from receiving to service or sale. To

[9] https://nchfp.uga.edu/#gsc.tab=0

find all the food safety **hazards** in your process, you need to know exactly what steps that product/process goes through.

Variations in a process may be desirable to allow for different methods of cooking, or other subtle differences, "occasional" or "optional" steps. It may be possible to address those differences within individual recipes, but all must be pre-planned and fully addressed in the **HACCP plan**. For example, for different products in the same food preparation process, different cooking methods may include poaching, roasting, baking or smoking. The cooking step may be addressed generically in the **HACCP plan**, providing **critical limits** and other required elements of the plan appropriate for each product, and referring to the individual recipes for product-specific cooking instructions. In another example, a retail **food establishment** may primarily use reduced oxygen packaging to store raw **meat** and **poultry** for internal use, but may also sell the product to consumers for home use. In this example, both options must be represented in the flow diagram, **hazard analysis**, and in the procedures provided for each option.

In certain processes (notably canning of acidified foods, pasteurization of juices, and certain curing processes for **preservation** of **meats**), guidance or testing by a **processing authority** may be required to ensure that the process steps follow an **approved** or "scheduled" process, and that the critical elements of those steps meet regulatory and scientific criteria. Consult the regulatory authority for guidance.

Step 5: Verify the Process Flow Diagram

After the **HACCP team** has completed the flow diagram, it needs to be checked for accuracy. To do this, walk through the kitchen and make sure that the steps listed on the diagram realistically describe what occurs during the production process. If possible, have someone who didn't make the flow diagram do the walk-through. Ask employees who conduct the process to describe how they do the process, and verify against the flow diagram. The person(s) who verified the accuracy of the flow diagram should sign and date each page to indicate the verification step was completed.

Conclusion

You have successfully completed the fact-finding part of the **HACCP** development process. Your work through the preliminary steps should have produced these tangible pieces of information:

1. A list of the **HACCP team** members – those who will be trained to work with this process.

2. A comprehensive list of finished products, ingredients, and raw materials (including product labels and packaging), and related equipment.

3. A description of how the product will be sold, and of the intended use and intended consumers.

4. A step-by-step production process breakdown, laid out simply in a flow diagram.

A Template for Preliminary Steps described above follows below. This template is general in nature; more specific requirements are determined by the nature of each process, as discussed above. Consult the regulatory authority for specific guidance.

Preliminary Steps – Template

Name of the process for which this HACCP plan is being developed. Establishment Name and Address	
Products:	List the final products for this process. If menu flexibility is a concern, discuss with the regulatory authority how best to build that flexibility into this plan.
Ingredients:	Provide a list of product names (such as acidified sushi rice, salad dressings, beef medallions) and ingredients, including the proteins and any marinades. To allow for menu flexibility, include all raw major and minor ingredients that might be used occasionally with this process (such as seasonal menu items). If making sausages, what type and diameter of edible sausage casing will be used? Exact recipes will be required for processes such as canning, fermentation, or curing. For more information, refer to the section of this manual that covers the specific process in which you are interested.
Packaging Spec's:	How will the finished product be packaged (vacuum, modified atmosphere, controlled atmosphere, canned, bottled, cartoned, bagged, or wrapped)? What type of ROP film will be used)?
Labeling Req's:	What information must be on the package label? What allergens are present in the product that must be specifically identified on the label? Packaging and use-by dates? If product may or will be sold to consumers for home use, what safe handling instructions are required? (If the consumer must maintain temperature control, or must cook or reheat to a certain temperature, those instructions must be included on the label along with a consume- or discard-by date). Provide an example of the label that will be used.
Intended Use:	Is the product displayed and sold refrigerated, or frozen? Is the finished product ready-to-eat, or will it be subjected to full cooking at point of use (such as by the consumer) or as an ingredient in a recipe? Describe the typical consumer – general population, or high-risk population? Is the product used in-house only, sold for consumers' home use, or both? Is the finished product used in-house in another recipe?
Time/Shelf Life:	What is the shelf life for each product? Is the product stored refrigerated, frozen, or at room temperature? If refrigerated or frozen, what are the required temperatures? If different products have different shelf-life and storage temperatures, list those as separate line-items. Refer to the section of this manual pertaining to your process for further guidance on shelf life.

PROCESS DESCRIPTION
Summarize briefly how this process is used. Is the product used in-house only, or is it sold for customer use off premises? Describe or provide a diagram of the space where this process will be conducted. Is there a dedicated work area, or a procedure to prevent the possibility of cross contamination?

MAJOR EQUIPMENT LIST (Include make, model, and link to specification sheet)	
Grinder	
Mixer	
Thermometers/Temperate Measuring Device	
Electronic Cooler Temperature Logger	

pH Meter	
Scale	
Smokehouse	
Vacuum Packaging Machine	
Assorted Food Grade Measuring Containers, Utensils, Lugs, Totes	
Add Other Equipment As Needed, e.g., Sous Vide Cooking Systems, Stuffers, Dehydrators, etc.	

HACCP TEAM	
Which staff members will be trained and have HACCP responsibilities? Who will be responsible for training team members and maintaining the HACCP plan?	
Title	**Role**
Example: Executive Chef	HACCP Team Leader
	HACCP Team Member

PROCESS FLOW DIAGRAM
Develop the flow diagram below or on a blank page. This can be done using a line list of process steps, or text boxes and arrows. The end result must include every step of the process from receiving of all ingredients, proteins, and packaging, to service or sale of the product. Consider the materials and workflow in your kitchen, and where there may be a potential source of contamination, as you develop the diagram. The flow diagram can be handwritten, or created on the computer.

SECTION 3: UTILIZING THE 7 PRINCIPLES OF HACCP

Understanding Hazards and Controls

This section is about using the seven principles of **HACCP**. All the specific information about the products for this process has been gathered.

Before starting with the first principle, quickly review two important ideas: food safety hazards and preventive measures. **Hazards** are defined as any biological, chemical, or physical property that is reasonably likely to cause food to be unsafe for human consumption. **Preventive measures** are physical, chemical, or other factors that can be used to **control** an identified **hazard**.

Appendices 1 and 2 provide resources for identifying biological, chemical and physical **hazards** and preventive **controls**.

Principle 1: Identify Hazards

Conduct a **hazard analysis**. Use the flow diagram prepared in the preliminary steps to identify the process steps where significant **hazards** could occur, and describe the preventive measures.

> **Here's a Tip**
>
> A common pitfall when figuring out which steps in your process might be CCPs is to name too many as a CCP.

A thorough **hazard analysis** is one of the keys to building an effective **HACCP plan**. The **hazard analysis** process involves identifying **hazards** that are reasonably likely to occur in the absence of **control** and their **preventive measures**. In the first "Identification" stage, the **HACCP team** identifies and lists food safety **hazards** that may be introduced or increased at each step in the production process. It is easy to focus on bacterial hazards that may be present in the raw materials, while overlooking hazards that may be introduced in the process. Some potentially significant hazards introduced in processing may continue with the food throughout the process. Some examples include:

- Human-transmitted viruses, which may not be destroyed at lower cooking temperatures.
- Histamine or scombroid toxin, which forms in certain fish species such as tune as a result of holding temperatures in the temperature danger zone. These toxins are not destroyed by cooking.

> **Preventive Measures**
>
> When determining the appropriate preventive measure for an existing food safety hazard, keep in mind the wealth of regulatory, scientific and historical support. Over the years, both industry and regulators have done a lot of work and identifying food safety hazards and preventive measures that can be used to control them in food production. Don't think that you have to go it alone in this search.

Each process must first be evaluated to identify the **hazards** that are reasonably likely to occur based on what is known about the raw materials and the nature of the process. Appendix 1 provides

FDA tables of biological, chemical, and physical **hazards** associated with raw materials and retail food processes that can assist in this step. Each identified food safety hazard is then evaluated based on its likelihood or frequency of occurrence, and on the severity of human consequences if the **hazard** does occur. The likelihood/severity profile of each potential **hazard** considered "reasonably likely to occur" determines whether a **hazard** is to be considered "significant." Each **hazard** identified as significant requires a specific **control measure** at some step of the process, and that step will be identified as a **critical control point**. In the **hazard analysis table**, a justification is required to explain why each **hazard** is considered significant. **Preventive measures** must be identified to control each significant **hazard** until the step at which specified **control measures** are applied to resolve the **hazard**.

***[Hazards** can vary greatly among **food establishments due** to differences in sources of ingredients, product formulations, processing equipment, processing methods, duration of the processes, and storage methods. Make sure your **hazard analysis** accounts for what's unique about your establishment.]*

Now, use the tables of biological, chemical, and physical **hazards** in Appendix 1 and a tool for assessing likelihood and severity, such as the Risk Analysis Matrix for Food Safety (below) to identify the significant **hazards** ("Yes" in the matrix). Each **hazard** classified as significant based on its **likelihood (frequency)** of occurring, and the **severity** of health consequences if the **hazard** does occur, requires at least one **preventive measure**. If identified at a **critical control point**, at least one specific **control measure** must be identified with **critical limits**, **monitoring, corrective action** procedures, verification measures, and record-keeping requirements.

Risk Analysis Matrix for Food Safety
For each potential hazard, rank the Severity and Frequency based on the chart below. Locate the intersection of these two criteria on the chart. For Potential Hazards scoring as indicated by "yes" in the table below, there is a high risk for negative consequences. Higher risk-severity values can be reviewed to determine whether they will be considered as a hazard or not. Remember that this is an analysis of food safety risk, not negative impact on product quality.

Frequency	**Severity**
A Common occurrence	1. Fatalities likely
B. Known to occur	2. Serious illness
C. Could occur (probable)	3. Product recall required
D. Not likely to occur	4. Consumer complaints
E. Nearly impossible	5. Minimal risk

	A	**B**	**C**	**D**	**E**
1	**Yes**	**Yes**	**Yes**	**Yes**	No
2	**Yes**	**Yes**	**Yes**	No	No
3	**Yes**	**Yes**	No	No	No
4	**Yes**	No	No	No	No
5	No	No	No	No	No

Risk Decisions may be based on several factors:
Facility experience; historical knowledge; customer complaint history
Expert advice; guidance from regulators or trade associations
Detailed knowledge of the product and/or process
Scientific information/data
Technical research

Levels of Severity

1. Fatalities likely – botulism toxin; Listeriosis
2. Serious illness – hospitalization is a distinct possibility; Salmonellosis
3. Product recall required, or illness reported; hospitalization generally not likely; parasites; shigellosis
4. Consumer complaints – off taste or smell; upset stomach, resolves quickly; foreign material observed
5. Illness or injury unlikely

Hazard Identification and Evaluation

The following steps can help you and the **HACCP team** get started conducting your **hazard analysis**.

1. Here are examples of questions you can ask yourself to better understand the hazard identification process:

   - Are additives or preservatives added to the product to kill or inhibit the growth of bacteria?
   - Is the presence of certain pathogens that can cause human illness possible even if growth is inhibited in the food?
   - Will the amount of acidic ingredients affect the growth/survival of bacteria?
   - Does the product need to be refrigerated/frozen or kept dry in storage and during transit?

2. Second, look at the ***product ingredients*** that you listed earlier. In order to find all *significant* food safety **hazards,** you need to know detailed characteristics about all the ingredients used in your process, as well as possible ingredient interactions.

   Here are some questions you can ask about the ingredients:

   - Could these ingredients contain any pathogenic bacteria, dangerous chemicals, or harmful physical objects?
   - If contaminated or mishandled, could the ingredients or materials support the survival or growth of pathogenic bacteria?
   - Are hazardous chemicals used in growing, harvesting, processing or packaging an ingredient?

- Is this ingredient hazardous if used in excessive amounts?

3. Third, determine if any food safety **hazards** exist for each processing step listed in the ***process flow diagram***.

   Here are some questions you can ask for each production step:

   - Could contaminants reach the product during this processing step? How could this happen? Can this be prevented? How?

   - Could this step create a situation where an ingredient, work in process, or finished product becomes contaminated with pathogens? Can this be prevented? How?

   - Could this step introduce a chemical or physical **hazard** into the product? How could this happen? Can this be prevented? How?

> **How Can You Be Sure You're Producing Safe Food?**
>
> A properly functioning HACCP system ensures the safety of your product. Critical control points exist in your establishment already. HACCP helps you to identify and use them to control food safety hazards. The system of HACCP (specifically, the correct identification and monitoring of CCPs) is what makes the answer to this question a sure thing.

Possibilities for the three questions above include: worker handling, contaminated equipment or materials, cross contamination from raw materials, splashing, etc.

- Could bacteria multiply during this process step to the point where they became a **hazard**? Consider product temperature, hold temperature, etc.

> **Keep Good Notes**
>
> A summary of the **HACCP team** meetings and the reasons for each decision during the **hazard** analysis should be kept for future reference. These documents will be a great help to you when you have to review and update your **hazard** analysis and **HACCP plan**.

Finding Preventive Measures

Now that you have a good idea of what you're looking for in the way of **hazards**, use the example tables of **preventive measures** in Appendix 1 as a reference to find ways to keep those **hazards** under **control**.

In some cases, more than one **preventive measure** may be required to **control** a specific **hazard**, or more than one **hazard** may be **controlled** by one **preventive measure**. As you go through the **hazard analysis**, you may recognize **preventive measures** already in place in your production processes.

*When a potential **hazard** is identified as "significant" based on its **risk/severity** profile (a "**Yes**" result using the table below), at least one specific **preventive measure** or **control** measure is required to prevent, eliminate, or reduce that **hazard** to an acceptable level*.

The key to a successful **hazard analysis** is to link the **preventive measures** to the food safety **hazards** you have just identified.

How to Use the Hazard Analysis Form

Here is an example of the Hazard Analysis form, the one for Beef Jerky/Heat-Treated, Shelf Stable. In completing this form, the specific questions found in the column headings must be answered for each step of the process.

Hazard Analysis Worksheet					
Product/Process Name: Beef Jerky/Heat-Treated, Shelf Stable					
Process Step	**What are the potential hazards? B: Biological C: Chemical P: Physical**	**Is this hazard significant?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Step 1					
Step 2					

Process Step: The name of each step, e.g., receiving, cold storage, cooking, etc. Each step of the process must be listed in order on the form, with each step matching the flow diagram or line list of process instructions.

Potential Hazards: Identify each **hazard** that could occur at the identified step, e.g., hazards that occur in an ingredient or food, or as a result of activities at that step. Must consider biological (bacteria, viruses, parasites, etc.), chemical (allergens, natural toxins, other types of chemicals), and physical **hazards**.

Significant Hazard? Using the table and guidance provided in the preceding pages, determine the significance of each potential type of **hazard** *at this particular step*. If no prerequisite program exists to provide **control**, a specific **control measure** is *required* to **control** the **hazard** somewhere in your process. However, **preventive measures** should be identified that will prevent an increase of the **hazard** until the critical step where the **hazard** will be controlled.

Justification of Decision: Explain the reasoning used to determine whether each identified potential **hazard** is significant or not significant based on likelihood that the **hazard** may occur, and severity of consequences to the consumer if the hazard does occur. Example: *E. coli* O157:H7 and *Salmonella* can cause serious/severe health effects, are known to occur on raw meat, and, if present, are not controlled by PRPs.

Preventive Measures: These are measures such as supplier approval policy, employee health and hygienic practices policies, and sanitation standard operating procedures (SSOPs) that provide the level of **control** required by the Food Code for identified potential **hazards** at each process step.

Is this step a CCP? Once the CCPs are identified, they will be indicated in this column. For now, leave the column on the form titled "Is this step a CCP?" blank. We address identifying CCPs next in Principle 2.

To explain how this form works, we'll show you three production steps for which an Example Establishment did a **hazard analysis** for the production of heat-treated, **shelf stable** beef jerky, starting with receiving of raw beef. The form is structured so that the three food safety **hazard** categories (chemical, biological, physical) are addressed in each of the four questions. Refer to the

FDA **hazard** tables in Appendix 1. Don't forget that you need to fill out the top of the form with the appropriate information, such as the product/process name, and the process steps from the flow diagram. You also need to sign or initial and date the form when it's complete.

The first process step we'll look at is receiving meat.

1. **List the hazards**. For the first question, state the potential food safety **hazards** that may be present at that step. The Example Establishment listed pesticides, hormones, and antibiotics as a chemical **hazard**. They listed pathogenic bacteria *E. coli* O157:H7 and *Salmonella* as biological **hazards** because these pathogens have been associated with raw **meat**. Note that it is not sufficient to identify "pathogens" because different pathogens require different **controls**. The intent of **HACCP** is to identify specific **hazards** so the correct **preventive measures** or **controls** can be identified. They also listed plastic and bone fragments as physical **hazards** because the **meat** comes to them in plastic sheaths and bone fragments have been historically associated with raw meat.

2. **Is it a significant hazard?** The second question asks you to decide whether the **hazard** is significant based on its likelihood to occur at that step, and the **severity** of health consequences if the **hazard** were to occur. The Example Establishment answered "No" for the chemical, "No" for the biological, and "No" for the Physical. Designating a **hazard** as "significant" at any step means that the **hazard** requires a specific **control** (CCP), but not necessarily at that step**.** A **hazard** that is reasonably likely to occur at a step may not be significant at that step because it is either **controlled** by a prerequisite program, or by a subsequent process step such as cooking.

3. **What is the justification for your decision?** The third question is where you explain why you answered "Yes" or "No" to the question, "Is this hazard significant?" A supplier Letter of Guaranty should address **control** of physical **hazards** (foreign material), and chemical **hazards** such as pesticide, hormone, and antibiotic residues. This letter should be cited as justification for a "No" response for these hazards. Physical inspection of product may be cited as additional justification for a "No" response for physical **hazards.** For the biological **hazard,** "Yes" because they assume that the identified pathogens are on the **meat** prior to arrival, so that it continues to be a potential **hazard**; however, the **hazard** is effectively destroyed at a later process step (cooking).

4. **What preventive measures can be used to control the hazards?** The next question on the **hazard analysis** form is where you write the specific **preventive measure(s)** that will **control** the potential **hazards**. With each shipment of **meat** the Example Establishment receives, they feel that the "Letter of Guaranty" from their supplier reasonably assures them the **meat** has been kept at a temperature adequate to **control** bacterial growth. However, just because they have one **preventive measure, it** hasn't stopped them from also having a second **preventive measure**. They also visually check the condition and temperature of both the truck and the **meat** products when they arrive at the establishment, to make sure everything meets their standards before they're received. Use prerequisite policies or procedures to **control** significant **hazards** when possible. Examples would be the use of "**approved** supplier" with "Letter of Guaranty" at receiving steps, or the use of Employee Health and Hygiene policies to prevent cross contamination from worker-transmitted illnesses. *When a significant **hazard** is identified, a specific procedural **control measure** must be prescribed at a **critical control point** somewhere in the process.*

Hazard Analysis Worksheet					
Product/Process Name: Beef Jerky/Heat-Treated, Shelf Stable					
Process Step	**What are the potential hazards? B: Biological C: Chemical P: Physical**	**Is this hazard significant?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Meat	**B:** Survival of *E. coli* O157:H7, *Salmonella*	Yes	Although from an approved supplier, these pathogens could still be present. Will be controlled by a later lethality step (cooking).	- Approved Supplier Letter of Guaranty meeting requirements for acceptance - Follow proper receiving and storage procedures.	No
	B: Recontamination with *E. coli* 0157:H7, *Salmonella, Listeria*	Yes	Potential for recontamination is controlled by proper receiving and storage procedures.		
	C: Pesticides, Hormones, Antibiotics	No	No historical occurrence from this supplier	- Approved Supplier, Letter of Guaranty meeting requirements for acceptance	No
	P: Plastic pieces, Bone, Fragments	No	No historical occurrence from this supplier	- Approved Supplier, Letter of Guaranty meeting requirements for acceptance	No
Developed by: Cindy Jones Date: 12/13/2018					

The second process step we'll look at is cooking (heat treatment).

1. **List the hazards**. The Example Establishment listed a chemical **hazard** of sanitizing chemicals because it's possible that traces of these substances could be on the equipment from the last time it was cleaned. They also listed the biological **hazards** of *E. coli* 0157:H7 and *Salmonella* because these pathogens have been associated with raw **meat,** were introduced to the process when raw meat was received, and they have not been adequately controlled by a previous step in the process.

   *[If you don't find a particular type of **hazard** at a step, it's OK to write "None identified" as the Example Establishment did for physical hazards.]*

2. **Is it a significant hazard?** They answered "No" for the chemical **hazard**, because that **hazard** is **controlled** by a prerequisite program (proper sanitation procedures). They answered "Yes" for the biological **hazard** because this step is essential to destroy the identified pathogens and prevent potential growth if the product is re-contaminated in the future.

3. **What is the basis for your decision?** The Example Establishment decided the sanitizing chemicals wouldn't be a **hazard** likely to occur because their proper use is thoroughly covered by existing Sanitation Standard Operating Procedures (SSOPs). They decided "Yes" for the biological **hazard** because cooking to the required minimum temperature at a high humidity level will effectively destroy the significant pathogen **hazards**, and dehydration removes water that is essential to support pathogen growth, if the product were to become re-contaminated.

   *[When working on your **HACCP** plan, you might want to revisit your SSOPs.]*

4. **What are the preventive measures?** The Example Establishment identified one **preventive measure**, cooking at high humidity to destroy the biological **hazard**. They said this is because the heat treatment with humidity above 85% to 90% will destroy any pathogens that may be present, and the water activity reduction will protect the product from potential growth if re-contaminated.

Hazard Analysis Worksheet					
Product/Process Name: Beef Jerky/Heat-Treated, Shelf Stable					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Cooking	**B:** Survival of *E. coli* O157:H7, *Salmonella*	Yes	Failure to meet cooking temperature/time and improper or underdrying may result in survival and growth of these pathogens.	- Cook at 85% to 90% relative humidity to destroy pathogens - Follow SSOPs	Yes
	B: Recontamination with *E. coli* 0157:H7, *Salmonella, Listeria*	Yes	Failing to follow sanitary handling procedures after cooking may result in recontamination.		
	C: Sanitizer residues	No	Following the SSOPs will prevent this hazard	- Follow SSOPs	No
	P: None identified				
Developed by: Cindy Jones Date: 12/13/2018					

The third process step we'll look at is dehydration.

1. **List the hazards**. The Example Establishment listed a biological **hazard** because handling will be required to package the finished product, so there is some **risk** of bacterial growth if the product is not properly dried and becomes re-contaminated.

   *[If you don't find a particular type of **hazard** at a step, it's OK to write "None identified" as the Example Establishment did.]*

2. **Is it a significant hazard?** They answered "Yes" for the biological **hazard** because this step is essential to prevent potential growth if the product is re-contaminated in the future. Sanitation **control** is also essential to reducing **risk** of re-contamination.

3. **What is the justification for your decision?** The Example Establishment decided "Yes" for the biological **hazard** because dehydration removes water that is essential to support pathogen growth, if the product became re-contaminated.

4. **What preventive measures can be used to control the hazards?** The Example Establishment identified one **preventive measure**, dehydration, to prevent growth of any biological **hazard**. They said this is because the water activity reduction will protect the product from potential growth if re-contaminated

Hazard Analysis Worksheet					
Product/Process Name: Beef Jerky/Heat-Treated, Shelf Stable					
Process Step	**What are the potential hazards? B: Biological C: Chemical P: Physical**	**Is this hazard significant?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Dehydration	**B:** Recontam-ination and growth of *E. coli* O157:H7, *Salmonella, Listeria*	Yes	Inadvertent recontamination after drying or underdrying may result in survival and growth of these pathogens	- Dehydrate to level of shelf stability - Follow SSOPs, sanitary handling procedures	Yes
	C: Sanitizer residues	No	Following the SSOPs will prevent this hazard	- Follow SSOPs	No
	P: None identified				
Developed by: Cindy Jones Date: 12/13/2018					

Principle 2: Identify Critical Control Points

A **critical control point** is defined as "*A point, step, or procedure in a food process at which **control** can be applied and is essential to prevent or eliminate a food hazard or reduce it to an acceptable level.*" Simply put, a CCP is the step at which, if the required **control measure** is not applied, or if it fails, the resulting product may be unsafe. Everything in your **HACCP plan** revolves around the proper identification of CCPs. Remember that when there is a prerequisite program that can serve as a **preventive measure** providing at least the same level of safety as would be provided by the Food Code **controls** against a specific **hazard**, a CCP may not be required. For example: If a jerky production process proceeds from smoking to cooking and directly to drying, and a water activity level less than 0.85 is achieved in the drying step, the next step (cooling) would not be a CCP. The Food Code requirements for the cooling rate apply only to **TCS** food; food with water activity less than 0.85 is non-**TCS**.

It is also essential to remember that the order of processing steps can influence placement of CCPs, and the number of CCPs. For this reason, two processes that at a glance might seem to be the same could actually be very different. For example, a jerky process that proceeds from smoking to cooking to dehydration as stages of a single process step should result in finished product with water activity less than 0.85 after dehydration. In this case, the cooking/dehydration step has three **critical limits** at the same CCP: cooking temperature/time, relative humidity during the cooking step, and the final water activity. Cooling after dehydration is not a CCP because the food is already non-**TCS**, and the cooling requirements of the Food Code only apply to **TCS** foods. On the other hand, if there is a cooldown step after cooking without humidity **control** followed by holding to the next day before dehydration, there will be three additional CCPs: cooling, cold storage, and dehydration. In this alternative process, the dehydration step must provide the critical heat treatment step at high humidity followed by drying, in which case the previous cooking step cannot be considered critical (there is a subsequent kill step). We will cover this in more detail below.

Some of the most common CCPs are:

- Chilling or freezing to a specified temperature to prevent bacteria from growing.
- Cooking that must occur for a specific time and temperature in order to destroy bacteria.

- Certain processing procedures, such as filling and sealing cans, mixing and spicing, etc.
- Cure to protein ratio (weight of cure in a specified weight of protein)
- Achieving a specified maximum "pH"
- Labeling to inform consumers of use-by dates and the need for refrigeration

These are just a few examples of possible CCPs. Different facilities, preparing the same food, can identify different food safety **hazards** and different **critical control points**. Two different facilities could also identify the same potential **hazard**, but identify two different locations at which they will place their **critical control point**. Usually, no two **food establishments** have the same floor plan, equipment, or ingredients. The CCPs you identify will reflect the uniqueness of your retail establishment.

One of the tools used to help determine **critical control points** is a **CCP Decision Tree**. The thought process in the decision tree will help you ensure that your **HACCP system** meets regulatory requirements.

Working With the CCP Decision Tree Form

The Example Establishment used the **CCP Decision Tree** to take a closer look at both steps in their process where they determined food safety **hazards** were significant. Go ahead and read the questions below and then we'll look at each one in detail. This approach is strongly encouraged to meet regulatory requirements.]

The first step to look at is receiving meat.

Question 1a – Do control measure(s) exist for the identified hazard? The Example Establishment answered "Yes" because seeing the Letter of Guaranty from the supplier and checking the temperature of the truck and products are the **preventive measures** for this biological **hazard**. Establishment history with the **approved** supplier has also proven effective in ensuring no presence of chemical or physical **hazards** in incoming product.

Question 1b – Must control be applied at this step for safety? If you answered "Yes" for question 1a, then you don't need to worry about question 1b. (If you haven't yet identified a **preventive measure** for a food safety **hazard**, question 1b will not let you move down the **CCP Decision Tree** until you do.)

Question 2 – Does this step prevent, eliminate, or reduce the hazard to an acceptable level? This question asks whether or not this step "prevents, eliminates, or reduces" to acceptable levels, the food safety **hazard** you are working with. The Example Establishment said "No" because simply receiving the **meat** doesn't mean the biological **hazard** is **controlled**.

Question 3 – Could contamination with the identified hazard occur at an unacceptable level, or could the hazard increase to an unacceptable level? The Example Establishment said "Yes" here because raw meats are potentially contaminated with *E. coli* 0157:H7 or *Salmonella*, whether or not growth occurs. If not **controlled**, the biological hazard could get worse.

Question 4 – Will a later process step either eliminate the significant hazard, or reduce it to an acceptable level? Here the **HACCP team** must decide if this step is the last point at which **control** could be applied to the **hazard**. In this case the Example Establishment found that, in fact, a later step (i.e., cooking) could **control** this biological food safety **hazard**. This process step was not a CCP.

- Could this step introduce a chemical or physical **hazard** into the product? How could this happen? Can this be prevented? How?

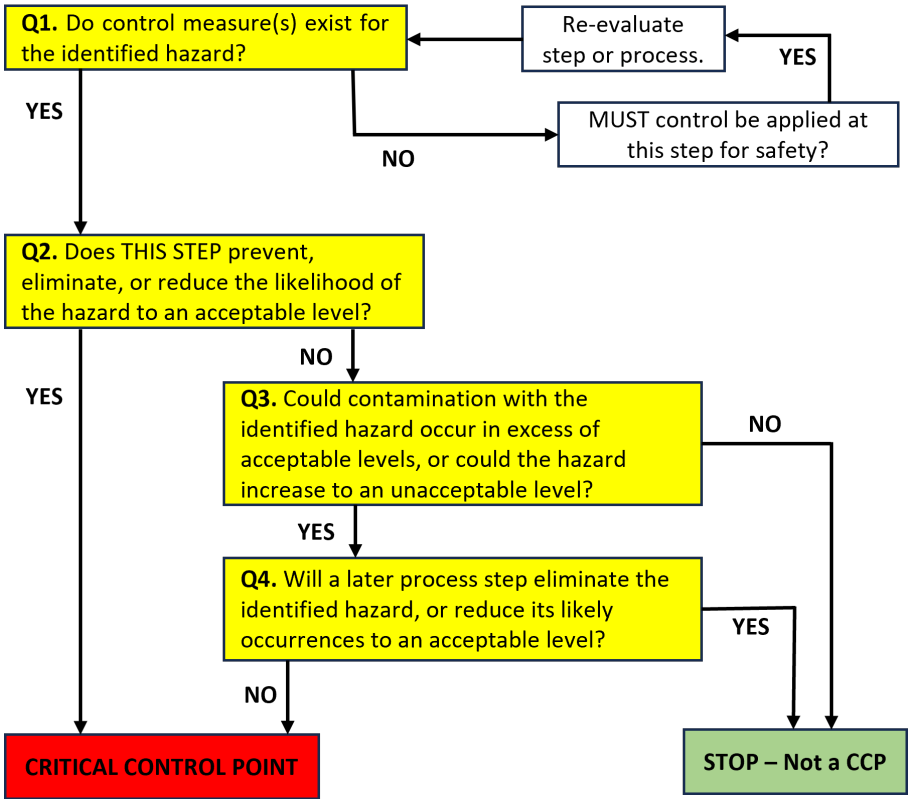
Numbering Your CCPs

Once you've been through your entire production process and have successfully identified all the CCPs, there's one more thing you need to do to get those CCPs set up: You need to organize them. Feel free to do this in any way that works for your business.

One easy way to accomplish this is to develop a simple numbering system. It's a good idea to always write "CCPs" before the numbers. This can make your documents easier to understand. For instance, you could write it like: CCP 1, CCP 2, CCP 3.

Also remember that you could have more than one CCP (for a designated food safety hazard) at a given process step or one CCP may control more than one hazard. In either case, you may want to include the letter 'B,' 'C,' or 'P' to identify whether it is a biological, chemical, or physical hazard, e.g., CCP 1B, CCP 1C, CCP 2P, CCP 2C.

CCP Decision Tree



Hazard Analysis Worksheet					
Product/Process Name: Beef Jerky/Heat-Treated, Shelf Stable					
Process Step	**What are the potential hazards? B: Biological C: Chemical P: Physical**	**Is this hazard significant?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Meat	**B:** Survival of *E. coli* O157:H7, *Salmonella*	Yes	Although from an approved supplier, these pathogens could still be present. Will be controlled by a later lethality step (cooking).	- Approved Supplier, Letter of Guaranty meeting requirements for acceptance - Follow proper receiving and storage procedures. - SSOPs, handling and storage SOPs.	No
	B: Recontamination with *E. coli* 0157:H7, *Salmonella, Listeria*	No	Potential for recontamination is controlled by proper receiving and storage procedures. Controlled by following SSOP, handling and storage SOPs		
	C: Pesticides, Hormones, Antibiotics	No	No historical occurrence from this supplier	- Approved Supplier, Letter of Guaranty meeting requirements for acceptance	No
	P: Plastic pieces, Bone fragments	No	No historical occurrence from this supplier	- Approved Supplier, Letter of Guaranty meeting requirements for acceptance	No
Developed by: Cindy Jones Date: 12/13/2018					

The second step is the cooking step.

Question 1a – Do control measure(s) exist for the identified hazard? The Example Establishment answered "Yes" here after identifying the **preventive measure** of cooking (i.e., time and temperature) as critical at this step.

Question 1b – Must control be applied at this step for safety? Since the answer to question 1a was "Yes," move on to question 2.

Question 2 – Does this step prevent, eliminate, or reduce the hazard to an acceptable level? The Example Establishment said that "Yes" cooking would eliminate the **hazard** at this step. They stopped here at question 2 because they reached a positive result ... their CCP. Thus, there was no need to go on to questions 3 and 4.

Hazard Analysis Worksheet					
Product/Process Name: Beef Jerky/Heat-Treated, Shelf Stable					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant ?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Cooking	**B:** Survival of *E. coli* O157:H7, *Salmonella*	Yes	Failure to meet cooking temperature/time and improper or underdrying may result in survival and growth of these pathogens.	- Cook to at least 145°F. while maintaining 90% relative humidity in a sealed oven or injecting steam for 50% of cooking time or 1 hour (whichever is longer) per USDA-FSIS Appendix A Options 1 and 2, and "Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Plants." - Dehydrate to critical aW of 0.85 or lower - SSOP (preventive)	YES CCP 1 (cook temp, time, and humidity)
	B: Recontam-ination with *E. coli* O157:H7, *Salmonella, Listeria*	Yes	Failure to follow sanitary handling procedures could result in recontamination.		
	C: Sanitizer residues	No	Following the SSOPs will prevent this hazard	- Follow SSOPs	No
	P: None identified				
Developed by: Cindy Jones Date: 12/13/2018					

After completion of this step, any pathogens have been destroyed, and the product must be dehydrated to prevent pathogen growth, should re-contamination occur during handling as the product is packaged.

The third production step is dehydration.

Question 1a – Is there a control measure at this step? The Example Establishment answered "Yes" here because they identified the **preventive measure** of dehydration (i.e., time and temperature) as critical at this step.

Question 1b – Is control essential at this step? Since the answer to question 1a was "Yes," move on to question 2.

Question 2 – Does this step prevent, eliminate, or reduce the hazard to an acceptable level? The Example Establishment said that "Yes" dehydration would prevent any further **hazard** at this step. They stopped here at question 2 because they reached a positive result ... their CCP. Thus, there was no need to go on to questions 3 and 4.

Hazard Analysis Worksheet					
Product/Process Name: Beef Jerky/Heat-Treated, Shelf Stable					
Process Step	**What are the potential hazards? B: Biological C: Chemical P: Physical**	**Is this hazard significant?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Dehydration	**B:** Recontam-ination and growth of *E. coli* O157:H7, *Salmonella*	Yes	Inadvertent re-contamination after underdrying may result in growth of these pathogens	- Dehydrate to level of shelf stability - Follow SSOPs including employee hygienic practices	YES CCP 2 (Final water activity)
	C: Sanitizer residues	No	Following the SSOPs will prevent this hazard	- Follow SSOPs	No
	P: None identified				
Developed by: Cindy Jones Date: 12/13/2018					

After identifying the CCPs in the process, label the CCPs on the flow diagram at the proper steps – in this example, the cooking and dehydration steps. Then create a **HACCP plan** summary table (CCP Audit Table). The example table summarizing data for Principles 3 through 7 is found at the end of Section 3.

Principle 3: Establish Critical Limits for Each Critical Control Point

A **critical limit** is defined as "*A maximum and/or minimum value to which a biological, chemical, or physical parameter must be **controlled** at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard*." You can think of a **critical limit** as a boundary separating safe from unsafe for a CCP. The **critical limit** is generally a numerical threshold value that is **controlled** or manipulated in the process and must be met to assure that **hazards** have been **controlled**. A **critical limit** can also be a specific observable characteristic, such as the presence of a date mark and consumer safe handling instructions on a product label. An example would be the presence of safe handling instructions on a consumer product label reading, "Keep refrigerated or frozen. All sausage products must be cooked to 155^{o}F. for 17 seconds before consuming."

Each CCP will have at least one (possibly more) **preventive measure(s)** that need to be **controlled** to assure this prevention, elimination, or reduction of food safety **hazards**. To be effective, each **critical limit** should be:

1. **Based on proven factual information.** A few ways that information and recommendations for appropriate limits can be obtained are: from regulatory requirements, scientific literature, and consultation with experts. If regulatory requirements exist, they must be met or exceeded unless scientific data is provided supporting an alternative **critical limit** and a **variance** from the regulatory requirement.

2. **Measurable or observable.** Time and temperature, for example, are measurable characteristics. The presence of an accurate date mark and safe handling instructions would be observable characteristics of a consumer product label.

3. **Appropriate and reasonable for the food** product **and operation.** You should consider the type of equipment, the volume of product being produced, how the **critical limit** will be **monitored,** and frequency of **monitoring**.

4. **Specific.** When drafting your **critical limits,** be specific in your language. An example procedure instruction for **poultry** could be, "Bake uncovered in preheated 350°F. oven to an instantaneous internal temperature of 165°F."

The **HACCP team** will find that many **critical limits** for your identified CCPs have already been established.

In some cases, you'll need more than one **critical limit** to **control** a particular **hazard**. For example, the typical critical limits for cooked beef patties are time/temperature. It is important that you identify all the **critical limits** for each of your products.

Making sure each **Critical Control Point** has critical limits is the responsibility of each retail establishment.

Applicable local regulations are the first source of certain critical limits – such as required cooking temperatures. The **HACCP team** may need to obtain guidance from the regulatory authority or outside **HACCP** experts when establishing critical limits not specified by the Food Code or local regulations. Remember that the **critical limits** found in regulatory requirements/guidance or other literature must be appropriate for the food you are processing, and must be able to maintain **control** over the food safety **hazard**. Once the team has identified all the limits, enter them onto the Critical Control Point Summary form.

Some Controls Commonly Used as Critical Limits

Time and Temperature – The temperature danger zone for biological **hazards** is between 41°F. and 135°F. (5°C. and 57.2°C.). Bacteria grow fast! They are able to multiply rapidly. Knowing this shows that **controlling** how long the product is in the danger zone (if at all) presents itself as an extremely effective critical limit.

pH – The pH of a food is the level of its acidity or alkalinity. The pH is measured on a scale of 0 to 14. The middle of the scale, pH = 7.0, is considered neutral. Altering a food's pH, such as by adding an acidic substance like vinegar or soy sauce, will decrease the growth rate of bacteria.

Water Activity – In addition to warm temperatures and a fairly neutral pH, bacteria also need water to grow. Water activity (aW) refers to the amount of water in a food that is available, or free, for bacteria to use for growth and multiplication. Dissolved compounds such as salt and sugar, and dehydration, decrease the available water and can reduce bacterial growth.

Documenting the Source

*When determining your **critical limits,** make sure you file your supporting documentation with your **HACCP plan**. This documentation will help validate that the limits have been properly established. This could be things such as citations from state regulations or USDA-FSIS directives, letters from Process Authorities, published scientific studies, or laboratory test results. By holding on to these supporting documents, you also provide **verification** material when needed. The templates provided in Section 5 include **validation** references for each process as hyperlinks at the end of each template. These reference citations should be included as part of the **HACCP plan**.*

Principle 4: Establish Monitoring Procedures

Monitoring involves a series of observations and/or measurements that are used to make sure a CCP is under **control**. The **HACCP team** can think of **monitoring** activities as the checks and balances for each CCP. When someone **monitors**, they are checking to see that the **critical limits** are being met.

What are 3 things monitoring can do for you?

- Shows you when a **deviation** from a **critical limit** has happened. For example, an employee tests the temperature of some beef patties in the cooler and discovers that the internal temperature has gone above the established **critical limit** of 41°F. If not caught here, this would be a potentially serious health **risk** to consumers.

- Helps you identify trends in your process that will allow you to predict a loss of **control** at a CCP. For example, an establishment may **monitor** the temperature of a cold storage area at 6 a.m., 8 a.m., and 10 a.m. Each time, the temperature is within acceptable limits, but it is steadily climbing toward the high end of the range. This information points towards a trend, and the establishment should take action to prevent the temperature from exceeding the **critical limits.**

- Produces written records for use in future **HACCP plan verification** steps. Written **monitoring** records will prove very valuable to your operation, should a serious problem occur along the production line. The records you keep prove that your company has established and carried out effective **monitoring** techniques.

Monitoring procedures can be thought of as continuous or non-continuous.

- **Continuous monitoring** is the constant **monitoring** of a **critical control point**.
- **Non-continuous monitoring** is the scheduled **monitoring** of a **critical control point**.

Continuous monitoring is always preferred when feasible. **Continuous monitoring** at a CCP is usually done with built-in measuring equipment, such as a recording thermometer used at a cooking step, or an electronic temperature logger used in a cooler. To make sure these activities stay accurate, you need to regularly check the **monitoring** equipment to make sure that it is calibrated correctly. Note that use of continuous electronic temperature loggers is required for **monitoring** coolers used to store sous vide cooked foods and packaged ROP Cook-Chill products.

If **continuous monitoring** isn't feasible for your CCP, then the **HACCP team** will need to establish **non-continuous monitoring** procedures. Non-continuous doesn't mean random. The team should decide in the development phase what the **monitoring** schedule should be. When you use **non-continuous monitoring**, make sure that it's scheduled often enough to keep the food safety **hazards** under **control**. Expert advice from people with knowledge of practical statistics and statistical process **control** will be important in making your decisions. Types of **non-continuous monitoring** procedures include visual examinations, **monitoring** ingredient specifications, measurements of pH or water activity (aW), taking product temperatures, etc.

Who's responsible?

Make sure to assign a specific person to be responsible for the **monitoring** of a CCP. More than one person may need to be identified as being responsible, based on hours of operation and shifts. The

Example Establishment has a designated shift leader/cook who is responsible for **monitoring** the cooking CCP. The person who actually does the **monitoring** must be the person who signs and dates all the records at the time of monitoring.

Monitoring will be most effective when:

- The **HACCP plan** clearly identifies the employee(s) responsible for **monitoring.**
- Employees are trained in the proper testing procedures, the established **critical limit**s, the methods of recording **monitoring** results, and the actions to be taken when **critical limits** are exceeded.
- Employee(s) understand the purpose and importance of **monitoring.**
- Management reviews the **monitoring** logs on a routine basis.

The last step in establishing your **monitoring** procedures is to develop the **monitoring** log(s) where the **monitoring** person will record the date for each CCP. Due to the variety of **monitoring** procedures, the **HACCP team** may need to develop different logs to record the **monitoring** data at different CCPs. When your **HACCP system** is up and running, you will use these logs to track the day-to-day **HACCP** activities. Sample logs are provided in the Appendix.

The **monitoring** procedures must include:

- The Who is the person responsible for the **monitoring** at each CCP.
- The What is the **critical limit** value (temperature/time, refrigeration temperature, date mark, etc.) that must be **monitored**.
- The When is the frequency of **monitoring** (once per batch, twice daily, continuous).
- The How is with the method of **monitoring** (e.g., calibrated thermometer, visual inspection).

Remembering Your Monitoring

The key to effective and reliable monitoring is to keep it simple and build it into the employees' normal routines. When establishing a time for the actual monitoring procedure, allow some flexibility. For example, if you say you will monitor a CCP at 10 a.m. and the person is not there at exactly 10 a.m., you could be opening yourself up for problems. It is suggested that you specify a time period during which monitoring will occur. For example, write your time as 10 a.m. +/- 10 minutes, or between the time period of 9:50 a.m. and 10:10 a.m.

Principle 5: Establish Corrective Actions

Corrective Action can be defined as "Procedures followed when a **deviation** occurs." A **deviation** is defined as a "failure to meet a **critical limit**."

Deviations can and do occur. After the **HACCP team** has established strict **monitoring** procedures, the next step is to draft **corrective actions** to be taken immediately when there is a loss of **control** at a CCP.

A corrective action may include, but is not limited to the following procedures:

1. Identifying and eliminating the cause of the **deviation**,
2. Demonstrating that the CCP is once again under **control**. (This means examining the process or product again at that CCP and getting results that are within the **critical limits**.),
3. Taking steps to prevent a recurrence of the **deviation**,
4. Making sure that no adulterated product enters commerce. There may be several acceptable options, such as continue cooking, reprocess, use an alternative safety **control measure**, discard, etc.)
5. Assessing when to discard product.
6. Maintaining detailed records of the **corrective actions**.

If a deviation occurs that is not covered by a specific corrective action in your HACCP plan, or if some unforeseen hazard arises, appropriate steps should be taken. These steps shall include, but not be limited to:

1. Segregate and hold any affected product until its acceptability can be determined.
2. Determine the acceptability of the affected product for distribution.
3. Do not allow sale or service of product that may be injurious to health or otherwise adulterated.
4. Reassess and, if necessary, modify your HACCP plan to properly address this type of deviation in the future.

Maintain detailed records of your actions.

Some examples of corrective actions are:

- Changing the process and holding the product for further evaluation.
- Empowering the **monitoring** personnel to stop production when a **deviation** occurs. They should have the authority to hold all batches of a product not in compliance.
- Rely on an **approved** alternate process that can be substituted for one that is out of **control** at the specific CCP.
- Adding cooking time.
- Quickly cooling product.
- Destroying and disposing of affected product.

Whatever type of corrective actions the HACCP team establishes, records for each one need to be kept that include:

- The **critical limit** that was not met.

- The reason for holding the product, the time and date of the hold, the amount of the product involved, and the disposition and/or release of the product.

- The actions that were taken to prevent the **deviation** from recurring.

- The dated signature of the employee who was responsible for taking the **corrective action**.

As with **monitoring** logs, the **HACCP team** also needs to develop the log(s) for the **corrective action** results.

Working with the "Corrective Action Procedures" Form

The Example Establishment's **corrective action** form outlines exactly what they think should be done if a problem occurs with the CCP 01.

- **Under the "Problem" heading.**

  They state the **critical limit** that has been established for this CCP.

- **Under the "Disposition of Product" heading.**

  If a **deviation** occurs, they have noted that the initial disposition would be to hold the product lot, and try to rework it if possible. The rework would consist of fixing the temperature and recooking the jerky.

- **Under the "Corrective Action Procedures/Steps" heading.**

  As you can see, the Example Establishment listed quite specific **corrective actions** for this CCP. Their directions are written concisely, and in the order they should be performed.

- **Under the "Person Responsible" heading.**

  They are specific in naming a particular person.

- **Under the "Compliance Procedures" heading.**

  The Example Establishment has projected that if this **deviation** happens at this CCP it will probably be because something went wrong with the thermostat in the oven. They list here what will probably need to be done to make sure this doesn't happen again. (If this **deviation** were to actually happen, the **monitoring** person would write on the **corrective action** log what he or she did to fix the problem, and what they did to make sure it wouldn't happen again.)

Corrective Action Log

CCP #	Date	Product	Problem	Disposition of Product	Corrective Actions	Person Responsible	Compliance Procedures (Preventive Measures)
CCP 1 Cooking	3/21/23	Jerky, Classic	Did not not reach CL for internal temp	Rework	Checked calib. of thermocouple – was inaccurate; called service, replaced and checked calibration of new thermocouple	JW	Production manager or trained designee will check calibration of thermocouple before each production batch.

Stopping Production

The more ownership employees feel they have in the **HACCP system**, the more effective they will be in ensuring that your establishment produces safe food.

One idea is to empower the person responsible for monitoring to be able to stop production when and if a **deviation** occurs. This accomplishes two important functions:

- First, it prevents the potentially hazardous product from continuing through production.
- Second, it makes timely communication easier; thus, you find out what's happening in the process as soon as possible.

Principle 6: Validate and Verify

Your team needs to decide on the procedures your establishment will perform to verify that the **HACCP system** is working effectively and how often these actions will be performed. **Verification** uses methods, procedures, or tests in addition to those used in **monitoring** to see whether the **HACCP system** is in compliance with the **HACCP plan** or whether the **HACCP plan** needs modification. There are three types of **verification**. These are initial **validation**, ongoing **verification**, and reassessment of the **HACCP plan**.

Initial Validation

Validation is defined as "*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*." The initial validation of your **HACCP plan** is the process by which your establishment proves that what is written in the **HACCP plan** will be effective in preventing, eliminating, or reducing food safety **hazards**. This **validation** activity is the exclusive responsibility of your establishment.

You carry out this **validation** by gathering evidence that supports your **HACCP plan**. The data you bring together can come from many sources. Such sources may include scientific literature, product testing results, regulatory requirements, and/or industry standards. Companies have a lot of flexibility regarding the sources and the amounts of such data in compiling this information. Monitoring records from a process that has been running successfully with properly implemented controls may provide data acceptable to the regulatory authority as additional validation that

critical limits can be consistently met for all product from the process. HACCP models from academic or food manufacturing sources may also be cited as validation for a comparable process conducted at retail.

Most likely, you already have the majority of the **validation** information you need. When you conducted your **hazard analysis** and researched the sources for your **critical limit**s, you were collecting data that could also be used to validate your entire **HACCP plan**.

The templates provided in Section 5 include **validation** references for the typical **critical controls** for the processes represented. Depending on an establishment's own procedures, other or additional **validation** references may be required. Your local jurisdiction may have additional **validation** requirements, such as review by a process authority or standard recipe sampling. Contact your regulatory authority for **validation** information and requirements.

Ongoing Verification

Verification is " … *those activities, other than monitoring, that determine the validity of the **HACCP plan** and that the system is operating according to the plan*." After a **HACCP plan** has been initially validated and put into action, **verification** activities continue on an ongoing basis.

Simply stated, you need to verify that your **HACCP system** is working the way you expected. There are several ways to do this; here are a few examples:

- Calibrate your monitoring equipment.
- Sample your product.
- Review your monitoring and corrective action logs on a routine basis.
- Observe employees as they do their work.
- Personally inspect your establishment's operations.

Whatever types of ongoing **verification** activities you decide to use, they should be included in your **HACCP plan** along with the specifics on your CCPs, **critical limits**, **monitoring**, and **corrective actions**. Also, the **HACCP team** needs to identify the schedules for conducting the **verification** checks. Like **corrective actions**, **verification** statements should identify the required activity, the responsible person, and the required frequency. Your regulatory authority may also verify your **HACCP plan** during an inspection. You should be able to provide complete records for review.

Reassessment of the HACCP Plan

The adequacy of your **HACCP plan** should be reassessed at least once a year and whenever any new changes occur that could affect the **hazard analysis** or alter the **HACCP plan**. Here are a few, but not all, of the instances that would require modification of your **HACCP plan**:

1. Potential new **hazards** are identified that may be introduced into the process.

2. A food safety failure has occurred.

3. A product recipe changes, new proteins or other ingredients added, or an ingredient supplier is changed.

4. New or different processing equipment is introduced.

5. Significant production volume changes require updated sanitation procedures or new equipment.

6. There are changes in personnel.

7. Changes are made in the regulations.

8. Verified consumer complaints or verified illnesses associated with product from the process, or trends of the same complaint are received.

9. Patterns of **deviations** result in **corrective actions**.

Your reassessment should include a review of the existing **HACCP plan**, including the product evaluation, **hazard analysis**, **critical control points**, **critical limits**, **monitoring** procedures, **corrective actions,** and record-keeping procedures. Review any PRPs identified as controlling a potential hazard in the hazard analysis. The performance of the PRPs since the last reassessment should be reviewed to ensure they are still effectively controlling the hazards and are thereby supporting the decisions made in the hazard analysis.

It is important to remember that when an ingredient is substituted in a recipe, or when there is a change to a different supplier of an ingredient, it is essential to review the new product label carefully. There may be differences such as acid strength (vinegar), salt content, water activity, or allergens. Any of these can affect product formulation, labeling, or labeling requirements.

It's important to remember that **verification** procedures are ongoing activities. For each CCP you will need a **monitoring** log, a **deviation**/**corrective action** log, and an equipment calibration log. These logs are the continual **verification** that **HACCP** is being implemented effectively.

Like the **monitoring** procedures, the **verification** procedures must specify who is responsible, what the activity is, how that activity is conducted, and how often that activity occurs.

Principle 7: Establish Record-Keeping Procedures

The records you keep for **HACCP** can make all the difference! Good **HACCP** records – meaning they are accurate and complete – can be a great help to you. Here's why:

- Records make it possible to trace ingredients, in-process operations, or finished products, should a problem occur.

- Records help you identify trends in your production.

- Records serve as written documentation of your establishment's compliance with the HACCP regulations.

- Records help identify training needs, trends, and opportunities for improvement in plan implementation and revision when needed.

Well-maintained records protect your customers, your business, and YOU.

Your **HACCP** records should include your development notes and your daily logs for each CCP. The **hazard analysis** and CCP summary (also may be called **HACCP** Summary or CCP audit table) represent the heart of the **HACCP plan**. The CCP summary must include the **critical limits** for each

food safety **hazard**, **monitoring** requirements for each CCP and **critical limit**, clear **corrective action** instructions, and the required records. When first establishing your record-keeping procedures, it's better to think of the different kinds of records you'll need in two ways:

- **First,** there are records that are used for development for archival purposes, such as your **hazard analysis**, your **risk** assessment tool, and your CCP decision-making tool.

- **Second,** there are records that you will work with on a day-to-day basis. These are the logs we've been discussing such as the **monitoring** or **corrective action** logs. As we've said before, the **HACCP team** will need to create these logs for each CCP in your process. Later in this book, example **monitoring** logs and other record forms are provided.

The FDA Food Code requires that you keep records on specified information; see HACCP Plan Record Keeping, p. 243, and Section 9 for further details and example forms and **monitoring** logs. Regardless of the type of record, all **HACCP** records must contain at least the following information:

- Title and date of record
- Product identification
- Signature of employee making entry
- A place for the reviewer's signature
- An orderly manner for entering the required data

All data entries must be made at the time of the observation or measurement!

Tips on Designing Records

One way to approach development of the record keeping requirements of your HACCP system is to review the records you already keep to see if they are suitable, in their present form or with minor modifications, to serve the purposes of your HACCP system. The best record-keeping system is usually the simplest one that can easily be integrated into the existing operation.

When developing and working with your forms and logs, remember to use ink (ballpoint pen – no pencils). On all records, whenever you make a change, strike through the original with a single line, and initial. Do not erase, white out, or mark the original so that it is unreadable.

Place a blank copy of all logs/forms in the **HACCP** plan to show how you record this information.

Section 4: General Food Code Requirements

Introduction

HACCP is a universal preventive system for assuring the safe production of food products. The Preliminary Steps and Seven Principles of **HACCP** can be applied to most any food production process including agriculture production, food processing, retail food preparation, and distribution systems. Previous sections in this manual have focused on the basics of developing a **HACCP plan**.

The Food Code applies to retail **food establishments** such as grocery stores, restaurants, **meat** markets, convenience stores, and retail caterers. It is important to note that establishments must submit the **HACCP plan** to the regulatory authority before the start of operation for approval.

In this book, Section 2 focused on Preliminary Steps. Basically, the preliminary steps are a method to collect information that is used in developing the **HACCP plan**. The Food Code requires that information in the preliminary steps becomes part of your official **HACCP plan**. Section 3 of this book focuses on developing the **HACCP plan** itself using the Seven Principles. In addition, the Food Code requires that the **HACCP plan** for your retail **food establishment** contain some additional essential components, called "prerequisite programs" (PRPs), which directly support the effectiveness of the HACCP plan.

Required Contents of a HACCP Plan

When a **food establishment** is required to have a **HACCP** plan, Section 8-201.14 of the FDA 2022 Food Code requires that the plan and specifications shall include:

(A) General information such as the name of the PERMIT applicant or PERMIT HOLDER, the FOOD ESTABLISHMENT address, and contact information.

(B) A categorization of the types of TIME/TEMPERATURE CONTROL FOR SAFETY FOODS that are to be controlled under the HACCP PLAN.

(C) A flow diagram or chart for each specific FOOD or category type that identifies:

- Each step in the process
- HAZARDS and controls for each step in the flow diagram or chart
- Steps that are CRITICAL CONTROL POINTS
- Ingredients, materials, and equipment used in the preparation of that FOOD
- Formulations or recipes that delineate methods and procedural control measures that address the FOOD safety concerns involved

(D) A CRITICAL CONTROL POINTS summary for each specific FOOD or category type that clearly identifies:

- Each CRITICAL CONTROL POINT

- The CRITICAL LIMITS for each CRITICAL CONTROL POINT
- The method and frequency for monitoring and controlling each CRITICAL CONTROL POINT by the designated FOOD EMPLOYEE or the PERSON IN CHARGE
- The method and frequency for the PERSON IN CHARGE to routinely verify that the FOOD EMPLOYEE is following standard operating procedures and monitoring CRITICAL CONTROL POINTS
- Action to be taken by the designated FOOD EMPLOYEE or PERSON IN CHARGE if the CRITICAL LIMITS for each CRITICAL CONTROL POINT are not met
- Records to be maintained by the PERSON IN CHARGE to demonstrate that the HACCP PLAN is properly operated and managed

(E) Supporting documents such as:

- FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern
- Copies of blank records forms that are necessary to implement the HACCP PLAN
- Additional scientific data or other information, as required by the REGULATORY AUTHORITY, supporting the determination that FOOD safety is not compromised by the proposal

(F) Any other information required by the REGULATORY AUTHORITY.

Variances and the HACCP Plan

An **approved variance** is required when a retail **food establishment** chooses to use a **control measure** outside of Food Code requirements. In such cases, supporting scientific evidence must be provided as **validation** to show that the alternative **control measure** provides a level of safety at least equal to that provided by the Food Code **control** that is being replaced. The regulatory authority may grant a **variance** by modifying or waiving the requirements of the Food Code if in the opinion of the regulatory authority a health **hazard** or nuisance will not result from the **variance**. Paragraph 8-103.11 of the Food Code requires that 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 the **food establishment** must include:

1. A statement of the proposed **variance** of the Code requirement citing relevant Code section numbers
2. 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
3. A **HACCP plan** if required

Compliance With Approved Procedures

In order to be in compliance with the **HACCP Plan**, ¶ 8-103.12 of the FDA 2022 Food Code requires that a retail establishment 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.

(B) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under § 8-201.14 (D) and (E)(3) that demonstrate that the following are routinely employed;

- Procedures for monitoring the CRITICAL CONTROL POINTS
- Monitoring of the CRITICAL CONTROL POINTS
- Verification of the effectiveness of the operation or process
- Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT

When the regulation requires that you prepare a **HACCP plan** for a certain operation, this **HACCP plan** becomes part of the rule for your establishment. The **approved HACCP plan** is your commitment to comply with the procedures described. By complying with the Standard Operating Procedures that you've prepared as part of your **HACCP plan** and when you have followed the steps in this publication for developing a **HACCP plan**, you will have the necessary information to develop records demonstrating that critical point **monitoring** procedures are detailed and followed, that the process is verified for effectiveness, and that necessary **corrective actions** are taken as necessary.

SECTION 5: REDUCED OXYGEN PACKAGING METHODS

Specific HACCP Requirements for Reduced Oxygen Packaging

REDUCED OXYGEN PACKAGING (ROP) is defined as any packaging procedure that results in a reduced oxygen level in a sealed oxygen barrier package. You may be more familiar with the term *vacuum packaging,* which is one type of reduced oxygen packaging method. ROP packaging is commonly used for storage of raw **meats**, **poultry,** and frozen **fish**, but may also be used for storage of raw vegetables or for marinating **meats** or **poultry**. Another term used is *modified atmosphere packaging*, or MAP; this process uses gas flushing and a sealing process in a one-time modification of the atmospheric contents of the package. In a MAP package, oxygen content may change over time due to the oxygen permeability of the packaging film, or due to respiration of certain foods such as fresh vegetables. MAP is commonly used to package heat-sealed trays of ground beef, or bags of potato chips. **Controlled** atmosphere packaging, or CAP, maintains continuous **control** of the atmosphere, different from air, by a combination of impermeable packaging, non-respiring food, and a means of absorbing and replacing oxygen – such as oxygen scavenger sachets – until the package is opened. CAP is commonly used for packaging jerky.

Another application of ROP packaging is sous vide cooking. The term *sous vide* literally means "under vacuum." In this technique, vacuum packaged foods are placed into a circulating water bath in which temperature is **controlled** precisely, often at lower temperatures and for longer times than the standard cooking conditions prescribed in Food Code ¶ 3-401.11(A). Sous vide cooking is discussed further on pp. 50-53.

A fifth application of ROP packaging is cook-chill packaging, in which food cooked within the retail **food establishment** is hot-filled into oxygen barrier bags that are then hermetically sealed, crimped, knotted, or stapled followed by rapid chilling and refrigeration at 41°F. or lower for storage. The cooking or heating process before packaging drives oxygen out of the food. When the package is sealed by any of these means, the resulting oxygen content reaches a new level less than that found in air – meeting the definition of "reduced oxygen." A revision in the 2022 Food Code clarifies that this package is considered ROP even if the air is not expressed from the bag, i.e., no vacuum is applied.

Examples of packaging methods that are not classified as reduced oxygen packaging include:

- Packaging **TCS** foods in zip-sealed bags
- Packaging TCS foods at less than 135°F. without drawing a vacuum or modifying the atmosphere in the bag or tray with sealed film covering
- Packaging TCS foods such as prepared but uncooked pizzas on a cardboard base with a heat-shrunk overwrap that does not completely enclose the product

Information from FDA on heat sealing without a vacuum is available.[10]

[10] http://www.foodprotect.org/issues/packets/2023Packet/attachments/III_026__all.pdf

Packaging With Non-Oxygen Barrier Bags or Films

Breathable plastic bags, or non-oxygen barrier bags, allow oxygen to pass through the plastic film for foods that need it, such as fresh seafood or produce. Packaging that provides an oxygen transmission rate (in the final package) of at least 10,000 cc/m2 /24 hours at 24°C. (also known as 10K OTR) is FDA-**approved** as an oxygen-permeable packaging material for raw **fish** with no additional ingredients. Use of an oxygen-permeable package may not compensate for restriction to oxygen exchange created by packing in oil, or in deep containers from which the air is expressed, or the use of oxygen scavengers in the packaging. The 10K OTR product is not **approved** for cooking or hot-filling applications, or for any other foods besides fresh **fish**. The 10K OTR film provides a skin-tight, oxygen-permeable barrier, and the leak-resistant bags retain weepage and purge from the product. (Weepage and purge occur when a small amount of fluid escapes under normal usage or in packaging.) The skin-tight bags also allow the product to be chilled quickly and shipped at the lowest possible temperature. Use of 10K OTR packaging or any other breathable plastic packaging material requires a regulatory **variance** under Subparagraph 3-502.11(D) of the Food Code. The retail firm must provide evidence to the regulatory authority that the packaging film produces a non-ROP atmosphere for the specific food packaged.

Other breathable films may be available with **validation** for other applications or commodities. To avoid confusion, **validation** should be provided to the regulatory authority by the retail establishment from the manufacturer or a **processing authority** when use of other packaging film technologies is proposed.

Primary Hazards of Concern in ROP Packaging

One primary **hazard** in all ROP processes is *Clostridium botulinum* (sometimes referred to as *C. botulinum* or *C. Bot).* This bacterium requires an oxygen-free environment such as the reduced oxygen package to thrive and produce its toxin. These spores are not easily destroyed by cooking at temperatures that destroy most other bacteria. As a result, spores may survive a cooking process. Without competition from other bacteria, the spores can then activate during excessive time in the temperature danger zone (improper cooling, reheating, or storage without temperature **control**), resulting in formation of toxin.

The other primary **hazard** in ROP processes is *Listeria monocytogenes* (often known as *Listeria*, or LM). *Listeria* species, including *L. monocytogenes,* are commonly found in nature, and often are introduced into the food processing environment on raw foods or packaging, as well as on shoes and equipment wheels. Food preparation environments with food residue on equipment, or with standing water in various locations, become a breeding ground for *Listeria*. Inadvertent cross contamination can easily result from improper handling or accidentally touching a contaminated surface, and then touching ready-to-eat food or its packaging. Unlike other pathogens, *Listeria* thrive in cold conditions, but also in the environment of a restaurant kitchen. For these reasons, several **controls** are essential in ROP cook-chill operations:

- All product must be bagged while still above 135°F. to provide a **control** against growth or toxin formation by any surviving bacteria.

- ROP cook-chill processing must be conducted in a sanitary environment, with careful attention to sanitary handling technique (including no bare-hand contact).

- The date marks allowed by the Food Code for all ROP processes are based on known growth times for *Listeria* under refrigeration. While refrigeration prevents growth of other pathogens, *Listeria* continue to grow slowly below 41°F. For this reason, the required shelf life stated as date mark requirements for ROP processes is a safety **control**. Foods not consumed by the expiration date of the product must be discarded.

Raw foods may contain other pathogenic bacteria such as Shiga-toxin producing *E. coli* O157:H7 and other STECs, or *Salmonella*. However, by using ROP packaging and following the storage temperature, date marking and other requirements of the Food Code, effective **control** is provided both for these two primary **hazards** as well as other pathogens.

Reduced Oxygen Packaging Criteria

For all reduced oxygen packaging processes conducted without a variance, the HACCP plan shall:

1. Identify the food to be packaged. This information was collected in the Preliminary Steps (Section 2 of this manual). If adequate detail was provided on this list, this requirement will have been met. Specific brand names of products would not need to be included if the products meet the requirements as listed in number 2 below. [Be sure this list is included as one of the documents in your official **HACCP plan**.]

2. Limit the food to be packaged to a food that does not support the growth of *Clostridium botulinum* because the food:

    - has a water activity of 0.91 or less
    - has a pH of 4.6 or less
    - is a food with a high level of competing organisms, including raw **meat**, raw **poultry**, OR
    - is a **meat** or **poultry** product that is cured at a USDA inspected **meat** facility and received in an intact package.

3. Specify how the food will be maintained at 41°F. or below. *Maintaining the food at a temperature of 41°F. or less is the primary barrier to the growth of* Clostridium botulinum. *Because temperature maintenance is such a vital factor to ensuring food safety, the method for ensuring this must be addressed in the **HACCP plan**.*

4. Describe how the food will be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background with instructions to:

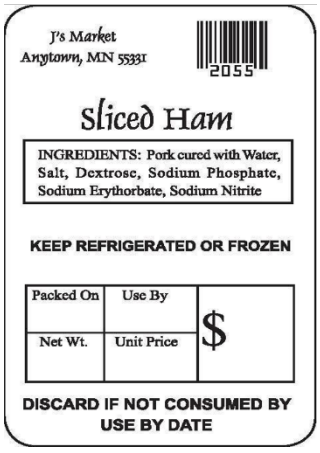
    - Keep refrigerated or frozen.
    - Discard the food if, within 30 calendar days of its packaging, it is not served (if for on-premise consumption) or consumed (if served or sold for off-premise consumption).

In addition to the normal mandatory labeling requirements, ROP foods must be labeled to include the above statements. These statements might be included on the same label with the other information or may be add-on stickers. These statements must be on the principal display panel (generally the front of the package) and must be conspicuous so that the consumer is readily made aware of these special requirements.

There is an example of the label with the required information below.

5. Limit the shelf life to no more than 30 days from packaging to consumption, or the original *manufacturer's* sell-by or use-by date, whichever occurs first, unless a **variance** has been granted.

EXAMPLE



*Pathogens, especially Listeria monocytogenes, may be a **hazard** even at refrigeration temperatures. Therefore, it is necessary to limit the shelf life of ROP products. Ensure that this is addressed in the **HACCP plan**.*

6. Include operational procedures that:

    - Comply with specific requirements relating to contamination from hands

    - Identify a designated area and the method by which:

        - Physical barriers or methods of separation of raw foods and **ready-to-eat** foods minimize cross contamination; and

        - Access to the processing equipment is restricted to responsible, trained personnel familiar with the potential **hazards** of the operation.

*As with any food processing operation, contamination between raw and **ready-to-eat** food can potentially create a serious food safety **hazard**. In addition, untrained personnel might contribute to hazardous food handling practices or the packaging of **unapproved** foods. Be sure operating procedures address these potential food safety **hazards**.*

- Delineate cleaning and sanitization procedures for food contact surfaces.

*Properly cleaned and sanitized food contact surfaces are critical to ensuring a safe, sanitary operation. Use of **approved** cleaners and sanitizers will reduce levels of pathogenic organisms to prevent cross contamination of the product. Ensure that a complete, detailed operating procedure and schedule for cleaning and sanitizing workspace and equipment used in the process is included in the **HACCP plan**.*

7. Describe the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:

    - Concepts required for a safe operation
    - Equipment and facilities
    - Procedures specified in sub-item 6 and Standard Operating Procedures for the **HACCP plan**

*A training program for employees conducting ROP operations is essential to producing a safe product. Areas to be included are limiting foods to be packaged, temperature **control**, separation of raw and ready-to-eat, employee health and hygiene, and must include the food safety issues of concern. A thorough understanding of product flow, how equipment operates, as well as the standard operating procedures for the establishment will also add to product safety. Ensure that these items are addressed.*

Additional Requirements and Considerations for Sous Vide Cooking and ROP Cook-Chill

Additional Requirements for Sous Vide Cooking and ROP Cook-Chill

Sous vide: The regulatory definition of sous vide includes cooking food in a sealed vacuum package in a water bath, followed by rapid chilling (shocking), cold storage, and reheating for service. A process in which food is cooked in the vacuum package and then removed from the bag is not considered sous vide.

ROP cook-chill: This process consists of cooking food by a traditional method, followed by hot-filling into a vacuum bag at above 135°F., rapid cooling, cold storage, and reheating for either immediate service or for hot holding. Traditional cooking methods include grilling, baking, roasting, or cooking in a stockpot.

Food Code Subparagraph 3-502.12(D) requires that retail **food establishments** that package **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 Subparagraph 8-201.14 (C) and (D)

2. Ensure the food is:

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

    - Cooked to heat all parts of the food to a temperature and for a time as specified under Subparagraph 3-401.11 (A), (B), and (C), protected from contamination before and after cooking as specified under Parts 3-3 and 3-4

    - 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.)

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

    - Cooled to 34°F. (1°C.) within forty-eight (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.

    - 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

    - 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

    - Labeled with the product name and the date packaged

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

    - Make such records available to the Regulatory Authority upon request.
    - Hold such records for at least six (6) months.
    - 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.

Special Considerations for Sous Vide Cooking and ROP Cook-Chill

The temperature danger zone (TDZ) between 41°F. and 135°F., and especially from 70°F. to 135°F., is the ideal temperature range for growth by pathogens. Of particular concern is the formation of toxins during excessive time in the TDZ. Cooking to internal temperatures specified in Food Code ¶ 3-401.11(A), or to the lower temperatures and longer times allowed in ¶ 3-401.11(B), will destroy vegetative pathogen cells but will not destroy biological toxins, and may not destroy all human-transmitted viruses such as Norovirus and Hepatitis A. Use of the alternative cooking temperatures and times requires a regulatory **variance**.

Properly prepared sous-vide foods must first reach temperature equilibrium with the water that is at a specific temperature. It is then held at that temperature for a specific amount of time. The Chef (or operator) must predetermine how long it will take the equipment and sous-vide pouched food to "come up" to that equilibrium temperature. This time is known as the come-up time, or CUT. CUT will depend on the state of the food (e.g., product type, the initial temperature of the food, thickness, added ingredients, portion size, liquid content), and the amount of food placed at one time in the equipment. It also impacts how long foods should be held at a specific temperature to achieve the effective pathogen log reduction. CUT must be pre-established by the Chef (operator).

Settings on the immersion circulator are recommended to be set at least 1°F. higher than the desired internal core temperature of the food. This is due to physics and the properties of thermal conduction. Once the internal temperature of the food has come up to the desired target, it must be held for another period of time that will be equivalent to a 6.5-$\log_{10}$ to 7-$\log_{10}$ reduction of bacteria to achieve a complete cook. Food Code § 3-401.11 lists minimum cooking times and temperatures and are detailed in the chart below, which corresponds to Table 3.2 in Food Code ¶ 3-401.11(B). The minimum allowed cooking temperatures and times at temperature are detailed in the chart on the next page, which corresponds to Table 3.2 in Food Code ¶ 3-401.11(B).

In the FDA 2022 Food Code, ¶ 3-401.11(B), a table of alternate cooking temperatures and times is provided for large roasts of beef, pork, and similar products. The alternate temperatures and times provided are not for use with poultry products. That table is sourced from the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) December 2021[11], USDA Food Safety and Inspection Service. The FSIS Cooking Guideline document provides the table below, and indicates that the sous vide package provides for the necessary humidity **control**, because it seals in the natural humidity of the product in a **controlled** atmosphere. The table below and accompanying guidelines provide **validation** for time/temperature and humidity **controls** supporting a **variance** from the regulatory authority.

Time-Temperature Combinations for Meat Products to Achieve Lethality

Temperatures stated are the minimum internal temperatures that must be met in all parts of the meat product for the total dwell time listed. Note that the table below is only for use with meat

[11] https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf (pp.33-35)

products; poultry products are discussed following the table below. An establishment must ensure both time and temperature parameters are met in order to use this table to support that its process achieves the Log retention target. Relative humidity[†] and heating come up time (CUT)[‡] are also critical operating parameters when using this table. (See pages 37 and 38 of the FSIS Cooking Guideline Appendix A[12] for poultry time and temperature tables.)

Degrees Fahrenheit	Degrees Centigrade	6.5-Log_{10} Lethality	7-Log_{10} Lethality
130°F.	54.4°C.	112 min.	121 min.
131°F.	55.0°C.	89 min.	97 min.
132°F.	55.6°C.	71 min.	77 min.
133°F.	56.1°C.	56 min.	62 min.
134°F.	56.7°C.	45 min.	47 min.
135°F.	57.2°C.	36 min.	37 min.
136°F.	57.8°C.	28 min.	32 min.
137°F.	58.4°C.	23 min.	24 min.
138°F.	58.9°C.	18 min.	19 min.
139°F.	59.5°C.	15 min.	15 min.
140°F.	60.0°C.	12 min.	12 min.
141°F.	60.6°C.	9 min.	10 min.
142°F.	61.1°C.	8 min.	8 min.
143°F.	61.7°C.	6 min.	6 min.
144°F.	62.2°C.	5 min.	5 min.
145°F.	62.8°C.	4 min.	4 min.
146°F.	63.3°C.	169 sec.	182 sec.
147°F.	63.9°C.	134 sec.	144 sec.
148°F.	64.4°C.	107 sec.	115 sec.
149°F.	65.0°C.	85 sec.	91 sec.
150°F.	65.6°C.	67 sec.	72 sec.
151°F.	66.1°C.	54 sec.	58 sec.
152°F.	66.7°C.	43 sec.	46 sec.
153°F.	67.2°C.	34 sec.	37 sec.
154°F.	67.8°C.	27 sec.	29 sec.
155°F.	68.3°C.	22 sec.	23 sec.
156°F.	68.9°C.	17 sec.	19 sec.
157°F.	69.4°C.	14 sec.	15 sec.
158°F.	70.0°C.	0 sec.	0 sec.
159°F.	70.6°C.	0 sec.	0 sec.
160°F.	71.6°C.	0 sec.	0 sec.

*The required log reductions are achieved instantly (0 seconds) when the internal temperature of the cooked meat product reaches 158°F. or above.

[†]Time-Temperatures ≥ 145°F. (in bolded square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply FSIS Relative Humidity Options 2 and 4 (page 26).

[‡]FSIS recommends limiting the total time that product temperature is between 50°F. and 130°F. to 6 hours or less (see page 23).

It is essential to review pp. 36-38 of the 2021 FSIS Cooking Guideline Appendix A for additional guidance pertaining to poultry, including not only chicken and turkey but also other poultry

[12] https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf

species. Effective December 14, 2022, the older versions of the guidance are no longer adequate scientific support for FSIS **HACCP systems** because they are out-of-date. The use of the 1999 and 2017 versions of Appendix A and B are replaced with the 2021 version of the guidance. The FSIS Cooking Guideline indicates that **poultry** and mixed **meat**+**poultry** products must follow the 7-Log Lethality column in the table above for cooking time and temperatures. Use of the 7-Log lethality time/temperature combinations for cooking **poultry** using the sous vide method will require a regulatory **variance**, because those time and temperature combinations are outside of the Food Code.

FSIS recommends that for safety, limit CUT in sous vide cooking to no more than two hours from 41°F. or lower until the internal cooking temperature is reached. Following FSIS guidance, under no circumstance should CUT longer than 6 hours be allowed. The water bath for cooking must not be overcrowded – that is, the number of packaged product portions placed in the bath for cooking must not prevent proper circulation of water in the bath. To ensure consistent cooking for all portions of product placed in the bath for cooking, portions should be of consistent dimensions and weight.

When sous vide will be used to cook large batches of standard portions, large roasts, hams, or other large portions of **meat**, CUT may be reduced by using a larger volume water bath, or by preheating the water bath to well above the required cooking temperature. This may require the operator to perform trial batches while developing the sous vide procedure to determine the correct combination of temperature setting, water volume required, and maximum batch size to reliably reach the required internal cooking temperature within six hours or less. Once an effective combination of conditions has been determined, the data from those trials must be saved as **validation** for the procedure. The correct conditions must then be included in the standard operating procedures for the process. Once the required internal cooking temperature is reached, the water bath temperature can be reduced to the required cooking temperature. In all sous vide cooking, product must be held at the required internal cooking temperature for the required amount of time. **Monitoring** of internal product temperature is essential from the time product is placed in the bath to cook, and through the cooking and cooling stages, to ensure that time and temperature requirements are met. Cooling within the maximum six-hour time required from 135°F. to 41°F. or lower may require use of a larger ice bath or other means of active cooling.

The term *ROP cook-chill* refers to the process of ROP packaging **TCS** ready-to-eat foods for storage that have been fully cooked by traditional methods. This technique is commonly used for buffet foods, soups, stocks, sauces, and other products prepared in bulk. However, this technique also may be used to store products such as cured hams after cooking or smoking. As with sous vide of large roasts or hams, cooling to 41°F. or lower after vacuum packaging must be accomplished in no more than six hours, as required by § 3-501.14. When foods cooked in the establishment are then ROP packaged, they must follow ¶ 3-502.12(D) under an **approved HACCP plan** with no **variance**.

Reduced Oxygen Packaging of Fish

Fish, including **finfish**, **shellfish**, crustaceans such as shrimp or **crayfish**, alligator, and frog, potentially carry the spores of *Clostridium botulinum* Type E and non-proteolytic Types B and F. Unlike the land-based strains of *C. botulinum*, these aquatic strains are able to multiply and produce botulism toxin at temperatures as low as 38°F. For this reason, Food Code ¶ 3-502.12(C) requires that **fish** must be frozen before packaging in traditional ROP bags, and must remain frozen while in the reduced-oxygen package. For guidance on cold-smoked or hot-smoked **fish**, refer to the section of this manual on smoking **fish** for **preservation**. While frozen, shelf life is not limited for safety. The product must be removed from the packaging for thawing.

With an **approved** regulatory **variance**, an alternative solution for ROP of fresh **fish** that does not require freezing is to use a vacuum bag that allows a high rate of oxygen transmission through the plastic film. This type of vacuum bag is known as 10K OTR, signifying its oxygen transmission rate of 10,000 cc/m. sq./24 hrs. This high oxygen transmission rate provides an effective barrier against growth and toxin formation by *C. botulinum*. However, in the presence of oxygen, spoilage bacteria and pathogens that need the oxygen are not prevented from multiplying. Fresh **fish** may be stored under refrigeration (not frozen) in 10K OTR vacuum bags, but shelf life will be no longer than for **fish** that is unpackaged. If the **fish** is to be served raw or undercooked, the product is considered **TCS** ready-to-eat food, and the product must be date marked with a shelf life not exceeding 7 days. The 10K OTR bags are **approved** for use with raw **fish**, and no other proteins. No other ingredients are allowed, as these may coat the inside of the bag and reduce the oxygen transmission rate, resulting in unsafe product. These bags are also not **approved** for processes that involve heat – such as sous vide cooking or ROP cook-chill packaging.

Reduced Oxygen Packaging of Cheeses

Paragraph 3-502.12(E) of the Food Code allows for ROP at retail for commercially processed hard cheeses (39% moisture or lower, or 61% solids or higher) and semi-soft cheeses greater than 39% moisture but no higher than 50% moisture. The use of ROP prevents drying from moisture loss, and preserves the flavor and visual characteristics while protecting from recontamination. In Annex 3 of the Food Code, § 3-501.17 provides a date marking exemption from the allowance in ¶ 3-502.12(E) for 30-day storage of hard and semi-soft cheeses in ROP. The date marking exemption may be allowed with a regulatory **variance**. Soft cheeses may not be reduced-oxygen packaged, due to the **risk** for cross contamination and survival of *Listeria*. Cheeses not in the Annex 3 exemptions from date marking may be considered for possible exemption with a **variance**, based on manufacturer specifications or product analysis for % moisture. If specifications or testing allow classification of the cheese as either hard or semi-soft based on moisture content, the product may be exempted from date marking. Raw milk cheeses must have been aged for at least 60 days, and must be classified as either hard or semi-soft based on their moisture content, to be exempted from date marking.

Other Methods of Reduced Oxygen Packaging (Requiring a Variance)

Products that need a HACCP plan and variance for ¶ 3-502.11(D) (ROP'd ready-to-eat TCS foods in which growth and/or toxin formation of *Listeria* or *Clostridium botulinum* are controlled by methods other than as prescribed in § 3-502.12.)

ROP processes without a **variance** must follow the exact requirements stated in the relevant sections of §3-502.12. Paragraph 3-502.11(D) of the Food Code allows for "packaging time/temperature **control** for safety food using a reduced oxygen packaging 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.*" While it is not possible to provide a list of all possible processes that would fall in this category, some examples would include:

- Using ROP to store nitrite-cured beef or **poultry** jerky. Properly cured jerky will have nitrite at a level that meets USDA regulations to **control** *C. botulinum*. Water activity (aW) of jerky will be less than 0.85, preventing growth of pathogens such as *Listeria*.

- If products are received pre-cooked from an **approved** source and then ROP'd inside the retail establishment, it should be received frozen or immediately frozen after packaging

and maintained frozen during storage and sale of the product. The goal is to decrease the amount of time the product is out of refrigeration during the packaging. **Food establishment**s should not ROP a large batch of product and let it sit out at room temperature before being placed in the freezer. Product label should include instructions to consume immediately after thawing and reheating to 165°F.

- Commercially processed **TCS** ready-to-eat cured **meats** from either a federally inspected source or from a state-inspected source equivalent to federal standards follow the criteria of ¶ 3-502.12(B). Likewise, if a retail **food establishment** produces and ROP packages cured **meats** under a **HACCP plan approved** by the regulatory authority, the criteria of ¶ 3-502.12(B) will apply – but a **variance** allowing curing based on ¶ 3-502.11(B) is also required.

Each process in this category must be evaluated based on scientific support (**validation**). Laboratory analysis may be required, or published, peer-reviewed research may be cited as **validation** for such methods.

Products That Can Be ROP'd Without a HACCP Plan

- Paragraph 3-502.12(F) of the FDA Food Code provides that food labeled with the packaged time and date, held at 41°F. or less, and removed from its package in the **food establishment** within 48 hours of refrigerated storage after packaging does not require a **HACCP plan**. If the product is frozen after packaging, the time during which the product is stored in the freezer does not count against those 48 hours; in that situation, the establishment must have a labeling system that accurately tracks the 48 hours of non-frozen storage. Depending on your local jurisdiction, a **variance** may be required to use this provision of the Food Code.

- Non-**TCS** foods such as acidic fruits, dry products, and raw vegetables such as green beans do not require a **HACCP plan** or any regulatory approval. Cut tomatoes, cut leafy greens such as lettuce or spinach, cut melons, and sprouts are included in the Food Code definition of **TCS** foods, and may not be ROP packaged without either an **approved HACCP plan** or a regulatory **variance**.

SECTION 6: PRESERVATION OF PROTEINS

Safe Practices for Curing and Preserving Meats

This section will cover a range of issues related to **meat preservation** and curing processes, including:

- Sausage production process
- Whole muscle curing processes
- Jerky production
- Safety and sanitation issues at each stage of the process
- Pathogens of concern
- Processes that combine curing with reduced oxygen packaging

The U.S. FDA has identified recommended retail standards in the FDA Model Food Code. **HACCP plans** are specifically required for retail facilities that use smoking, curing, or acidifying; food additives; alternative cooking time/temperature combinations; or reduced oxygen packaging (see § 3-502.11, § 3-502.12, subparagraph 3-401.11 (B)(1), § 8-201.13 of the Food Code). The Food Code requires that a **food establishment** obtain a **variance** from the regulatory authority before conducting these operations.

This material presents detailed information regarding specialized processes that may not be specifically addressed in state laws or the model Food Code. This information may be helpful, when used in conjunction with the FDA Food Code, for evaluation of requests for **variances** from establishments. The information can also be useful when evaluating the scientific soundness of a **food establishment's HACCP plan**, which requires approval from the regulatory agency.

Categories of Preserved Meats

The steps of preserving and curing **meats** are widely varied, and each product often has specific production and storage requirements. Sausage types range from simple mixing of fresh ground **meat** containing salt and spice to the complex steps of making fermented dried and semi-dried sausages that rely on starter culture to ferment, sodium nitrite to cure, heat/cooking for a thermal lethality (kill step), and subsequent drying to produce a **shelf-stable** product. Developing processes to extend shelf life or to make **meat** products **shelf stable** must meet scientifically sound criteria to ensure the safety of these products.

Fresh Sausage

Fresh pork sausages are produced from selected cuts of fresh and sometimes frozen pork along with salt and seasonings. Since fresh sausages do not contain curing agents, and are sold in raw form, they require refrigeration. These types of sausages must be thoroughly cooked before serving.

Cooked, Cured, and Smoked Sausage

Frankfurters are examples of cooked and smoked sausages. They are produced from fresh **meat** that is fully cooked and cured. The flavor of this product is largely due to spice blends, the addition of curing ingredients, and the cooking and smoking processes. Although they are fully cooked, they are not shelf stable, and must be refrigerated until the time of consumption.

Fermented and Dried Sausage

Meat snack sticks and salamis such as pepperoni and soppressata are examples of cured products produced using **controlled**, bacterially-induced fermentation along with a drying period to preserve the **meat**. This specialized process is designed to produce a shelf-stable product.

Fermented, Semi-Dry Sausage

Summer sausage, Lebanon bologna, and cervelat are examples of cured products produced using **controlled**, bacterially-induced fermentation along with a drying period to preserve the **meat**. The drying step is less extensive, and results in a non-**shelf stable** product.

Whole Muscle Products

Hams, pancetta, bacon, and pastrami are a few of many examples of whole muscle products processed to achieve desired flavor and shelf life. Depending on the process, certain products may or may not include curing with sodium nitrite, although salt is always part of the process. Production of certain products may not include a cooking step as part of the production process; these products will require a final cooking step before consumption.

Producing Sausages

In this section, you will go over the main steps that are utilized to produce standard sausage products, including cooked and smoked Sausages, and dry sausages.

Cooked, Cured, and Smoked Sausages

Cooked, cured, and smoked sausages account for the largest percentage of sausages produced today. Sausages such as frankfurters or bologna are made from fresh or frozen **meat** that is cured during processing, fully cooked, and smoked. These types of sausages are perishable and must be refrigerated until time of consumption.

This category of sausages contains many process variations that result in the wide range of cooked and smoked sausages that can be seen at retail. Although most are smoked, some are fully cooked and cured without smoking. This manual does not cover all of the possible variations in sausage style and formulation. It will discuss a few of the most common processes for manufacturing cooked, cured, and smoked sausages.

One type of cooked, cured, and smoked sausage is made from emulsified (finely ground) **meats**. This type includes frankfurters (hot dogs) and bologna. This class of sausage is allowed to contain a combination of fat and added water of up to 40%, with no more than 30% fat in the finished product. These product standards are found in FSIS regulation § 319.180 (see appendix).

Some cooked, cured, and smoked sausages are more coarsely ground, such as kielbasa sausage and andouille sausage. Fat is considered visible to the consumer in these types of sausages, so there is no fat limitation, however, water is limited to 10% of the finished product weight. These product standards are found in FSIS regulation § 319.140 (see appendix).

Other types of cooked sausage (unsmoked), such as braunschweiger, liver sausage, blood sausage, and tongue items, are cooked in water inside an impervious casing or steel mold, often inside a steam cabinet or water bath instead of a smokehouse. The impervious casing causes these types of

cooked sausage to retain all moisture during cooking, so the manufacturer must closely **control** the amount of water during formulation to ensure that it does not exceed the 10% limit.

In addition to the standard production steps used to produce fresh sausages, cooked and smoked sausages have additional production stages, including:

- Smoking
- Cooking
- Showering
- Chilling
- Peeling

Now we will briefly review each of these additional stages that are used to produce cooked, cured, and smoked sausages.

In the production of many sausages, the mixture of comminuted **meat** and other ingredients ("forcemeat") is stuffed into a casing that gives the final product its size and shape. Casings may be natural or synthetic, or an extruded natural collagen or cellulose product. Natural casings commonly used are sourced from the intestines (middles or bungs) of beef cattle, hogs, or sheep. Regardless of the type casing, there are varying degrees of permeability to air and smoke, as well as other physical characteristics such as stretch and shrink, and resistance to tearing. Natural casings are generally edible, whereas inedible casings are generally plastic or a plant-based material. The forcemeat is pumped and tightly packed into the casing. This results in greatly limited air content, creating the potential for a food safety **hazard** from *Clostridium botulinum* (botulism). The type and diameter of the casing have a great impact on the safety concerns. In dry and semi-dry sausages, **controlling** the rate of drying is essential to uniform dryness throughout the sausage. Careful humidity **control** is essential to all drying processes. Larger sausage diameters will require slower drying to prevent case hardening (exterior becomes dry while the interior retains too much moisture). Appropriate formulation and processing procedures are vital to maintaining the safety of sausages, as well as all other cured or preserved **meats**.

Cooked, cured, and smoked sausages start out very similar to the fresh sausages. Raw **meat** ingredients are ground and blended with non-**meat** ingredients. A bowl chopper (known in the industry as a silent cutter) is sometimes used to simultaneously blend and chop the mixture. The bowl chopper passes a series of knives through the mixture, usually resulting in an increase in temperature due to friction. A combination of ice and water is often added to the mixture to **control** the temperature and facilitate the grinding and blending process.

Smoking

Smoking is used to impart characteristic color, flavor, and aroma to the final product. Smoking was traditionally important because it inhibited bacterial growth on the finished product, however, in modern times we rely on refrigeration to inhibit bacteria. A smoke generator creates natural smoke via a carefully **controlled** burning of hardwood sawdust, wood chips, or logs. Hickory is the most popular wood used for smoking, but other hardwoods and fruitwoods are also used. Coniferous trees such as pine are unacceptable because they contain resins; smoke from that type of wood has a high tar content and imparts a bitter flavor.

The distinctive effects of smoking are imparted through absorption of the condensable phase of the smoke. This phase consists of acids, carbonyls, phenolics, and polycyclic hydrocarbons. The amount of these materials that is deposited on the product surface is **controlled** by varying the

density of the smoke, the duration of the smoking cycle, and the air velocity within the smoking chamber.

Sausage manufacturers also **control** the moisture level of the product before and during the smoking process in order to produce a high-quality product. The surface of the product must be slightly moist in order for the smoke volatiles to properly adhere to the product. If the product surface is too moist, the smoke process will cause streaking. If the casing is too dry, the smoke will not properly adhere to and permeate the casing. Producers therefore ensure that the drying cycles are carefully **controlled** to ensure a consistent smoked product.

Smoke condensate or liquid smoke can be used to impart the smoke flavors. Liquid smoke is created by distilling and refining the condensable elements of natural wood smoke to create a liquid concentrate of the desired elements. This product can be applied by dipping or drenching the product in a bath of the condensate product. It can also be applied within a smokehouse environment by atomizing the liquid into a fine mist. Another approach is to add smoke condensate into the sausage formulation. When this is done, it must be included in the ingredients statement of the final product.

Sample Smokehouse Schedule

Function	Time	Smokehouse Temperature	Relative Humidity	Damper
Drying	30 min.	125°F.	25%	Open
Smoking	1 hour	140°F.	35%	Closed
Cooking	1 hour	165°F.	35%	Closed
Steam Cooking	10 min.	180°F.	100%	Closed

As this chart indicates, the smokehouse may also serve as a **controlled** thermal processing chamber, and is used to dry, smoke, heat (cook), and add humidity to the product.

Cooking

Manufacturers cook sausage products to enhance the flavor and color, produce the desired final product, and to inhibit the bacteria responsible for spoilage. In order to produce a safe product, cooking must also destroy parasites and pathogenic bacteria. Sausages can be cooked through immersion in a heated water bath, within a smokehouse environment, or within ovens.

The cooking process is carefully **controlled** to ensure that the product reaches a specific internal temperature for a defined period of time. Thermocouples are used to **monitor** the temperature during the cooking process.

Showering/Chilling

After the smoking and cooking phase, the sausage must be properly cooled to meet Food Code cooling requirements. The cooling method may be immersion in an ice-water bath or a cold-water shower. Either method maintains the product humidity and stops the cooking process by reducing the product temperature as quickly as possible. Showering also helps to prevent shrinkage and wrinkling of the product casing. The cooling process is also carefully **monitored** and **controlled**. The temperature of the cooked product must be lowered to a specific temperature within a desired

time. The FDA Food Code specifies that a product must be lowered from 135°F. to 70°F. within 2 hours, then from 70°F. to 41°F. or less within a total of 6 hours.

Dry Sausages

Producers of dry sausages and semi-dry sausages utilize **controlled**, bacterially-induced fermentation to preserve the **meat** and impart flavor. The most common examples of dry sausages are salami and pepperoni. The dry category also includes shelf-stable non-fermented products such as beef jerky. Again, there are many variations of process steps and ingredients, resulting in the vast array of products available to the consumer. We are not going to deal with all possible products, rather, we will concentrate on the most common examples of these types of products.

In addition to the standard production stages identified for fresh, cooked, and smoked sausages, dry sausages have additional production steps, including:

- Blending special curing ingredients
- Fermentation
- Cooking/smoking
- Drying process

Let's briefly review each of these additional special production steps used to produce dry and semi-dry sausages.

Blending Special Curing Ingredients

The **meats** used in dry sausages are typically ground or chopped at low **meat** temperatures (20°F. to 25°F.) to maintain the well-defined fat and lean particles that are desired in this type of sausage. The ground **meats** and spices are then mixed with curing ingredients, such as curing salt (6.25% sodium nitrite and 93.75% sodium chloride), antioxidants, and bacterial starter culture.

Salts have traditionally been used to help preserve sausages. Eventually, producers learned that nitrates and nitrites in the salts were essential to the curing process. Manufacturers of dry and semi-dry sausages use a curing agent consisting of salt and sodium nitrite. **Approved** antioxidants such as beta hydroxy acids (BHA), dibutyl hydroxytoluene (BHT), and propyl gallate may also be added to protect flavor and prevent rancidity, and are limited to .003% individually, or 0.006% in combination with other antioxidants. These ingredients must be uniformly distributed throughout the mixture to achieve the maximum microbiological stability.

Fermentation

Bacterial fermentation is needed to produce the lower pH (4.7 to 5.3) and create the desired flavor associated with this type of sausage. Historically, bacteria growth in fermented sausages was left to wild or natural growth of unknown cultures. Sausage makers held the salted **meat** at low temperatures for a week or more to allow lactic acid bacteria growth in the **meat** mixture. This bacteria growth was largely **uncontrolled** and resulted in bacterial flora on the **meat** or production equipment. At times acceptable product was made, but spoiled or low-quality product was also a potential result.

Modern producers of dry sausage use a commercial lactic bacteria starter culture and simple sugars, such as dextrose, that promote lactic acid bacterial growth by serving as food to fuel the bacteria during fermentation. The bacteria starters are harmless, and are limited to 0.5% in both dry and semi-dry sausage formulations. Commercial bacteria starter cultures typically consist of a blend of

microorganisms such as *Pediococcus, Micrococcus,* and *Lactobacillus,* using specific species such as *P. cerevisiae, P. acidilactici, M. aurantiacus,* and *L. plantarum.* The bacterial fermentation lowers the sausage pH by producing lactic acid. The lowered pH causes muscle protein to give up water, allowing more efficient drying. This lower water activity preserves the product and presents an environment that is unfavorable to bacteria.

During production of certain types of sausage, mold culture may be applied to the surface of the sausage as it dries. These mold cultures are food-**approved**, desirable, and serve to both protect from surface bacterial contamination and to impart a desirable flavor profile.

Modern processors stuff the mixture directly into casings, which then undergoes a fermentation process at about 70°F. to 110°F. (depending on the starter culture). This fermentation process is designed to allow the bacteria to incubate. The fermentation occurs during a one- to three-day process that takes place in a carefully **controlled** environment designed to obtain specific fermentation results. Relative humidity is typically maintained at 80% to 90% during fermentation. Semi-dry sausages are usually fermented for shorter periods at slightly higher temperatures. Fermentation times are limited by the number of degree-hours above 60°F. (the critical temperature for growth of *Staphylococcus aureus).* The pH of the product must be reduced to 5.3 or lower within the allowed maximum time allowed at fermentation temperature to prevent growth of the heat-stable toxin *Staphylococcus aureus.* **See page 240 for instructions on pH meter calibration and product pH testing.**

The time-temperature relationships for constant temperature processes are as follows:

Degree-Hours Above 60°F.	Chamber Temperature (°F.)	Maximum Hours to pH 5.3
1,200	75°F.	80
1,200	80°F.	60
1,200	85°F.	48
1,000	90°F.	33
1,000	95°F.	28
1,000	100°F.	25
900	105°F.	20
900	110°F.	18

Example

Process A: Constant 80°F. for 55 hours with a pH decline to 5.3
Degrees: 80 **- 60** = 20
Hours: 55
Calculate Degree-Hours: (20) x (55) = 1,100 degree-hours
Process A **passes** the guideline (Limit: 1,200 degree-hours at 80°F.)

Process B: Constant 90°F. for 40 hours with a pH decline to 5.3
Degrees: 90 **- 60** = 30
Hours: 40
Calculate Degree-Hours: (30) x (40) = 1,200 degree-hours
Process B **fails** the guideline (Limit: 1,000 degree-hours at 90°F.)

Cooking/Smoking

What happens after fermentation depends on the type of product being produced. Semi-dry sausages like summer sausage are almost always smoked and cooked before drying. Dry sausages like pepperoni are rarely smoked, and may or may not be cooked.

Drying Process

The drying process is a critical step in ensuring product safety. These products undergo a carefully **controlled** and **monitored** drying process that cures the product by removing moisture from the product.

The drying process consists of placing the product in a drying room under a relative humidity of 60% to 70%, in a process that can last from 21 days to as long as 120 days, depending on the product diameter, size, and type. The drying process is designed to produce a final product with approximately 30% to 40% moisture. Facilities must keep accurate records of the temperature and the number of days in the drying room for each product manufacturing run to help ensure product safety and consistency.

The drying environment is **controlled** to ensure that the drying rate is slightly higher than the rate required to remove moisture from the sausage surface as it migrates from the sausage center. Drying too quickly will produce a product with a hard and dry casing. Drying too slowly results in excessive mold and yeast growth, and excessive bacterial slime on the product surface.

Semi-dry sausages are prepared in a similar manner but undergo a shorter drying period, producing a product with a moisture level of about 50%. These products are often fermented and finished by cooking in a smokehouse, at first at a temperature of approximately 100°F. and a relative humidity of 80%. The temperature is later increased to approximately 140°F. to 155°F. to ensure that microbiological activity is halted. Since the moisture level of the final product is about 50%, semi-dry sausages must be refrigerated to prevent spoilage.

Sausage Production Processes

In this section we'll take a brief look at some of the processes that are used to produce sausages, along with the safety issues that should be addressed for each item. There are many different manufacturers of equipment, and you will see many variations of these basic equipment types. **Meat** processing equipment such as slicers, choppers, grinders, and stuffers should be evaluated for the potential for physical **hazards** resulting from wear and tear of normal use. In retail **HACCP plans**, prevention of physical **hazards** from processing equipment can be addressed by requiring routine inspection of the equipment as part of the SSOP when reassembled for use after cleaning and sanitizing.

Ingredients in Sausages

In this section, we will go over the types of ingredients that are used to produce standard sausage products, including fresh sausages, cooked and smoked sausages, and dry sausages. Each type of sausage uses a different mix of ingredients.

Ensuring Wholesomeness

All **meat** used in sausage formulations must be clean, wholesome, and properly labeled. Receiving of raw ingredients is an important step in ensuring food safety. The manufacturing facility should

inspect all incoming **meat** to ensure there is no visible physical contamination. Even previously inspected **meat** should be reinspected to ensure that it hasn't become contaminated during transit. Best practice would be to use fresh raw **meat** ingredients that are less than 5 days from time of harvest. Frozen product is acceptable but the **meat** should have been frozen very soon after harvest.

Properly Identifying Meat Ingredients

Once the **meat** products are chopped or ground, they lose their visual identity, making it difficult to identify specific ingredients in a formulation. Sausage manufacturers are therefore required to carefully identify and track ingredients throughout the production process, and ensure that unlisted **meat** items are not accidentally or purposely substituted during the production process.

Non-Meat Ingredients

A number of non-**meat** ingredients are essential to the sausage making process. These non-**meat** ingredients stabilize the mixture and add specific characteristics and flavors. These typically include extenders and binders, water, salt, sodium nitrite, ascorbates, sodium erythorbate, sugars, antioxidants, sodium phosphates, mold inhibitors, extenders, along with traditional spices, seasonings and flavorings. In this section, we will look at the effect and use of each of these ingredients.

Binders and Extenders

Binders and extenders have a number of uses in a sausage formulation. Manufacturers use extenders such as dry milk powder, cereal flours, and soy protein as a lower cost method to increase the overall yield of the formulation, to improve binding qualities and slicing characteristics, and to add specific flavor characteristics. A sausage formulation can include up to 3.5% of these substances. Keep in mind many binders and extenders are considered food allergens. Proper product labeling and proper handling practices would be prudent in order to reduce the **risk** to allergen exposure.

Water

Water is a naturally-occurring component of **meat**. Depending on the type and style of product, manufacturers may add water to the formula in specific amounts to increase moisture perception, change texture, and improve cook yield.

FSIS regulations permit manufacturers of fresh sausages to add water up to 3% of the total product weight.

Cooked sausage manufacturers are allowed to vary the amount of added water according to the amount of fat. The maximum fat content is limited to 30%, and the amount of fat and water combined is limited to 40%, so the manufacturer can increase water to substitute for reduced fat. Typically, the amount of naturally occurring water is determined by computing four times the protein content. Any moisture above that amount is considered added water.

Dry and semi-dry sausages are typically not formulated with significant percentages of added water. This is due to the desire to remove moisture during the drying and maturing stage of production.

Salt

Salt is an essential ingredient of any sausage formulation.

Salt is used to preserve the product, enhance the flavor, and to solubilize the **meat** proteins in order to improve the binding properties of the formulation.

In cases where a reduced sodium product is desired, alternative ingredients, such as potassium and calcium chloride, are sometimes substituted for a portion of the sodium chloride in a formulation. These salts have similar functionality compared to sodium chloride but their flavor is often described as bitter or metallic. Less than 50% replacement of sodium chloride with these alterative salts is often the recommendation.

Curing Agents

Sodium nitrite is an important functional ingredient when making cured sausages. It prevents the outgrowth of *Clostridium botulinum* vegetative cells and spores, reduces oxidation of fats and the development of oxidative rancidity, facilitates the characteristic cured flavor of these products, and is responsible for the pink cured color. In the FSIS "Cured Meat and Poultry Product Operations" manual, USDA defines curing as "placing specific chemical agents in or on **meat** and **poultry**, such as pork ham, pork shoulder picnics, pork bellies, beef top and bottom rounds, beef knuckles, beef briskets, beef tongues, and **poultry** cuts to preserve it." Chemical curing agents include sodium or potassium nitrate (or saltpeter), sodium nitrite, and salt, with various combinations of salt, sugar, seasonings, phosphates, and cure accelerators, e.g., sodium ascorbate.

Sodium nitrite cure (Cure #1, 6.25% sodium nitrite) is an ingredient commonly used to produce cured products. The use of sodium nitrate (Cure #2, 6.25% sodium nitrite and 1.0% sodium nitrate), by processors is rare, because the process of converting the sodium nitrate into sodium nitrite within the product is much slower and less reliable than the addition of sodium nitrite directly. When a slow cure is desired (Cure #2), the use of a cure accelerator is required.

Sodium nitrite can be toxic to humans if improper amounts are added to a formulation. The use of these ingredients in sausage formulations is carefully **controlled**. They are sometimes referred to as "restricted ingredients." Supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept securely under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accordingly. The maximum acceptable level of these additives is spelled out in the FSIS regulations, as indicated below.

Using Cure #1 in Cured Meat or Poultry Products					
Cure #1: 6.25% sodium nitrite and 93.75% sodium chloride (table salt)					
	Comminuted	**Immersion**	**Dry Rub**	**Bacon Immersion**	**Bacon Dry Rub**
[1]**USDA critical limit**	≤156 ppm	≤200 ppm	≤625 ppm	≤120 ppm	≤200 ppm
[1] *The regulatory critical limit for nitrite is published in 9 CFR Part 424. Always follow manufacturer instructions for use of curing salt, as formulation differences may result in variation in the weight percent of nitrite between different products. USDA FSIS recommends using no more and no less than these specified amounts.*					

The amount of sodium nitrite added to product must be regulated at the formulation step, based on the total amount of **meat** and **meat** by-products. Sodium nitrite dissipates quickly in the finished product, and the parts per million in the finished product does not necessarily reflect the amount used in formulation.

NOTE: FSIS requires the use of either 550 ppm sodium erythorbate or sodium ascorbate when nitrite-cured bacon is massaged or pumped. FSIS regulations do not allow use of nitrate (Cure #2) in curing bacon.

Products to which nitrate or nitrite is permitted or required to be added may be prepared without nitrate or nitrite when the product name is immediately preceded with the term "Uncured" as part of the product name in the same size and style of lettering. The uncured product must comply with the standard performance characteristics for the cured product. See FSIS Regulation in 9 CFR Part 319.2.

Cure Accelerators

Cure accelerators such as ascorbates and erythorbates are used to speed the curing process when nitrates are used. They also stabilize the color of the final product.

Ingredient	Maximum amount
Ascorbic acid	3/4 oz. per 100 pounds of meat
Erythorbic acid	3/4 oz. per 100 pounds of meat
Sodium erythorbate	7/8 oz. per 100 pounds of meat
Citric acid	May replace up to 50% of above listed ingredients
Sodium citrate	May replace up to 50% of above listed ingredients
Sodium acid pyrophosphate	Alone or in combination with others may not exceed 8 oz. (0.5%)
Glucono delta lactone (GDL)	8 oz. per 100 pounds of meat

Sugars

Sugars are used in sausage formulations to reduce the flavor intensity of the salt and flavorings, and to provide a food source to enable microbial fermentation. Sugars used in sausage products include sucrose and dextrose.

Smoke

Smoke is often used to impart desirable flavor to many processed **meat** products, whether cured or uncured. The guidelines for approving labels for products prepared with natural smoke and/or smoke flavoring are as follows:

- Products that have been exposed to smoke generated from burning hardwoods may be labeled as "Smoked," or with the term "Naturally Smoked" to indicate that the traditional smoking process was used.

- Products that have been exposed to natural liquid smoke flavor that has been transformed into a true gaseous state by application of heat, or transformed into vapor by mechanical means, may be labeled "Smoked."

- Products that have been exposed to natural liquid smoke flavor via spraying, dipping, liquid flooding, or similar processes prior to or during heat processing, may be labeled "Smoked."

- Products that have been exposed to natural or artificial smoke flavor via direct application to the product surface or via injection must be labeled to identify the smoke flavor as part of the product name (e.g., "Pork Sausage, Natural Smoke Flavor Added").

The use of smoke flavoring (natural or artificial) in a component of a **meat** or **poultry** food product does not require that the product name state the presence of the smoke flavoring. However, the smoke flavoring must be declared on the ingredients statement.

Antioxidants

Antioxidants are **approved** for use in fresh sausages to retard oxidative rancidity and protect flavor. **Approved** antioxidants include butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), propyl gallate, tertiary butylhydroquinone (TBHQ), and tocopherols. These compounds are added to the spice mixtures, based on the actual percentage of fat in the fresh product formulations (typically 0.01% separately, 0.02% in combination), or the total **meat** block weight for dry sausage formulations (typically 0.003%).

Spices, Seasonings, and Flavorings

Spices, seasonings, and flavorings are used to add flavor to the sausage, and also affect the consistency of the ground mixture. The wide range of available spices, seasonings, and flavorings is a primary reason for the variety available in sausages.

Spices are defined as any aromatic vegetable substance that is intended to function as contributing flavoring in food instead of contributing to the nutritional substance of the food. The active aromatic or pungent properties of spices that contribute the most to the flavoring effect are mostly present in the volatile oils, resins, or oleoresins of the spice. These properties are present in the whole spice, or in extracts of the active components. The use of spice extracts has some advantages over using whole spices, including providing more **control** over the intensity of the flavor, less opportunity for microbial contamination, easier storage, and a less conspicuous visual appearance compared with spice particles.

Spice extracts must be labeled as "*Flavorings*" in the product ingredients list. Flavorings are substances extracted from a food (such as fruits, herbs, roots, **meats**, seafood) that are also intended to contribute flavoring instead of nutritional substance. "*Seasonings*" is another general term that refers to any substances used to impart flavor to the food product. Some examples of common spices and seasonings include allspice, pepper, cardamom, caraway, coriander, cumin, garlic, sage, mustard, nutmeg, paprika, pepper, rosemary, sage, thyme, and turmeric.

Dry Cured Whole Muscle Products

Dry cured **meat** traditions in the United States began as early as the 1500s. Explorers and settlers brought pigs to North America to provide a source of food. It was then critical to utilize a **preservation** method that would provide a food supply into the future. Prior to the availability of modern refrigeration, salting and drying whole pieces of **meat** were the most widely used methods of **preservation**.

Country Ham

Dry cured country ham became a popular **meat** product made for home use and commercial sale within early colonial America. The United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) defines *country ham* as the uncooked, cured, dried, smoked or un-smoked **meat** product made from a single piece of pork ham muscle. Most consumers of country ham will cook it prior to eating. Common methods of cooking include baking the whole ham or pan-frying thin slices of **meat**. However, a small percentage of long aged and low water activity country hams are being consumed uncooked, similar to European dry cured ham products.

Dry cure ham muscle (e.g., prosciutto, Serrano)

A dry-cured ham is, unlike a cooked ham, salt-cured, dried, and aged for a considerable amount of time. Many counties around the world produce a dry cured ham … prosciutto from Italy, Serrano from Spain, prsut from Croatia, and Jinhua from China, to name a few.

Dry cured pork belly (e.g., pancetta, country cured bacon)

Pancetta is cured pork belly Italian style. It is often cured with salt and spices like black pepper, garlic, and juniper berries. It can be found in a number of forms: round slices from a rolled belly, thin flat slices, or small cubes. It differs from American dry cured bacon in that it is milder in cured flavor, is less salty, and not smoked.

Pancetta is sometimes sold sliced paper thin, or cubed.

Dry cured shoulder muscle (e.g., capicola)

Traditionally from the muscle running from the neck to the fourth or fifth rib of the pork shoulder. In the U.S. this cut is referred to as the CT Butt (IMPS #407). It is cured with salt, garlic, black pepper, paprika, and red wine. The finished whole-muscle coppa is typically sliced very thin.

Other products (salt pork, fat back, lardo)

Salt pork is pork fat packed in salt to prolong its shelf life. Traditionally, salt pork is an ingredient that adds flavor to greens and other dishes. In addition to adding flavor to meals it is also used as a source of cooking fat. Lardo is an Italian specialty product made by curing fresh fatback with salt, herbs, garlic, and other seasonings. Typically, the curing process requires long periods of time (greater than 6 months). This finished cured fat is often sliced thin and served over toasted slices of bread as an appetizer.

Dry Curing Process for Country Ham

The curing process begins with quality fresh ham free of blood splash, bruising, or broken bones (femur). It is recommended that the curing process start within 4 to 5 days postmortem. A variety of raw weights can be used, but the larger the hams (greater than 25 lbs.), the longer the cure time. Raw ham weights from 16 to 22 lbs. would be preferred.

Curing

The first step in the process is the application of the dry cure ingredients.

1. Salt provides flavor to dry-cured meat and acts as a preservative by inhibiting growth and destroying microorganisms. Additionally, it helps other dry-cure components migrate through and dehydrates the meat, which also decreases bacterial growth. Finished product must have more than 4% brine content of salt (percentage of salt in formulation divided by the percentage of water in the raw meat). Applying 5% to 7% (by raw meat green weight) is recommended.

2. Sodium nitrite and sodium nitrate help to give cured ham the reddish/pink color that country ham is known for. The sodium nitrate and sodium nitrite act as preservatives and inhibit growth of *Clostridium botulinum,* the organism that causes botulism. These ingredients contribute the distinctive flavor of cured meats. Cure ingredients reduce the development of oxidative rancidity and the associated rancid taste. USDA limits are 625 ppm for sodium nitrite and 2,187 ppm for sodium nitrate in dry cured whole muscle products.

3. Sugar is included to sweeten the taste of the ham, and to reduce the salty flavor of the ham to some degree. Sugar also provides an energy source for microorganisms that convert sodium nitrate to sodium nitrite during the curing process. Sugar in the formulation is limited to no more than 2% of the meat block weight. Higher amounts of added sugar provide nutrients to spoilage bacteria, which can cause problems through the process.

4. Other spices, such as black or red pepper, may be added to provide flavor differences in dry cured ham.

The dry cure mixture is spread evenly or rubbed onto the ham; pay particular attention to the lean surfaces. Typically, the dry cure mixture is packed into the hock to prevent spoilage that can occur around the bone of the ham. Approximately one-half of the dry cure mixture is applied in the initial application of the dry cure ingredients. After the application of the dry-cure mixture has occurred, the hams are placed fat side down into large stainless-steel containers or plastic combo vats and held under refrigeration. After 4 to 5 days, the hams are resalted and reworked (top to bottom, bottom to top). During this process the remainder of the dry cure is applied to the partially cured meat. There may be benefit to reworking again at day 14. It is critical during curing that salt cover the exposed surface of the ham. You do not want to allow the salt to totally dissolve into the ham. Periodic resalting (pure salt, no nitrite, sugar, or spice) is the best practice. Ham curing is done under refrigeration for 45 to 50 days at 35°F. to 40°F.

Example:

Using a 20-lb. ham (percentages are based on the weight of the raw meat)

Make a cure mix using 6% salt, 2% sugar, cure ingredients, and spice. Each ham will receive approximately 1.6 lbs. of the cure mix.

Day 1 - 1st salting – Apply 0.8 to 1.0 lbs. of cure mix. Apply the bulk of the mix to the cut exposed surface of the ham. Also add salt to cut surface of the hock, where the foot was removed.

Days 4-5 - 2nd salting – Add the remaining 0.8 to 0.6 lbs. of cure mix. Apply cure mix over the entire ham surface.

Day 14 – If curing multiple hams, “rework” by covering each ham with a light coat of pure salt. Keep the containers covered with plastic to avoid drying. If condensation begins to build under the plastic cover, remove cover to reduce moisture. Excess humidity may result in mold growing on the ham surface. Some mold development is normal during this step. It can simply be removed by cold water rinse prior to moving hams to EQ.

Days 14-50 – Maintain salted hams at 35°F. to 40°F.

Equalization (EQ)

After the initial curing process, excess salt (and mold, if present) is washed from the surface of the ham. After washing, the hams are placed in a mesh stockinette made of plastic or cotton and then hung hock down. This next stage of product is called equalization. In this process, the hams need to be held in environmentally **controlled** chambers for a minimum of 15 days, out to 30 days. The temperature of the rooms needs to be maintained at 50°F. to 55°F. with a relative humidity maintained between 60% and 70%, and with very slow airflow. This process slowly begins to dry the hams. **Controlling** the relative humidity will also help to **control** mold growth on the surface of the hams. If the relative humidity is maintained above 70%, there may be an issue with excessive mold growth on the ham surface.

Smoking

After equalization has occurred, hams can be smoked for 7 to 8 days below 100°F. Smoking will give the surface of the hams a desirable deep golden-brown color. Smoking is done not only for aesthetic purposes, but also to add flavor and aroma.

Aging/Drying

The next step in the process is referred to as aging. The aging period can last 30 days or longer. Regulations require that finished hams must lose 18% of the green weight. At the 5% to 7% brine content, most finished country hams will be at a 0.90 water activity after they lose 18% to 20% of their green weight. Some country hams are aged 6 to 12 months. The longer the ham is allowed to age, the bolder and more complex the flavor will become. These aged hams will also become saltier in taste. Drying conditions are set to temperatures from 80°F. to 90°F. Relative humidity is maintained at 60% to 70%, with very little airflow, similar to that utilized during the equalization step.

Dry Cure Process for Prosciutto-Style Ham

The curing process begins with quality fresh ham free of blood splash, bruising, or broken bones (femur). It is recommended that the curing process start within 4 to 5 days postmortem. A variety of raw weights can be used, but the larger the hams (greater than 25 lbs.), the longer the cure time. Raw ham weights from 16 to 22 lbs. would be preferred.

Ham Selection and Trimming

Long shank ham works well for this style ham. Leaving the hock join intact helps to prevent spoilage during the long curing and aging process. Exposing more lean on the inside muscle of the ham by removing a 2- to 3-inch band of skin from the collar will improve salt uptake. It is also common practice to remove the aitch bone, exposing the ball of the femur bone. This requires special skill and tools to avoid creating deep gauges in the ham, which can lead to spoilage and mold problems later in the process.

Process

The first step in the process is the application of the dry cure ingredients. Traditionally, Italian-style prosciutto does not include sodium nitrite or sodium nitrate in the dry cure mix. On the other hand,

Spanish-style Serrano ham will include these cure ingredients in the mix. The regulations for use in dry cured whole muscle products are 625 ppm for sodium nitrite and 2,187 ppm for sodium nitrate.

Day 1 - Salting – Using coarse sea salt, apply 2.0% to 2.5% salt (percentage based on raw **meat** green weight) to the entire ham; be sure to cover all exposed **meat** surface with salt. Lay the salted ham (skin-side down) on a rack that will allow moisture to drain. Maintain a temperature of 35°F. to 40°F. and 75% to 80% relative humidity.

Day 14 - Resalt – Apply an additional 1.5% to 2.0% salt to the ham; be sure to cover all exposed **meat** surface with salt. Maintain a temperature of 35°F. to 40°F. and 75% to 80% relative humidity.

Days 15-100 - Rest Period – Brush off remaining salt and tie ham around the hock. Hang on racks in an environment of 40°F. to 50°F. and 75% relative humidity.

Days 101-200 - Curing Step – Wash and brush hams clean with water and move to an environment of 65°F. to 70°F. and a 65% to 70% relative humidity.

Days 201-500 - Aging Step – Sugna, a mixture of rendered lard and rice flour (1:1) is applied to the exposed face of the ham. This slows the loss of moisture during this long drying and aging step. During this step, hams are held at 70°F. to 75°F. and 65% relative humidity.

Finished product – If the ham will continue to age, the sugna is left on the ham. If the product is going to be consumed, the sugna is washed and brushed clean prior to slicing.

Dry Cure Process for Bacon

Dry curing a belly is very easy. Below is a basic dry rub for bacon.

Cure mix for 25 lbs. of raw skin on skinless pork bellies (approximately 2 trimmed bellies)

325 g salt
150 g brown sugar
50 g black pepper (coarse)
10 g red pepper (fine)
30 g cure (6.25% sodium nitrite)

The **meat** should be coated on both sides with the cure mix and held under refrigeration for 7 to 10 days. After “curing,” the bellies can be smoked at a temperature of 135°F. to 145°F. until reaching an internal temperature of 130°F. If a darker external color is desired, bellies can be smoked for extended periods of time. Keep in mind that the longer the bacon is smoked, the saltier the product will be come, due to more water loss. Store under refrigeration and fully cook before eating.

Dry Cure Formula for Shoulder (Capicola)

Percentages are based on the raw weight (green weight) of the **meat**.

3-4 lbs. CT (*cellar trim*) pork butts (IMPS #407) work well for this product.

Mild

3.5% unrefined sea salt
2 grams of cure salt (6.25% sodium nitrite) per pound of raw meat weight

0.2% fennel seeds
0.2% cracked black pepper
0.1% ground mace
0.1% granulated garlic
1.0 % red wine

Hot and Spicy

3.5% unrefined sea salt
2 grams of cure salt (6.25% sodium nitrite) per pound of raw meat weight
0.3% smoked sweet Spanish paprika
0.2% cracked black pepper
0.1% red pepper flakes
0.1% granulated garlic

Coat both sides of the raw meat with the cure mix. Hold under refrigeration for 21 days; drain any liquid that purges from the meat. After curing, tightly stuff into perforated fibrous casing, and clip or tie the ends. Pull a tight elastic cotton netting around the cased coppa. Hang piece to dry in a 60°F. to 65°F. and 65% to 70% relative humidity environment, with light air movement. Product is finished when the water activity reaches 0.90 or lower. This drying and aging step will take approximately 60 days. Remove casing and netting. Whip off any mold that has formed. Finished pieces may be stored at room temperature or vacuum packaged and stored in refrigerator for months.

Dry Cure Process for Salt Pork or Fatback

Curing of fat slabs requires a bit more time compared with cuts that have a greater percentage **meat**. There is no need for any ingredient other than salt. Pack fatback in salt and keep refrigerated at 40°F. or below for no more than 30 days before use. Any variations of the curing time or temperature because of the product size (diameter or thickness) or target water activity must be validated by a process authority. Fatback stores well vacuum-packaged and refrigerated.

Performing Sausage Formulation Calculations

One of the most important tasks for the inspector in the sausage production facility is to check the formulation of the product. Inspection program personnel should select a batch of sausage product, check the sample batch for accurate identification of the types and weights of the component ingredients, and calculate the maximum and minimum amounts of restricted ingredients.

Establishments which produce sausage product are encouraged to use as a reference a procedure chart that identifies the production process and ingredients for the product.

The chart should include:

Product type and name

- Type and amounts of meats and meat by-products in the product
- Type and amounts of cure agents
- Method of formulation, such as chopping time and emulsifying time and method

- Type of casing and method of stuffing
- Smoking/cooking time and temperature, along with expected shrinks
- Chilling time and expected chill shrinks

Calculating Added Water, and Antioxidant Fresh Pork Sausage Formulation

(with BHA added to protect flavor)

Ingredients: Pork, water, salt, sugar, spices, BHA (formulated to yield a finished product fat limit of 40%)

Batch formula

Regular Pork Trimmings (60% fat)	280.00 lbs.
Special Pork Trimmings (30% fat)	156.00 lbs.
Water	15.00 lbs.
Fresh Sausage Seasoning	9.00 lbs.
Total	460.00 lbs.

The Fresh Sausage Seasoning formulation is:

Salt	5.00 lbs.
Sugar	2.00 lbs.
Black Pepper	15.00 oz.
Sage	11.00 oz.
Nutmeg	5.64 oz.
BHA (antioxidant)	0.36 oz.
Total	9.00 lbs.

The inspector reviews the sausage formulation and evaluates a number of issues. For example, the inspector would determine whether the added water content in the above formulation complies with the limit for this type of product, or whether the type and amount of antioxidant is allowed in this type of product. Let's quickly go over the process to answer each of these questions.

Is added water content within limits?

The amount of added water and/or ice in fresh sausage is limited to 3% of the product weight. The inspector will use these steps to determine the amount of water permitted in this formulation.

460 lbs. (100%) -15 lbs. - (3%) 445 lbs. (97%)	First, subtract the water from the total formula weight to determine the total weight minus the water.
445/.97 = 458.76	Then divide the formula weight minus the water by the total weight without water (.97) to determine the total formulation weight with the allowed amount of water added.
458.76 lbs. x .03 = 13.76	Then multiply the total formulation weight with the allowed amount of water added by 3% (allowed percentage of water). This results in a total allowed water amount of 13.76 lbs. in this formulation. In this case, the added water exceeds the allowable limits for this product.

Is the type and amount of antioxidant within limits?

Antioxidants in fresh sausage are limited to 0.01% of the total amount of fat in the product. In this example, we will assume that the target fat amount of 40% in this formulation has been confirmed.

460 x 0.40 = 184 lbs.	The first step is to determine the weight of the fat. Then, multiply the batch weight by the fat content (40%).
445/.97 = 458.76	Then multiply the fat content by the permitted amount of antioxidant (0.01%) to determine the maximum allowable amount of BHA in this formulation.
458.76 lbs. x .03 = 13.76	Then multiply the fat content by the permitted amount of antioxidant (0.01%) to determine the maximum allowable amount of BHA in this formulation

In this case, the maximum allowed amount of the antioxidant BHA in this formulation is 0.294 oz. The Fresh Sausage Seasoning formulation specifies 0.36 oz. The BHA in this formulation exceeds the regulatory limit.

Inspectors can use similar calculations to determine a range of issues, such as whether the fat percentage or binder and extender amount targets will be achieved.

Calculating Curing Agents - Frankfurter Formulation

Ingredients: Beef and pork, water, nonfat dry milk, mustard, spices, erythorbate, sodium nitrite

Batch formula

Beef (80% lean)	200 lbs.
Pork (80% lean)	150 lbs.
Pork (50% lean)	150 lbs.
Water and ice	80 lbs.
Rework (like product)	50 lbs.
Nonfat dry milk	20 lbs.
Salt	9 lbs.
Mustard powder	5 lbs.
Spice mix	4 lbs.
Erythorbate	4 oz.
Cure mix (6.25% nitrite)	24 oz.

Inspectors analyze sausage formulations to determine if the amount of sodium nitrite is within acceptable limits.

Since it may be difficult to accurately measure small amounts in a commercial production environment, manufacturers often use a commercially premixed cure mix, containing the proper amount of sodium nitrites and nitrates along with a salt carrier. To minimize the **risk** of using too much of these ingredients, cure mix is often marketed in small packets that are pre-weighed for a certain size batch of product. This eliminates the need to weigh out the cure mix at the facility. It is still important to ensure that the cure mix packet is being added to the proper size batch of product.

200 150 + 150 500	For example, to review the amount of sodium nitrites in the above formulation, first determine the total amount of meat and meat by-products. In this case, add together the beef and pork. Note that the bacon ends and pieces and rework are not factored in, since they are already assumed to have cure added to their formulation.
500/100 = 5.0	The total allowed amount of sodium nitrite (pure) for chopped meat sausage is .25 ounces per 100 pounds of meat, so the next step is to divide the total amount of meat by 100 to determine how many "units" of 100 pounds are in the formulation.
5.0 x .25 = 1.25 oz. nitrite allowed	Then multiply the units of 100 pounds of meat by .25 to determine how many ounces of nitrite (pure) are allowed in the formulation.
1.25 ÷ .0625 = 20.0 oz. cure mix allowed	Since the amount of sodium nitrite in the cure is 6.25%, divide the amount of allowed nitrite by .0625 to determine the total amount of cure mix that is allowed in this mixture.

In this case, the example of 24 oz. of cure mix is **not correct** and should be lowered within acceptable limits.

Biological Hazards of Concern When Processing Meat and Poultry

In this section we will review some common types of microorganisms and pathogens that can be present in the **meats** typically used to produce sausages and other cured **meats**, common methods of reducing or eliminating these pathogens, and product characteristics and conditions that influence the type and rate of growth of these microorganisms and pathogens.

Trichinella spiralis

Trichinosis, the potentially deadly disease caused by consumption of the *trichina* parasite, *Trichinella spiralis*, is a potential concern for pork processors. *Trichina* parasite larva may infest pork muscle, so most cases occur in persons who have consumed improperly treated or prepared pork products. Infections from consumption of pork products typically occur when a fresh pork product has not been adequately cooked by the consumer, or the product has not been properly treated by the producer. In 2018, FSIS determined that *Trichinella* is not likely to occur in confinement-raised domestic swine. However, processors using free-range or feral hogs must assess their **risk** in the **hazard analysis**, as described below.

Because FSIS has removed the prescriptive *Trichinae* control regulations[13], establishments have greater flexibility to choose validated **control** procedures and to support their use as part of their **HACCP system** to **control** *Trichinella* and other parasitic **hazards** in pork products. Establishments producing ready-to-eat (RTE) or non-ready-to-eat (NRTE) pork products must assess in their **hazard analysis** whether *Trichinella* and other parasites are **hazards** reasonably likely to occur (RLTO) or not reasonably likely to occur (NRLTO) in their processes. Establishments must include **control** procedures for these parasites in their **HACCP plans** if they determine that the parasites are a **hazard** that is RLTO, including **critical control points** (CCPs) designed to **control** the parasitic **hazard** and **critical limits** that must be met at each CCP. Establishments may determine that the parasitic

[13] https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/Compliance-Guidelines-Trichinella.pdf

hazard is NRLTO because a prerequisite program prevents the **hazard**, but they must have documentation to support the decisions in their **hazard analysis**.

Shiga toxin-producing *Escherichia coli* including *Escherichia coli* O157:H7

Shiga toxin-producing *Escherichia coli* (STEC) including *Escherichia coli* O157:H7 is a bacterial contaminant of sausage and other **meat** products that can cause serious diarrheal illness, sometimes resulting in complications that can lead to death. The presence of *E. coli* in cooked sausages can be **controlled** by proper cooking temperatures and times.

E. coli contamination of dry sausages can be reduced by closely **controlling** the fermentation heating process, the acid content, and via post-fermentation heating to 145°F. or above. And with all sausage products, the proper hygiene, handling, and storage procedures are essential to **controlling** contamination. One of the five options described by the *Blue Ribbon Task Force* of the National Cattlemen's Beef Association in its *Dry Fermented Sausage and E. coli* O157:H7 report[14] can be used to eliminate *E. coli* O157:H7 in the finished product.

Salmonella

Nontyphoidal salmonellosis is a leading cause of foodborne illness in the United States. As with *E. coli, Salmonella* organisms can be eliminated from cooked sausages by proper cooking processes. In dry sausages, the producer must follow a combination of processes to **control** the pathogen, including use of a fermentation starter culture, increased product temperatures during fermentation, and careful **control** of the product pH, cure, and salt content.

In addition, product handling procedures must be designed and **monitored** to ensure that cross contamination of the finished product with contaminants present in raw materials does not occur.

Listeria monocytogenes

Listeria monocytogenes is a bacterium found in soil and water that can contaminate **meats**, and can cause a serious infection in humans, called listeriosis. The organism can be found in many food processing environments, and has been isolated from floor drains and refrigeration drip pans. From these niches the organism gets moved throughout the facility, and it can end up on food contact surfaces. Cross contamination between raw and cooked product can also result in the presence of the bacteria on **ready-to-eat** product. Improper handling practices and inadequate sanitation can result in cross contamination and in proliferation of these bacteria within the processing equipment and environment.

Processors should consider the following elements in elimination of *Listeria monocytogenes:*

- Examine how raw materials are handled before they are cooked and determine how handling procedures might affect *L. monocytogenes* levels in the product.
- Determine the impact of rework practices on *L. monocytogenes* levels in the raw product.
- Examine product flow, processing patterns, and employee practices to determine where opportunities for cross contamination to occur.

[14] https://meatsci.osu.edu/sites/meatsci/files/imce/1996_dry_fermented_sausage.pdf

Healthy persons rarely develop serious illnesses from exposure to *Listeria*. However, listeriosis is especially dangerous for pregnant women, newborns, and persons with weakened immune systems. Even with prompt treatment using antibiotics, listeriosis can cause death.

FSIS has a zero tolerance for *Listeria monocytogenes* in ready-to-eat products, such as hot dogs and luncheon **meats**, and conducts a **monitoring** program in facilities to test for the pathogen. Treatment of sausages to eliminate *Listeria monocytogenes* is similar to the steps to eliminate *Salmonella*, including thorough cooking and proper storage of the product.

Clostridium botulinum

Clostridium botulinum is the naturally occurring bacterium responsible for production of the deadly botulinum toxin. Often known as *C. bot,* this organism produces spores as a mechanism to survive in hostile environments. *C. botulinum* requires an oxygen-free environment to multiply and produce toxin. Improperly preserved **meats** and **fish**, and improperly canned foods are at particular **risk**. The spores are only destroyed at temperatures above 240°F. (116°C.). Combinations of salt and nitrite as specified in 9 CFR 424.21 are effective in preventing the spores from activating and the bacteria from multiplying and producing toxin. FSIS requires a minimum nitrite concentration of 120 ppm in all cured products to **control** *C. botulinum.* Strains of *C. botulinum* associated with land-based foods (**meats**, **poultry**, vegetables, but not **fish**) cannot multiply or produce toxin below 45°F. (7.2°C.), or at pH values below 4.6.

Campylobacter jejuni

Campylobacter jejuni is the most commonly reported bacterial cause of foodborne infection in the United States, with an estimated 2.1 to 2.4 million cases each year. *Campylobacter jejuni* is found in many foods of animal origin, including **poultry** and **meats**.

Yersinia enterocolitica

Yersinia enterocolitica, the pathogen that causes the gastroenteritis illness yersiniosis, is another pathogen of concern. Yersiniosis is an infection caused most often by eating raw or undercooked pork contaminated with *Yersinia enterocolitica* bacteria. CDC estimates *Y. enterocolitica* causes almost 117,000 illnesses, 640 hospitalizations, and 35 deaths in the United States every year. Children are infected more often than adults, and the infection is more common in the winter.

Conditions That Influence Microbial Growth and Product Spoilage

Several product characteristics influence the growth of microorganisms. Each one must be **controlled** to create an environment that is hostile to microbial growth. Characteristics include:

- Water activity (aW) present in the product
- Product's pH level
- Type/level of fermentable carbohydrate in formulation
- Level of smoke (natural or artificial) used on product
- Phosphate content of product
- Residual nitrite level in product
- Type/amount of spices/condiments applied to product surface
- Time/temperature of product heat processing (cooking)
- Product temperature during packaging
- Amount of vacuum used in packaging
- Rate of oxygen permeability of packaging materials

Microbial growth also results from defects in the product production process and/or during product handling. Microorganisms can survive the heating process due to inadequate heating time and temperatures. Heat-resistant bacteria may be present in rework. Contamination can occur after processing, and during handling and packaging. And spoilage may occur during the retail sale phase, if the product is stored for an excessive length of time or at temperatures in excess of 41°F.

Producers of each category of sausage must **control** each of these factors to minimize or eliminate the presence of pathogens.

Pathogen Control in Cooked and Smoked Meats

Producers of cooked and smoked products also must take steps to control pathogens. The heating process used during the production of cooked sausage and other meat products is usually sufficient to destroy pathogenic organisms. For example, manufacturers cook pork at temperatures from 120°F. to 144°F. to destroy *trichinae.*

The USDA has prescribed a 6.5-log reduction of *Salmonella* in **meat** and a 7-log reduction in **poultry** during heat treatment or cooking of ready-to-eat **meat** and **poultry** products to eliminate or reduce *Salmonella*.

Pathogen Control in Dry and Semi-Dry Sausage and Other Dry-Cured Meats

Producers of dry and semi-dry sausages must **control** the fermentation, smoking, and drying processes to reduce any pathogens present in the **meat** formulations. The pathogens of concern in uncooked fermented sausages such as summer sausage and other cured, uncooked **meats** such as Virginia hams are *Salmonella, E. coli* O157:H7, *Listeria monocytogenes, and Staphylococcus aureus*. FSIS has recommended a 5-log reduction of *E. coli* O157:H7 in fermented sausage by **validation** of the process. The pH and water activity of the final product can also **control** the other pathogens of concern, especially for shelf-stable fermented sausage products.

Typical Hazards in Meats With Standard Control/Prevention Measures

(B - Biological contamination, C - Chemical contamination, P - Physical contamination)

Ingredients	B	C	P	Hazard Descriptions	Control/Prevention Measure
Acidifiers, antioxidants, binders/extenders, curing agents, flavorings, mold inhibitors, phosphates, sweeteners		X		Toxicological effects if limits are exceeded	Use ingredients guaranteed to meet product specifications / requirements.
Meat ingredients (beef, pork, poultry and meat by-products)	X			Growth of pathogens due to improper storage, handling, and/or transport; foreign particle contamination (e.g., bone particles)	Product temperature must be sufficient to limit excess microbial growth. Product must meet specifications. Product must be produced under HACCP plan. Visual examination of product to identify particle contamination.

Ingredients	B	C	P	Hazard Descriptions	Control/Prevention Measure
Packaging materials		X	X	Toxicological effects	Use only packaging materials certified as safe by the manufacturer.
Spices/herbs	X	X	X	Contamination from microorganisms, agricultural chemicals, and/or foreign materials	Use ingredients guaranteed by the manufacturer to meet product specifications / requirements.
Vegetables	X	X	X	Growth of pathogens due to improper storage, handling, contamination with agricultural chemicals, and/or foreign materials	Ingredient spec sheet identifying required ingredient parameters; control storage temperatures to preclude microbial growth.
Cooking	X			Survival of pathogens due to improper procedures	Time/temperature combination adequate to destroy specific pathogens.
Cooling	X			Growth of pathogens due to improper temperatures, germination of spore-forming pathogens due to slow chilling (e.g., *C. perfringens*)	Cooked product must be cooled according to established procedures.
Drying (Meat)	X			Bacterial growth due to inadequate control over time, temperature, and humidity	Achieving specific water activity levels to inhibit the growth of pathogenic microorganisms.
Formulation	X	X		Contamination during employee handling, incorrect formulations, contamination through damaged packages	Maintaining careful employee practices, ensure ingredients are consistent with requirements, ensure packaging is clean and intact.
Freezing (Meats)	X			Survival of parasites due to improper time/temperature application, growth of pathogens due to temperature abuse	Rapid cooling and freezing.
Grinding	X	X	X	Contamination during handling, contamination from lubricants, contamination from damaged equipment	Careful employee practices, careful maintenance of equipment, temperature control in grinding room (<50°F.).
Stuffing	X	X	X	Contamination during handling, contamination from lubricants, contamination from damaged equipment	Careful employee practices, careful maintenance of equipment, temperature control in grinding room (<50°F.).
Packaging	X	X	X	Contamination from packaging, contamination from damaged containers	Ensure that packaging materials are protected from contamination, and that packaging is properly utilized to ensure adequate barrier.

Ingredients	B	C	P	Hazard Descriptions	Control/Prevention Measure
Peeling	X		X	Contamination by pathogens in product accumulations, contamination from employee handling, contamination from foreign materials	Ensure careful employee handling processes, do not allow product to accumulate in/on equipment, maintain peeling equipment in proper condition.
Receiving	X	X	X	Contamination through damaged containers, inappropriate storage conditions (temp/humidity), contamination on receiving equipment, cross contamination from non-food chemicals, contamination from extraneous materials	Product must be received in sound containers, and stored at appropriate temperature.
Reworking	X		X	Contamination during employee handling, contamination from pathogens in improperly stored product, contamination by foreign materials	Ensure proper/careful employee practices, proper storage temperatures.
Shipping	X		X	Pathogen growth due to inadequate shipping temperatures, contamination from extraneous materials or through damaged packages	Product must be stored/shipped at proper temperatures, packaging should be intact, transport vehicles must be clean.
Thawing	X			Growth of pathogens due to improper temperatures	Thawing room temperature should not exceed 50°F.

HACCP Requirements for Jerky Produced at Retail

Dried meats fall into one of two basic categories: ready-to-eat (**RTE**) and non-**ready to eat** (**NRTE**) products. Drying of **meats** has been practiced for thousands of years as a **preservation** technique; it's commonly used in combination with one or more other factors, such as smoking and curing. Production of **RTE** dried **meats** must include at least one kill step to destroy pathogens, and require no additional preparation to be safe for consumption. **NRTE** products require a cooking step before eating. This section is focused on safe production of **RTE meats** in which drying is used to achieve shelf stability. The raw **meats** used to produce these products generally include beef, pork, and **poultry**. Examples of these **RTE** products include jerky, carne seca, tasajo, and biltong.

The distinction between **shelf stable** and non-**shelf stable** dried **meats** is based on whether or not the final product requires time and temperature **control** in storage and cooking before consumption. **RTE** dried **meats** are typically dried along with salt and heat to no more than 50% of their original moisture content, and do not require time and temperature **control** for safety in storage.

NRTE meats must be cooked before eating. These may include kippered **meat**, as well as certain types of sausages, such as chorizo, summer sausages, and soujouk. Of concern with these products is that the consumer may fail to cook the product because it appears ready to eat. As part of a

validated **HACCP plan**, proper labeling is essential for consumer safety. A consumer advisory must be printed on the product label if the product has not had a lethality treatment (kill step to destroy pathogens). Safe handling instructions should be provided on the packaging, to include guidance on refrigerated storage and proper cooking. However, the focus of this section will be on shelf-stable, **RTE meats** generally described by USDA as jerky.

Outbreaks of foodborne illness have been associated with jerky and similar dried **meat** products.

- In 2022, more than 1,600 pounds of jerky were recalled because of possible adulteration with *Listeria monocytogenes*, after routine FSIS product sampling identified the pathogen in jerky product from one firm.[15]

- FSIS Directive 10240.4, first issued in 2003, and most recently updated in 2022, was issued to prescribe specific requirements for all federally inspected facilities producing ready-to-eat **meat** in all forms.[16] This directive was issued in response to the determination that *Listeria* is of great concern in all facilities producing **meat** products that have environmental exposure after heat treatment and before packaging.

- In 2021, a multi-state outbreak of *Salmonella* was traced to Italian-style Salame snack sticks. At least 34 people were sickened, and seven were hospitalized.[17]

- In 2003, an outbreak of *Salmonella Kiambu* from jerky sickened 22 people.[18] A very slow drying process under low humidity conditions was believed to have been a contributing factor. The dry conditions allowed *Salmonella* to develop resistance to the subsequent heat treatment, resulting in survival of the pathogen.

- In 1995, an outbreak involving several strains of *Salmonella* sickened 93 people in New Mexico, all of whom had consumed carne seca from a local producer.[19] Insufficient heat treatment was cited as a contributing factor.

- Numerous other outbreaks have been traced to various jerky or related products made from beef, pork, or venison.

Pathogens of Concern and Their Sources

Several pathogens are of significant concern in the production of jerky and other dried **meat** products.

The most commonly reported pathogens associated with foodborne outbreaks reported to the Centers for Disease Control and Prevention (CDC) include *Salmonella*, *Staphylococcus aureus* (produces a toxin), and the mold *Aspergillus flavus* (produces an aflatoxin). Nitrite poisoning has also been reported, caused by excessive concentrations of sodium nitrite cure in the product.

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[15] https://www.fsis.usda.gov/recalls-alerts/boyd-specialties-llc-recalls-jerky-products-due-possible-listeria-contamination

[16] https://www.fsis.usda.gov/recalls-alerts/boyd-specialties-llc-recalls-jerky-products-due-possible-listeria-contamination#:~:text=WASHINGTON%2C%20March%204%2C%202022%20%E2%80%93,Service%20(FSIS)%20announced%20today

[17] https://www.cdc.gov/salmonella/i45-10-21/index.html

[18] https://www.cidrap.umn.edu/news-perspective/2003/10/new-mexico-salmonella-outbreak-prompts-beef-jerky-recall

[19] https://www.cdc.gov/mmwr/PDF/wk/mm4442.pdf

In general, dried **meats** are processed to **control** bacteria by reaching water activity levels less than 0.88. Water activity is the free water in the product that is available to support growth and toxin formation by bacteria. However, reaching water activity <0.88 is not adequate to **control** certain organisms. *Aspergillus flavus* can grow and produce toxin at water activity down to 0.70. Mold growth can become a problem in **shelf-stable meats** because of storage at room temperature for extended periods of time. If jerky becomes moldy, it should be discarded cautiously. The spores of this mold contain the aflatoxin, and can become airborne. Certain other organisms can also survive drying, such as *Staphylococcus aureus*, spores of certain bacteria, and *Trichinella spiralis*.

Pork products and game **meats** require a validated treatment to destroy *Trichinella spiralis.* USDA regulations found in 9 CFR Part 318.10(c)(1-3) prescribe cooking, freezing and curing options for parasite destruction in pork. *Trichinella spiralis* is easily destroyed in a drying process with temperatures above 137°F. (58°C.). Improvements in commercial feeding practices have greatly reduced the **risk** of *Trichinella* exposure for hogs raised in confinement, and in 2018 FSIS removed the requirement of 9 CFR 318.10 for pork products to be treated to destroy *Trichinella* except when the **HACCP hazard** analysis identifies *Trichinella* as a **hazard** that is reasonably likely to occur. FSIS has explained[20]that pasture-raised or feral swine are more likely than confinement-raised swine to be exposed to *Trichinella* and other parasites.

Processing and Critical Controls

Retail **food establishments** producing these **RTE meats** must achieve destruction of pathogens in the product. When *Salmonella* is effectively destroyed, other pathogenic bacteria will also be destroyed. The product must also be stabilized to prevent growth of spore-forming bacteria such as *Clostridium botulinum* and *Clostridium perfringens*. Finally, the process and the formulation of the product must **control** growth of toxin-forming bacteria such as *Staphylococcus aureus* during processing, storage, and distribution. The 2003 *Salmonella Kiambu* outbreak from jerky sickened 22 people, and resulted in USDA's first publication of the guidance document "Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments." The most recent version of this guidance published in 2014[21] provides more detailed information and recommends a combination of steps that will, when properly implemented in the stated order, result in production of safe dried **meat** products. FSIS has published validated recommendations for production of shelf-stable dried **meat** products (jerky), which are summarized below.

Step 1 – Meat preparation: It is critical to use **meats** produced under Good Manufacturing Practices (GMPs) to minimize contamination entering this process and the presence and growth of pathogens. Raw materials must be as fresh as possible so the initial quantities of pathogens present are not higher than this process is designed to **control** or eliminate. **Meats** for jerky production from game animals must come from an **approved** source – that is, farm-raised and inspected by the appropriate regulatory authority. Whole muscle is either sliced or ground. Slices must be of uniform thickness; one slice should be cut at double thickness to facilitate **monitoring** of internal product temperature during processing. Alternatively, whole muscle may be ground and formed into strips, or stuffed into casings to produce snack sticks. Reserve one piece for temperature probe placement to allow for internal temperature **monitoring**.

Step 2 – Marination: Non-**meat** ingredients and spices used should be produced under Good Manufacturing Practices (GMPs) to minimize contamination entering this process and the presence and growth of pathogens. Raw materials must be as fresh as possible so the initial quantities of pathogens present are not higher than this process is designed to **control** or eliminate. To prevent

[20] www.fsis.usda.gov/policy/fsis-directives/7320.1
[21] fsis.usda.gov/guidelines/2014-0010

cross contamination from one **meat** batch to the next, new batches of marinade solution or dry seasoning mix should be used for each process batch. The prepared **meat** strips or snack sticks must be held under refrigeration in a marinade solution that contains salt, sugar, flavoring ingredients, and may or may not contain curing salt (Cure #1, 6.25% sodium nitrite). If curing salt is used, the nitrite concentration must not exceed the amounts allowed under 9 CFR Part 424.21 (200 ppm for whole muscle, or 156 ppm if cure salt was comminuted with the ground **meat**).

Liquid smoke is sometimes used in production of jerky. The National Institutes of Health have published research demonstrating that liquid smoke may provide some antimicrobial effects in the finished product, and the FDA has declared that liquid concentrates of wood smoke in water are generally recognized as safe (GRAS) additives in food.[22] The combination of process steps and factors in product formulation, such as heat treatment, dehydration to water activity less than 0.85, and salt or curing salt, when used in combination with liquid smoke, provides a set of **controls** for production of a safe product. Although retail **food establishments** are not regulated by USDA, that agency has published guidelines[23], on labeling in compliance with federal laws when liquid smoke is used in the product formulation.

Step 3 – Interventions: Some heating processes may not provide adequate lethality on their own, and may require an additional microbial load reduction step to ensure product safety. In particular, certain characteristics of the product such as large or non-uniform product dimensions may contribute to this challenge. Additional intervention steps before, during, and after the marinating step have been shown to enhance the pathogen reduction beyond what is achieved by heat treatment alone. Examples of recommended antimicrobial interventions that may enhance lethality of the process include:

- Preheating **meat** or **poultry** jerky strips or snack sticks in water to a minimum of 160°F. internal temperature provides an immediate reduction of *Salmonella*. Internal temperature of the product must be **monitored** to ensure that the required temperature and sufficient lethality are achieved. Instead of water, heating in marinade will achieve the same results, but may also result in undesirable flavor.

- Dipping the product in 5% acetic acid for 10 minutes before marinating can enhance the microbial reduction effects of the heating and drying steps. However, the resulting reduction is not enough to eliminate pathogens. An undesirable flavor may also result from this treatment.

- Dipping the product in 1:2 or 1:3 mixtures of calcium sulfate (Mionix $Safe_2O^{TM}$) and water for 30 seconds, or dipping in acidified sodium chlorite (Keeper®) at between 500 and 1,200 ppm can reduce populations of *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes*. Both of these treatments have to be demonstrated as effective in both dehydrator and smokehouse processing.

Step 4 - Surface preparation: Prepared strips or snack sticks are subjected to a low temperature heat step for a short time, generally 30 minutes. The **meat** develops a tacky surface as a result, assisting in adherence of smoke and improved product texture. This short-duration dry heat exposure is not long enough to result in increased heat resistance of *Salmonella*, and is therefore not a safety concern. In some cases, a color setting step may be added; however, the combination of the surface preparation step and the color setting step should not exceed 30 minutes total time.

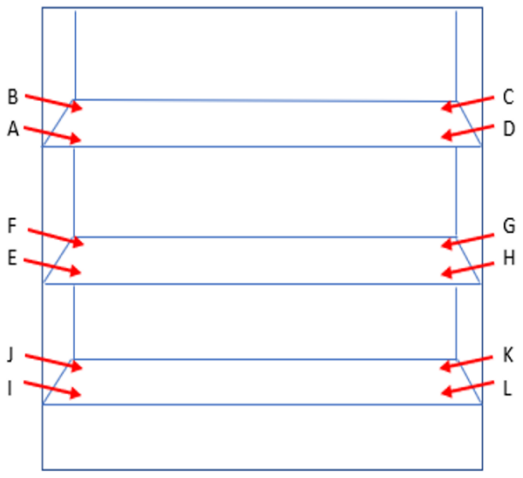
[22] https://pubmed.ncbi.nlm.nih.gov/24583328/
[23] www.fsis.usda.gov/sites/default/files/import/Labeling-Policy-Book.pdf), pp. 162-163

Step 5 - Lethality (Kill) Step: The lethality treatment is the step or combination of steps in which specific treatments are applied to destroy pathogens, making the product safe to eat. The lethality treatment begins when the product is placed in the heated oven for surface preparation and color setting, and ends when the required time and temperature combination for lethality (cooking time) have been reached. The lethality step for **shelf-stable** dried **meat** products must achieve a 5-log (100,000-fold) reduction of *Salmonella* and *E. coli* (STECs) in beef and **poultry**, and at least a 3-log reduction of *Listeria monocytogenes*. The critical operational parameters for effectively reaching the required lethality as intended are the product time-and-temperature combination, and the relative humidity during the lethality step.

- **Product time-temperature combination:** For retail **food establishments** engaging in preparation of dried, shelf-stable **RTE meats**, the FSIS "Appendix A"[24] guidelines are the most convenient source of validated time-and-temperature combinations for lethality treatments. It is essential to note that these values are to be used for establishing **critical limits** for internal product temperatures held for the specified time – not oven temperature settings. Setting the oven to the specified temperature does not ensure that the product will reach the required temperature within reasonable time. It is critical that the internal product temperature be held for the specified time to achieve the required lethality.

  Awareness of temperature distribution in the oven is essential (see diagram below). To obtain this information, a study should be conducted and kept on file recording numbered or lettered locations with temperatures at the corners of the oven or smoker chamber from top to bottom, front to back, after the unit has been set at the required cooking temperature and allowed to stabilize before each reading. **Monitoring** of internal product temperatures should be conducted at the coldest locations in the unit. It is also important to adjust for any seasonal variations in oven or smoker performance to ensure the product is heated to the required temperature.

Temperature Mapping



View from front

- **Relative humidity:** High relative humidity in addition to the required product temperature/time combination is critical to achieving the required lethality. Humidity is added and maintained above 90% during a limited time 15 to 30 minutes after product is

[24] https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf

placed into the preheated oven, for a brief time only, resulting in no quality defects. Case hardening is prevented, so product texture is kept at a consistent level of quality. When levels of relative humidity are too low, the product surface may dry too quickly, and pathogens may become more heat resistant as a result. FSIS recommends applying the lethality and drying steps in that order, and as separate stages of the process, to ensure that lethality is achieved before the product is dried.

During the addition of humidity in the lethality step, the smokehouse doors and dampers are closed to seal the oven and prevent moisture loss. Moisture may be added by placing one or more shallow, wide pans of pre-heated hot water into the oven, or by injecting steam or fine water mist into the oven. Relative humidity must be **monitored** during the lethality step. A test run is recommended to be sure the required level above 90% relative humidity is reached.

An electronic humidity sensor or the use of wet bulb and dry bulb thermometers are appropriate methods for **monitoring** relative humidity. The lethality step is a **critical control point** (CCP), so records of these measurements during the lethality step, along with the time and internal product temperature, are required as part of the **HACCP plan**.

Humidity options recommended by the FSIS in Appendix A[25] for processing of jerky during cooking steps of at least one-hour duration:

- Heating jerky in the oven at any internal temperature and time combination recommended in Appendix A while maintaining relative humidity at 90% or higher for at least 25% of the cooking time, but no less than 1 hour. Or,

- Heating jerky to minimum internal temperature of 145°F. in a sealed oven or while continuously introducing steam for 50% of the cooking time. Or,

- Heating jerky to minimum internal temperature of 145°F. while maintaining relative humidity at or above 90% for at least 25% of the cooking time but no less than 1 hour.

- For cooking times less than 1 hour at a time/temperature combination cited in the FSIS Appendix A, maintain relative humidity at 90% or higher for the entire cooking step.

- At higher altitudes, the amount of moisture added during the lethality step may need to be increased to compensate for lower atmospheric pressure and lower atmospheric relative humidity. Seasonal differences in relative humidity in the atmosphere must also be considered. When ambient temperatures are below freezing, atmospheric relative humidity is extremely low, so more moisture must be introduced into the chamber to compensate. Failing to **monitor** relative humidity in the smokehouse chamber and make necessary adjustments to the moisture input can result in survival of pathogens due to underprocessing of the product.

- To make a wet-bulb thermometer, fit a wet, moisture-wicking cloth around a normal dry-bulb thermometer. Submerge the free end of the cloth in a water supply such as a jar of water, and ensure that there is sufficient water to keep the cloth wet through the lethality step, especially if smoke is being applied. More guidance on correct use of a wet-bulb

[25] https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf

thermometer is available at "Measuring Relative Humidity in a Smokehouse".[26] An online calculator for determining percent relative humidity is available.[27]

Step 6 - Drying: The drying step must remove enough moisture (water) from the product after the lethality step to reduce water activity (aW) to a level that prevents growth and toxin formation by pathogenic bacteria such as *Listeria monocytogenes* and toxin-forming bacteria such as *Staphylococcus aureus*. Although there is no FSIS standard of identity for jerky, consumer expectation is that jerky and similar products are **shelf stable** (require no refrigeration and remain stable through the producer's stated shelf life). Dried **meats** are often packaged in bags that are impervious to oxygen, and with a reduced oxygen atmosphere, such as with oxygen scrubbing pillows. Water activity, salt, and often sodium nitrite are safety factors used in combination when producing these products. Considering those factors, FSIS recommends as a **critical limit** maximum aW values of 0.85 when dried **meats** are packaged in air, or 0.91 when packaged in reduced oxygen or modified atmosphere packaging. In retail **food establishments** where no water activity meter is available, specifications for weight loss from drying may be used with specifications for percent fat in the raw **meat**. A minimum target weight loss with 2% to 3% margin of safety should be set as a specification for each batch based on green weight minus final weight. Third-party **validation** must be provided as water activity data from **product assessment** testing if this approach is used.

When raw **meat** or **poultry** is dehydrated in a warm oven or a consumer food dehydrator to make **shelf stable** jerky, pathogenic bacteria may survive the dry heat of a warm oven or the 130°F. to 140°F. of a food dehydrator. Use of a commercial dehydrator with means to **control** humidity to the required levels is vital to providing the required destruction of pathogens such as *E. coli*, *Salmonella,* and *Listeria*.

Without Step 5 (Lethality Step), drying is not sufficient to ensure the safety of the product. A validated lethality step such as described in Step 5 is necessary. The lethality treatment should be applied before drying to provide the required reduction of *Salmonella*.

Products packaged in vacuum packaging or modified atmosphere packaging with water activity (aW) values greater than 0.85 and less than 0.91 should be refrigerated after opening if the product is not expected to be consumed as a single serving immediately after opening. Such products cannot safely be considered **shelf stable**. These products should be labeled with "Keep Refrigerated After Opening" or similar.

Step 7 - Post-Drying Heat Step: This step may be added to increase the level of pathogen reduction when Step 5 is not fully implemented. In this situation, FSIS recommends heating the dried product for 10 minutes in a 275°F. oven.

Step 8 - Handling: Packaging of the finished product involves handling, which introduces **risk** of recontamination from a number of potential sources. Drying to a water activity that renders the product **shelf stable** does not prevent survival of pathogens that may be introduced accidentally during handling. Cross contamination from various sources must be prevented:

- Equipment used to process raw **meats**, such as preparation tables, packaging equipment, utensils, containers, or scales, must be completely cleaned and sanitized before use for finished product.

[26] https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf
[27] https://www.1728.org/relhum.htm

- Airborne movement of aerosols, dust of dry ingredients, or condensation into the processing area can result in contamination of finished products.

- Food workers moving between raw and ready-to-eat food preparation areas must follow policies such as hand-washing, garment changing, and no bare-hands contact with ready-to-eat food.

- Ensure that the seal of the finished product packaging is complete and without defects such as wrinkles or trapped product that can result in air infiltration or introduction of contaminants.

- Robust sanitation procedures are necessary to ensure that the food production environment and equipment are maintained in sanitary condition, free from pathogens such as *Salmonella* or *Listeria monocytogenes*.

In-Facility Observations

Production of jerky and other dried **meats** may be taking place if:

- One or more commercial or home-style dehydrators are observed in a retail **food establishment**.

- Commercial "seasoning packets" for dried **meats** or jerky are observed, with or without sodium nitrite.

- Fresh jerky is advertised either in print or digital media.

- Unpackaged jerky or other dried meats are observed in jars, tubs, or other containers (not commercially packaged).

References:

FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A), December 2021, https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf

FSIS Prevention and Control of *Trichinella* in Pork Products - Revision 2, March 2021, https://www.fsis.usda.gov/policy/fsis-directives/7320.1

FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork Products, 2018, http://www.fsis.usda.gov/sites/default/files/import/Trichinella-Compliance-Guide-03162016.pdf

Functionality of Liquid Smoke as an All-Natural Antimicrobial in Food Preservation, National Institutes of Health, in *Meat Science*, June 2014, https://pubmed.ncbi.nlm.nih.gov/24583328/

Food Standards and Labeling Policy Book, USDA – FSIS, 2005, https://www.fsis.usda.gov/sites/default/files/import/Labeling-Policy-Book.pdf

FSIS Ready-to-Eat Fermented, Salt Cured, and Dried Products Guideline May 5, 2023,https://www.fsis.usda.gov/guidelines/2023-0002

Related Resources to Guideline FSIS-GD-2023-0002
https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-GD-2023-0002.pdf

Aging of Beef

It's not uncommon for regulators to encounter questions about aging of beef. This process does not involve curing and the aged final product will be cooked before it is served to the consumer. Throughout the aging process and when the final product is sold to the consumer for home preparation, the beef is still a raw **TCS** food requiring refrigerated storage. The aged product is not a ready-to-eat food until after cooking, so according to Food Code requirements, date marking is not required for safety. Dry-aging processes are not "special processes" as identified by **preservation** of the product, according to § 3-502.11 of the Food Code. However, specific **controls** are recommended to ensure the safety of the final product. Some jurisdictions may choose to require a **variance** and a **HACCP plan** based on the recommended safety **controls** and 3-502.11(G) of the Food Code. This unit focuses only on the aging process and **control** parameters.

The aging process is to be understood as holding a carcass, primal or sub-primal cuts under refrigeration for an extended time to allow naturally occurring changes in the proteins and fats to result in enhanced flavor characteristics and tenderness. The highest grades of beef with excellent marbling are selected to ensure the most desirable final product. While a concentrated flavor and aroma of the aged product are generally desirable to many consumers, undesirable sensory properties can also develop due to undesirable bacterial growth, adsorption of off-odors present in the aging environment, and developing rancidity of fat. For this reason, it is essential to maintain the aging environment in clean, sanitary conditions and to implement measures that will properly **control** bacterial growth and the chemical changes taking place during aging.

Aging Conditions

While different sources vary on the recommended conditions for aging, there is agreement that temperature, relative humidity, and air movement all are important factors in dry aging to achieve a good and safe final product. Thanks to new technology, dry aging may also be conducted using specialized vacuum packaging films with high permeability to moisture. Because moisture can escape through the film, the product will undergo drying under conditions similar to those for traditional dry aging.

Wet aging of beef is a modern technique in which a pre-portioned cut of beef such as a steak is placed in a vacuum-sealed bag and aged with the steak's natural juices locked in tight. The beef is still kept in a carefully regulated environment, with special attention paid to temperature just as would be used in dry aging steaks. Wet aging recommendations follow the same temperature guidelines as dry aging. Generally recommended conditions for both wet and dry aging are as follows:

- Dedicated coolers or environmental chambers are used to prevent odors of other products from being adsorbed onto the aging beef, and to maintain the necessary **control** of temperature, humidity, and airflow. These units are used specifically for aging and no other purpose.

- Floors and walls of the aging chamber or cooler should be cleaned with alkaline cleaner to thoroughly remove any **meat** residues and sanitized at least weekly. Ceilings, walls, and floors of the aging cooler or chamber should be kept as dry as possible except when cleaning.

- **Meat** products should be hung or placed on racks in a manner that allows for excellent air circulation on all sides of the product.

- Temperature should be continuously maintained between 34°F. and 38°F. (1°C. and 3.3°C.).
- Relative humidity should be maintained between 75% and 90% to ensure uniform drying.
- Airflow of 15 to 20 linear foot per minute at the surface of the product should be maintained.

When aging in vacuum packages, inspect each bag at the time of sealing to ensure a tight seal. Loss of vacuum will allow air to enter the bag, and aerobic bacteria will be able to grow and produce spoilage.

Depending on the type of aging process as described above, bacterial populations may increase significantly during the aging process. The breakdown of proteins and fats by natural chemical processes as well as by bacterial action drive the tenderization process during aging. Because of the potential for higher bacterial populations, all aged beef should be cooked according to Food Code guidelines found in § 3-401.11; if cooked to order, the consumer advisory is required per § 3-603.11.

Other Considerations

- Poor sanitation in the aging cooler or chamber can result in off-odors, off-flavor, and spoilage.
- Excess aging, and aging at higher temperatures, will result in growth of bacteria, especially spoilage organisms. The result is unacceptable odor and the appearance of a slimy surface on the **meat**. This is most likely to occur on moist, lean surfaces such as flanks, rounds, and necks, and the result is unacceptable odor and flavor. The contaminated areas should be trimmed off and discarded.
- In general, well-aged beef can be achieved in 10 to 28 days, although longer aging times may also be observed. Longer aging times result in the need to trim fat and lean surfaces that have dried to an unacceptable degree, have developed discoloration, or that have evident growth of micro-organisms. A regulatory **variance** is required to age **meats** beyond 30 days, by either wet aging or dry aging.

Additional information is available at the following references.

Recommendations for Aging Beef – University of Missouri Extension[28]

Dry Aging of Beef; Review – NCBI/National Institutes of Health, 2016[29]

Institutional Meat Purchase Specifications – (p. 6) USDA, November 2014[30]

HACCP Requirements for Hot Smoking Fish for Preservation

At the discretion of the regulatory authority, hot smoked ready-to-eat fish may be allowed shelf life beyond 7 days when critical parameters of water phase salt, water activity, cooking time/temperature, and storage temperature are met. The FDA Food Code provides that TCS foods

[28] https://extension.missouri.edu/publications/g2209#:~:text=Temperature%20of%20the%20aging%20room,off%2Dodors%20at%20all%20times.
[29] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4872334/
[30] https://www.ams.usda.gov/sites/default/files/media/IMPS_100_Fresh_Beef%5B1%5D.pdf

do not include products classified as “product assessment required” which have undergone product assessment testing showing that growth and toxin formation by pathogenic organisms is prevented by certain factors. Those factors may include:

- Intrinsic factors such as water activity, pH, water phase salt, and others;
- Extrinsic factors such as method of packaging and temperature range of storage;
- A combination of intrinsic and extrinsic factors.

The guidance of a **Processing Authority** in combination with a product assessment is necessary to support a variance allowing for smoking fish to preserve the ready-to-eat product by extending shelf life beyond 7 days. Processing conditions for preservation of fish by smoking are discussed in this section.

Smoking **fish** has a long tradition in food cooking and **preservation**. Cold- and hot-smoking processes have, however, different aims and effects on the quality and safety of **fish**. Smoking combined with heat induces a cooking effect, decreases moisture, reduces microbial load, and may favor some ripening by promoting enzymatic action. **Cold smoking** is mainly used for flavor and to extend shelf life due to the antioxidant and antimicrobial effects of smoke compounds. However, research has shown that smoke chemicals alone provide insufficient antimicrobial **control**. Additional required **controls** include brining, drying, and refrigeration of the finished product. Food safety issues can arise if improper food safety controls occur prior to, during, or after the smoking process.

Observations During Inspection

The following are indications that a retail establishment may be smoking **fish**:

- A smokehouse is present within the establishment or in the surrounding perimeter.
- Firewood and bags of sawdust are stored on-site.
- Fish are observed to be submerged in a liquid brine under refrigeration.
- Display of bulk or packaged smoked **fish** products for direct sale to customers are found.

Any of these observations should lead inspectors to ask questions to determine whether the establishment is smoking fish requiring process approval.

Definitions

Air packaged: Food-packaging technique in which air exchange in a package is not restricted by a seal or nonpermeable film, and air has not been removed by a manual or mechanical activity, e.g., overwrapped tray packaging.

Approved source: Acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

Brine: Water that is saturated or nearly saturated with salt. Typical brines may contain other additives. Sodium chloride (common house salt) has a saturation point of around 37% in water at 32°F. (0°C).

Brining or wet brining: The process or processing step where seafood is placed in a brine solution, under refrigerated temperature, for a predetermined period of time to increase the levels of water phase salt and improve product sensory characteristics.

Cold-smoked fish: Smoked fish that has been produced by subjecting it to smoke at a temperature, generally less than 90°F. (32.2°C), where the product undergoes only incomplete heat coagulation of protein.

Dry salting: The processing step involving the salting of seafood by applying a layer of salt or a dry mixture of salt plus other ingredients to increase the salt content of the seafood prior to the smoking process.

Fish: Fresh or saltwater finfish, crustaceans, and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, sea urchin, and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption. **"Fish"** includes an edible human food product derived in whole or in part from fish, including fish that have been processed in any manner.)

Hot-smoked fish: Smoked fish that has been produced by subjecting it to heat during smoke processing.

Loin muscle: The longitudinal quarter of the great lateral muscle, a part known anatomically as the median superficial muscle.

Pellicle: A skin or coating of proteins on the surface of fish that can form after fish has been salted and dried for a period of time during which exposed surface proteins are denatured. This artificial, glossy skin helps seal in natural juices and flavors, and can enhance smoke absorption to fish flesh.

NOTE: Recent studies indicate that bacteria can be embedded in or under the pellicle before inhibitory concentrations of smoke constituents are deposited. As a result, the inactivation of Listeria monocytogenes *and* Staphylococcus aureus *is markedly reduced in both cold- and hot-smoked fish.*

Smoked fish: Fish which, for the prime purpose of taking on the flavor and/or color of smoke, has been subjected to the direct action of smoke or smoke flavor from the burning of wood, sawdust, or similar burning material, or immersed in or sprayed with a smoke-flavored solution.

Water phase salt (WPS): A measure of the amount of salt in the fish product relative to the product's moisture content. WPS is calculated as percent salt (sodium chloride) multiplied by 100 and divided by percent salt plus percentage moisture.

- WPS = (% salt x 100) / (%salt + % moisture)

Potential Hazards

The Food Code prohibits smoked **fish** from being reduced oxygen packaged at retail unless the product is frozen before, during, or right after packaging. This prohibition is due, in part, to the botulism outbreaks that have occurred associated with vacuum packaged smoked fish. Retail food establishments can conduct smoking of fish that will not be reduced oxygen packaged. When smoking fish at retail is conducted for preservation purposes, a **variance** and an approved **HACCP plan** are required. Smoking fish at retail for flavor does not require a variance or a HACCP plan.

The type of **fish** chosen for smoking is important. While one can smoke most any kind of **fish**, the best **fish** to smoke are fatty **fish** such as mackerel, trout, salmon, tuna, and bluefish. Fatty **fish** are ideal because they will absorb the wood flavors better than lean **fish**.

Scombroid species of **fish** have been implicated in scombroid poisoning. The most common types of scombroid **fish** are tuna, bluefish, mahi-mahi, and mackerel. These **fish** can produce elevated levels of histamine if temperature-abused during harvesting, handling, processing, or storage. Histamines are not destroyed by freezing, cooking, smoking, curing, or canning. NOTE: For more information, see Chapter 7 of the Fish and Fishery Hazards and Controls Guidance.[31]

All living organisms, including certain species of **fish**, can have parasites.

NOTE: Chapter 3 of *Potential Species-Related and Process-Related Hazards; Fish and Fishery Hazards and Controls Guidance* provides species that present a parasite hazard.[32]

Parasites do not present a health concern in thoroughly cooked **fish**, but become a concern when consumers eat raw uncooked **fish** such as sashimi, sushi, ceviche, and cold smoked **fish.** They may be destroyed by heat during the hot smoking of fish to an internal temperature of at least 140°F., or 60°C. Normal hot-smoking procedures generally exceed this temperature. **Cold smoking**, on the other hand, does not have a heating step. Therefore, parasites must be controlled by freezing the **fish**. There is guidance for parasite destruction in Paragraphs 3-402.11 and 3-402.12 of the FDA Food Code. Parasites should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate it.

A retail establishment may receive **fish** for smoking that are either eviscerated or uneviscerated. Evisceration is cutting down the belly of a **fish** and removing the internal organs. **Fish** should be carefully eviscerated and the visceral cavity thoroughly rinsed to eliminate *Clostridium botulinum* spores that are commonly present in the digestive tract. Evisceration should be performed with minimal disturbance of the intestinal tract contents.

Listeria monocytogenes[33] is another concern when handling **fish**. The best way to **control** for *Listeria monocytogenes* is to use proper sanitation and prevent cross contamination of raw products. This organism is a huge concern with cold smoked **fish** as there is no known **control measure** to eliminate *L. monocytogenes* on cold smoked product, unless it is cooked prior to eating by the consumer. This is not a popular practice. Since cold smoked fish is considered a raw, ready to eat (RTE) food, it is recommended that operators control the hazard of pathogen growth and toxin formation throughout processing, including during refrigerated receiving, storage, brining, and finished product storage.

NOTE: For fish processors, FDA recommends sanitation controls with environmental monitoring as provided in *Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-To-Eat Foods.*[34]

Processing Operations

Receiving

Fish should be obtained from an identifiable, **approved** source. All supplies and ingredients must be from licensed and/or recognized suppliers, operating in accordance with applicable food safety

[31] https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls
[32] https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls
[33] http://www.fda.gov/food/fooborne-pathogens/listeria-listeriosis
[34] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-control-*Listeria*-monocytogenes-ready-eat-foods

requirements. Identifiers can include the name and address of the immediate supplier and the actual source or location of the suppliers. No seafood from a recreational fisherman or other **nonapproved** sources should be used in the smoked **fish** operation.

All **fish** must come from a source that can provide evidence (if requested) that they have implemented a valid **HACCP plan** to **control** all relevant food safety **hazards** and processing records to demonstrate that specific **hazards** have been **controlled**. Wholesalers operating and shipping only within the state may not be required to have a HACCP plan, but they must operate in compliance with state regulations. Evidence for such a source can include a Letter of Guaranty from the supplier that indicates where and how the **HACCP** information can be obtained. The **HACCP** information and/or records and prior agreements with the fish supplier provide **controls** to prevent potential problems due to parasites, elevated histamine levels, and other fish safety concerns.

All **fish** are delivered below 41°F. (5°C.) or solidly frozen. A calibrated thermometer should be used to **monitor** the internal and/or surface temperature of the incoming **fish** before acceptance. The receiving of refrigerated fish (not frozen) intended for cold smoking is a **CCP** with a **critical limit** that ensures the fish were maintained at 41°F. (5°C.) or below throughout transit to control pathogen growth and toxin formation. This can be accomplished by transport records of continuous time and temperature monitoring of the ambient air temperature, or adequacy of ice/cooling media.

NOTE: See Chapter 12, page 220, of the *Fish and Fishery Products Hazards and Controls Guidance.*[35]

Food Storage

The storage of **fish** should be in appropriate temperature **control** units (walk-in coolers, refrigerators, or freezers) capable of maintaining proper product temperatures of 41°F. or less, and frozen items at 0°F. or less. Storage units should be clean and orderly. Ready-to-eat items should be segregated from raw products or products that require further handling or processing. **Fish** should be stored in a manner that protects the product from contamination by condensate drippage and other wet sources.

Raw Materials

The work area, facilities, and utensils should be designated or dedicated for the smoking operations. If it is necessary to share workspace and facilities, a schedule of operations, personnel traffic, product traffic, and cleaning practices must be developed to prevent potential cross contamination of the ready-to-eat smoked products.

Thawing of frozen **fish** should be conducted under refrigeration. This can be expedited by placing **fish** in potable running water, so long as the temperature of the **fish** does not exceed 41°F. (5°C.) and the temperature of the running water does not exceed 70°F., or 21.1°C. A maximum water temperature of 70°F. (5°C). without a time limit is concerning for fish that will be cold smoked. The primary concern is for the surface temperature of the fish, which will warm the fastest due to the ambient temperature of the water. It is the ambient temperature of the water that should be controlled. The maximum cumulative time limit for controlling pathogen growth for temperatures that do not exceed 70°F. (21.1°C.) is 5 hours. This is important because the cold smoke will not

[35] https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls

eliminate pathogens. NOTE: See Chapter 12 of the *Fish and Fishery Products Hazards and Controls Guidance.*[36]

After thawing, **fish** should be rinsed to eliminate microorganisms on the skin. The body cavity should be washed with running cold water to remove all traces of blood and kidney tissue (i.e., dark red mass along the backbone).

Different **fish** species generally require specific preparation methods. For example, salmon are generally split with the backbone removed. After splitting large **fish**, the sides should be cut into uniform pieces so they will smoke evenly. Some **fish** are filleted, and others, such as herring, are beheaded and eviscerated.

Uneviscerated whole **fish** that are dried, smoked, pickled, or fermented can also pose a public health **hazard**. Because *Clostridium botulinum (C. botulinum)* spores are known to be present in the viscera, **fish** that will be preserved by salting, drying, pickling, or fermentation must be eviscerated prior to processing. **Fish** that have been gutted and cleaned prior to delivery to the retail establishment should be used if possible. If **fish** are eviscerated onsite, it should be done in a segregated area separate from other processing operations. **Fish** should be eviscerated with minimal disturbance of gut contents, and the body cavity should be thoroughly washed in a designated area and manner that will not contaminate other food handling areas. Knives, cutting boards, and other food contact surfaces are to be cleaned and sanitized routinely to prevent product contamination. The preparation schedule should be arranged to prevent the exposure of **fish** for more than 4 hours outside of refrigeration.

Dry Salting/Brining

The infusion of salt into the **fish** product is the first critical step in smoking **fish** for **preservation**. This is accomplished by either dry salting or brining. The salt has a preserving effect as it extracts water from the **fish** muscle and transports salt into it. The salt lowers the water activity inside the muscle, making the remaining water less accessible for microorganisms, which inactivates or inhibits microbial growth. In addition, the salt helps change the structure of proteins and deactivates certain enzymes.

Dry salting usually occurs by layering the fillets with salt in a vat or container. This removes moisture from within the flesh of the **fish**. Dry salting should be done under refrigeration. Salt levels are **controlled** by the amount of time the products are dry salted and the thickness of the fillets.

Brining occurs by placing the **fish** fillets within a liquid brine solution. Brining varies depending on the type of **fish** processed and the level of salt desired in the product. These issues are **controlled** by **controlling** the time, the **fish**-to-brine ratio, and the thickness of the **fish** being brined. Different species of **fish** should not be mixed in the same brine container. When brining time will not exceed 4 hours, brining should be carried out so that the temperature of the brine does not exceed 60°F. (15°C.) at the start of brining. When the brining process will require more than 4 hours, brining should be conducted under refrigeration at 41°F. (5°C.) or lower. The brine strength should be **monitored** with a salinometer.

General guidelines for brining are as follows: Smaller **fish**, such as gutted herring, require about 30 minutes brining time under refrigeration; oily **fish** and larger **fish** (e.g., 2- to 3-inch chunks or steaks from a salmon) require about 2 hours. Required brine time for low-fat and skinned **fish** is less. It

[36] https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls

may be helpful to experiment with brining time. Begin with 15 minutes per half inch of **fish** thickness. Do not overlap **fish** pieces while brining, or salt uptake will not be uniform. A smoked **fish** with distinct but not excessive salt flavor has probably absorbed enough salt. Dry salting is also acceptable, and the same general rules apply. However, the use of a brining solution typically yields a more uniform salt concentration. It is also recommended that producers verify their brining process periodically by obtaining a product analysis from a food laboratory for water phase salt. For safety, it is recommended there is a minimum water phase salt (WPS) value of 2.5% in open bulk stored or air-packed product. Following an **approved** brine recipe and time is critical to the safety of the final product.

Nitrites can only be used for salmon, shad, sable **fish**, chubs, and tuna in accordance with FDA regulations (21 CFR 172.175 & 21 CFR 172.177). Nitrite levels in salmon, **sablefish**, shad, and chubs shall not exceed 200 ppm and shall not exceed 10 ppm in tuna. Nitrites are commonly used in the curing of **meats** to impart red color, enhance flavor, and protect the product from the growth of *Clostridium botulinum* in case of contamination or mishandling. In the curing of fishery products, the addition of sodium nitrite ($NaNO_2$) prior to smoking will inhibit the growth of *C. botulinum.*

Smoking/Drying

The smoking and drying steps are critical in the process to eliminate bacterial pathogens or reduce the potential for pathogens to grow, and/or prevent the formation of toxins in finished products. The brining step often does not result in sufficient water phase salt in the product without the added effect of drying, so the drying time is a critical element in both hot smoking and **cold smoking**. Drying the **fish** before smoking gives a nice coat for the smoked fillets to help seal in moisture, and provides a better-looking finished product – this is called forming a **pellicle**. After rinsing the **fish** from a brine, let the surface air dry, about 30 minutes for most **fish**. Using a fan will aid in getting the outside dry before smoking.

One of the following specific time/temperature combinations must be met during the smoking/drying step to ensure finished product safety:

- For **hot smoked fish** for preservation, the product must be continuously heated, to achieve an internal product temperature of at least 145°F. (62.8°C.) for at least 30 minutes. The internal product temperature should be obtained by inserting a calibrated thermometer into the center of the thickest portion of three or more of the largest **fish** in the batch and the coldest reading used to determine that the time and temperature combination has been met. Records (manual or electronic) showing that the internal temperature reached a minimum temperature of 145°F. (62.8°C.) for at least 30 minutes shall be kept for each batch of fish. Drying may be allowed to continue after the critical temperature and time requirements have been met. Continued drying will result in increased water phase salt.

- It is important to note that in **cold smoking fish**, the product does not receive enough heat to significantly reduce the number of spoilage organisms. The presence of spoilage organisms is necessary to inhibit the growth and toxin formation of *C. botulinum* type E and non-proteolytic types B and F. This inhibition is essential in cold-smoked **fish** because the heat applied during this process is not sufficient to inactivate the *C. botulinum* spores. Temperature **control** during the cold-smoking process is critical to the safety of the finished product. For cold smoked fish, the temperature of the smoking chamber must either 1) not exceed 90°F. (32.2°C.) during a drying and smoking period that does not exceed 20 hours, or 2) not exceed 50°F. (10°C.) for a drying and smoking period that does not exceed 24 hours. A calibrated temperature recording device must be used to document that these time and temperature limits have not been exceeded. Records documenting the results of

this **monitoring** should be kept for each batch of fish processed. Additionally, **fish** that is being cold smoked should be arranged in the smoking chamber in such a way that it will receive the maximum exposure to smoke for its anti-microbial effects.

Cooling

Product must be cooled from 135°F. (57.2°C.) to 70°F. (21°C.) or less within 2 hours of the smoking process and from 70°F. (21°C.) to 41°F. (5°C.) or less within 4 hours. Total cooling time shall not exceed 6 hours from start of cooling. Cooling should occur in refrigerated storage units maintained as described in the preceding section for the Storage processing step.

Packaging

The Food Code prohibits smoked **fish** from being reduced oxygen packaged at retail unless the product is frozen before packaging and remains frozen while it is in reduced oxygen packaging.

Operators should minimize the amount of time that smoked **fish** products are out of temperature **control** (above 41°F. (5°C.)) during packaging and labeling. Additionally, there should be no bare-hand contact with the finished product. Single-use gloves should be clean and sanitized prior to use to prevent cross contamination, and proper hand washing is necessary.

Use packaging material, such as wrapping film and trays that are clean and **approved** for the particular process. Finished packaged products that can be purchased by consumers must comply with all federal and/or state labeling requirements.

Display

Display involves holding the finished products in temperature **control** units for a specified duration and condition for public sale. Retail preparation and display introduce more prolonged storage that must be **controlled** and **monitored** to assure product safety before consumption. The display unit must maintain the smoked **fish** products at or below 41°F. (5°C.). Product is rotated to ensure first in, first out (FIFO) movement of product. Out-of-date product should be discarded.

HACCP Plan and Regulatory Requirements

Smoking as a method of food **preservation** is considered a special process requiring a **variance** and **HACCP plan**. Smoking as a method of flavoring is not considered a specialized process.

Process Controls

To achieve the desired WPS, aW, and nitrite levels, the following factors should be predetermined for each batch:

- minimum volume of brine
- minimum concentration of salt and/or other ingredients affecting WPS and aW within the brine
- prescribed volume of nitrite (where allowed)
- maximum volume of **fish**

- maximum size of **fish**/**fish** fillet/**fish** portion
- minimum volume and type of liquid smoke (if used)
- minimum time in brine.

Dry-salting of **fish** shall be conducted with a quantifiable level of salt, sugar, nitrites, and/or other dry curing mixture distributed across all surfaces of each **fish**, **fish** fillet or **fish** portion to achieve the desired WPS, aW, and nitrite levels in the finished product.

Different species of **fish** shall not be mixed in the same brining tank. When a different species is brined, a new brine mixture must be used.

Brines shall not be reused unless there is an adequate process available to return the brine to an acceptable microbiological level and shall only be reused on the same species.

Additional process **controls** include the following:

- **Approved** vendor documentation and product labeled for traceability.
- **Fish** is received and maintained at 41°F. (5°C) or lower before processing.
- Only thoroughly eviscerated **fish** used for processing .
- Following the dry salting of **fish**, the product is held under appropriate refrigeration temperatures.
- Brining of **fish** is carried out under refrigeration except for periods less than 4 hours.
- **Fish** to be smoked are properly arranged in the smokehouse.
- Hot smoked **fish** is heated in accordance with the **HACCP Plan** and the temperature shall be met in the loin muscle of the largest **fish** to be smoked.
- Product cooled in accordance with Food Code requirements.
- The cooled product shall be air packaged or sold in bulk.
- Packaged or bulk displayed product should be stored in the refrigerated display case. that is equipped with thermometers to assure the product is maintained at 41F. (5°C) or below.

References:

Retail Food Establishment Guide for Developing a HACCP Plan, AFDO 2014, https://www.afdo.org/product/a-retail-food-establishment-guide-for-developing-a-haccp-plan/

Guidance for Processing Smoked Seafood in Retail Operations, AFDO 2004, https://edis.ifas.ufl.edu/pdf/FS/FS11100.pdf

Chapter 7: Smoked Fish and Fishery Products, Oregon State University, https://seafood.oregonstate.edu/sites/agscid7/files/snic/compendium/chapter-7-smoked-fish.pdf

Cured, Salted and Smoked Fish Establishments Good Manufacturing Practices, AFDO 2019, https://www.afdo.org/wp-content/uploads/2020/11/Cured_salted_and_smoked_fish_establishments_good_manufacturing_practices_acc_updated_2019.pdf

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21 CFR Part 123, https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123

Generic HACCP Model for Hot Smoked Fish, Oregon Sea Grant Extension Program, 12/30/1997, https://seagrant.oregonstate.edu/sites/seagrant.oregonstate.edu/files/sgpubs/onlinepubs/i97001.html

SECTION 7: OTHER SPECIALIZED PROCESSING METHODS

HACCP Requirements for Molluscan Shellfish Tanks

Bivalve Molluscan Shellfish (molluscan shellfish) are edible species of fresh or frozen clams, mussels, oysters, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle. Molluscan **shellfish** are an extremely popular form of seafood, but consuming the product raw creates great **risk** for foodborne illness for consumers. These **shellfish** filter the water to obtain nutrients, but in so doing they also accumulate viruses, bacteria, and toxins in their tissues and gut. Life-threatening illness can result from these **hazards**. Highly susceptible persons are at particularly high **risk** when consuming raw **shellfish**.

The commercial growing, harvesting, shucking, shipping, packing, and repacking of molluscan **shellfish** are highly regulated due to the public health concerns. The Interstate Shellfish Sanitation Conference has published the *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish,* which contains the Model Ordinance for member states.

Observations During Inspection
The following are indications that a retail establishment may be operating a live molluscan **shellfish** storage or display tank:

- Molluscan **shellfish** such as oysters, clams, or mussels in a water tank or mixed in a water tank with crustacean **shellfish** such as crabs or lobsters
- A **fish** tank or large aquarium with molluscan **shellfish**
- Seasonal displays or storage of molluscan **shellfish** in water

Any of these observations should lead inspectors to ask questions to determine whether the establishment requires specialized process approval.

Definitions

Commingle: Combining *shellstock* harvested on different days or from different growing areas based on the tag or label into the same container, box, bag, or tote. Shucked shellfish also should not be commingled so that shellfish from different harvest areas or dates are combined into a commingled lot.

Shellstock: This is raw, in-shell molluscan shellfish.

Shucked shellfish: Molluscan shellfish that have both shells removed.

Potential Hazards and Their Sources

The **hazards** of concern associated with **shellfish** result from environmental factors:

- Fecal waste dumping and runoff of contaminated stormwater – fecal-associated pathogens such as Hepatitis A virus, Norovirus, *E. coli,* and *Salmonella*
- Warm inshore salt water and brackish water – pathogenic *Vibrio* species bacteria (*V. vulnificus* and *V. parahaemolyticus*)

- Certain species of algae (phytoplankton) in the water – toxins formed by certain types of algae accumulate in **shellfish** tissues, and can cause various types of **shellfish** toxin poisoning (diarrhetic, amnesic, paralytic, neurotoxic)

Pathogenic bacteria and most viruses are destroyed by proper cooking. Marine toxins cannot be destroyed by cooking! These toxins are reportedly not of concern if only the adductor muscle is consumed. However, products such as whole scallops or scallops with roe do present a potential **hazard**.

All **shellfish** must be harvested from waters known to be free from environmental factors that result in bacterial, viral, or chemical contamination. Commercial sales of molluscan **shellfish** are strictly regulated due to potential concerns for human health. States participating in the Interstate Shellfish Sanitation Conference (ISSC) use the *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish,* which includes the model ordinance for regulation of the growing, shipping, shucking, packing, and repacking of molluscan **shellfish**. **Approved** suppliers are published monthly in the ICSSL, or Interstate Certified Shellfish Shippers List[37] by the FDA. Product obtained from recreational harvesters is not allowed. Retailers should only purchase from certified dealers listed on the ICSSL. They should not purchase from licensed harvesters unless that harvester is also a certified dealer listed on the ICSSL.

All **shellfish** received at retail must be checked to ensure it's from an **approved** source. A **shellfish** tag must be attached to the bag or container to document the source of the **shellfish**. This tag provides critical information in the event of foodborne illness requiring a traceback. The **shellfish** tag must include the following information:

- Name, address, and certification number of the dealer assigned by the regulatory authority
- Date of harvesting
- Location of harvesting
- Type and quantity of **shellfish**
- The following statement: **"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL THE CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE) _____."**

The tag must remain attached to the original container until the last **shellfish** is sold, after which the date of sale of the last **shellfish** from the container must be written on the tag. Tags must be retained for 90 days thereafter, in chronological order.

Additionally, upon receiving by a retail **food establishment**, containers of shellstock must not contain dead **shellfish**, shellstock with badly broken shells, and must be relatively free of mud. Dead **shellfish** and those with badly broken shells must be discarded. Shellstock must be received at 50°F. (10°C.) or lower, stored at 41°F. (5°C.) either wet or dry, and culled as necessary to remove dead **shellfish**.

[37] www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list

Live Molluscan Shellfish Display/Storage Tanks

Shellfish may be held live at retail in holding tanks to keep them fresh for sale or preparation, if allowed by the local jurisdiction's regulations. Retail **food establishments** must obtain a **variance** from the regulatory authority allowing operation of molluscan **shellfish** life support display tanks. State, local, tribal, and territorial jurisdictions generally follow FDA Food Code when determining how to regulate retail holding and sales of molluscan **shellfish**.

The water in **shellfish** tanks may be synthetic saltwater, or if natural saltwater, it must be sourced from **approved** open growing areas. **Shellfish** filter new nutrients from the water in which they are held, and as they take in new nutrients, waste is expelled. Any contaminants present in the water will naturally be concentrated in their tissues and gut. In a properly designed **shellfish** tank, the water will have little or no nutrients because the sand filter efficiently binds most nutrients, making them unavailable to the **shellfish**. As a result, the **shellfish** produce very little waste that could be exchanged with other **shellfish** in the tank.

Shellfish must be stored or displayed in a manner that prevents cross contamination by biological, chemical, and physical **hazards** at retail. Shellfish should never be stored in wet storage with any other type of fisheries products. They must be stored under temperature **control** at 41°F. (5°C.) or lower. Certain **controls** must be in place to prevent contamination of **shellfish** during storage and display in holding tanks.

- When shellstock from more than one lot share the same tank, each lot must be in its own bag. Bags must remain separated by harvest area or date, and must retain their original tags.

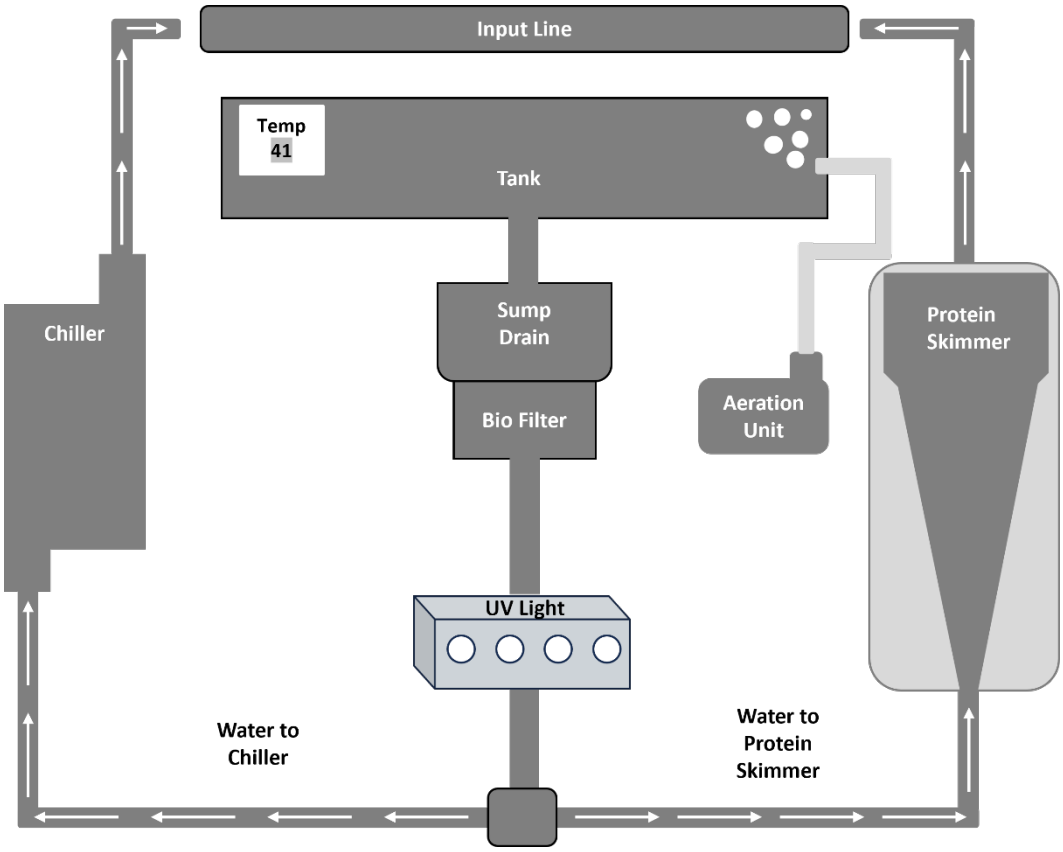
- Clams, mussels, and oysters (bivalves) should not share the same water with gastropods (snails, slugs, conches). Fecal matter discharged into the water by the gastropods can be taken up by the bivalves. For the same reason, other species such as shrimp, lobster, crab, and **fish** also may not be added to the same tank or share the same water with molluscan **shellfish**. Fecal waste may contain bacteria and viruses that can be filtered and concentrated by molluscan **shellfish**.

- All molluscan **shellfish** must be from **approved** harvesting areas open for harvesting.

- Strict monitoring of the tank, including the filtering and disinfection system is required to prevent accumulation of increasing levels of pathogens in the water. Weekly testing of the tank water is recommended by the National Shellfish Sanitation Program. Coliform bacterial concentrations should be reported as MPN (most probable number) per 100 mL; no coliform bacteria should be detected.

- Turbidity and salinity should be checked on a regular schedule, and salinity should be maintained according to the manufacturer's instructions. The tank and recirculation system should be washed, rinsed, and sanitized weekly to prevent accumulation of bacteria.

Properly Designed Shellfish Tank



HACCP Plan and Regulatory Requirements (Variance)

The FDA Food Code, Subparagraph 3-502.11(E) requires that retail **food establishments** operating molluscan **shellfish** life-support display tanks to store or display **shellfish** offered for human consumption must obtain a **variance** from the regulatory authority based on an **approved HACCP plan**. The **HACCP plan** must provide specific **controls** to ensure the safety of the **shellfish** for consumption. ¶ 8-201.14 of the 2022 Food Code requires the following elements to be included in the **HACCP plan**:

- List the types of **shellfish** the **food establishment** will be holding in life-support tanks.
- Provide a flow diagram or chart describing the **shellfish** life support tank setup and operation, listing the **critical control points** (CCPs) and **critical limits**, **control measures**, the methods and frequencies for **monitoring** the CCPs, management **verification** procedures, **corrective action**s to be taken in the event that a **critical limit** is not met, and identifying the records to be maintained to document compliance with the **HACCP plan**.
- Management and food worker training on proper maintenance of the **shellfish** storage tank system and food safety issues of concern must be provided and documented.
- Weekly analysis of the tank water for total coliform bacterial counts (MPN method).

Required shellfish tank controls:

Certain **shellfish** tank **controls** should be confirmed in the regulatory plan review, and must be included in the tank storage system.

- Each tank should have adequate capacity, e.g., 100-gallon capacity for 75 pounds of **shellfish.**
- Chiller unit must maintain tank water at $\leq$ 41°F. (5°C.). An in-system thermometer enabling the operator to monitor temperatures is required, and monitoring should be documented daily.
- Filtration pad to remove particulates.
- Biological filter (sand filter) to remove fecal wastes.
- Protein skimmer to remove foam.
- Activated charcoal filter to control odor and remove color.
- Backflow prevention (air gap or other) on influent lines.
- No water mixing between tanks containing **fish**, crustaceans, and mollusks.
- The water used to fill the tank must either be potable water mixed with marine salts, or must be from open marine shellfish growing waters approved by the regulatory authority.
- The water must be disinfected using an ultraviolet (UV) light disinfection unit of at least 7,500 watt hours to kill bacteria and viruses.
- Scheduled monitoring and maintenance are required.

Shellfish receiving and storage controls:

- **Shellfish** must be received live at $\leq$ 50°F. (10°C.), wet or dry, and must be culled as necessary to remove dead **shellfish** and those with badly broken shells.
- **Shellfish** from different harvest dates, locations, harvesters, and **shellfish** of different species must not be commingled.
- **Shellfish** *dealer's* tags must remain attached to the original bags, and must contain the following information: dealer's name, address, and certification number assigned by the **shellfish** regulatory authority; the original *shipper's* certification number along with the abbreviation of the state or country in which the **shellfish** were harvested; harvest location or that of the aquaculture site; date of harvest; type and quantity of **shellfish**; and the following statement in bold, capitalized type: **"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL THE CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE) _____."**

References:

Retail Food Establishment Guide for Developing a HACCP Plan, AFDO 2014

Molluscan Shellfish Guidance Document, Washoe County Health District, https://www.washoecounty.us/health/files/ehs/food-protection-services/Resources/Molluscan-Shellfish-Guidance-Document-updated.pdf

Direct Acidification, Use of Additives, and Fermentation Processes

Direct Acidification and Use of Additives

Acidification for **preservation** of foods by addition of an acid component has been used commercially for well over 100 years. As a **preservation** process, acidification is commonly associated with canning, resulting in a product which is sealed in a hermetically sealed container such as a mason jar. Properly canned products prepared according to a scientifically validated process have greatly extended shelf life, and may also be classified as **shelf stable**. However, the fact that these products are packaged in a tightly sealed container with little to no oxygen present creates an ideal environment for formation of the deadly botulinum toxin produced by *Clostridium botulinum*.

Canning was developed as a commercial process in the mid-1800s, but the industry experienced numerous outbreaks of illness caused by canned goods due to the lack of specific required **controls**. A series of outbreaks in 1919 and 1920 resulted in 18 deaths and many more illnesses in the United States. As a result, the current regulations for commercial canning were introduced into law as 21 CFR Part 114 for acidified foods, and 21 CFR Part 113 for low-acid canned foods (those canned without the addition of an acid to reduce pH). Part 114 prescribes a required pH of 4.6 or lower for acidified foods and a thermal process for inactivation of *Clostridium botulinum* prescribed by a **processing authority** for shelf-stable, acidified canned foods.

The FDA Food Code requires that acidification processes and the use of additives for the **preservation** of food require a **variance** based on approval of a **HACCP plan** by the regulatory authority. For products acidified by either direct acidification or fermentation, an independent product analysis is generally required to confirm that the final product meets the requirements of Interaction Table A (heat-treated and packaged) or Interaction Table B (not heat-treated, or heat-treated but not packaged), found in the Food Code definition of **TCS** food. See *FDA JOB AID; Time and Temperature Control for Safety Foods*.[38] This job aid is intended to be used in conjunction with the FDA Food Code. It will help the user determine if a food is considered a **TCS** food. "Packaging" requires adherence to a validated thermal process, such as prescribed by an FDA-recognized **processing authority**.

When **TCS** foods are processed to reduce pH for **preservation**, whether by addition of an acid or by fermentation, the final pH must meet the requirements of either Interaction Table A or B. Published recipes with specific process instructions from a recognized academic source may be accepted by the regulatory authority without requirement of a product analysis and process letter from a **processing authority**, provided that the retail **food establishment** follows the prescribed recipe and process without modification.

The Food Code requirement for a **variance** and **HACCP plan** for acidification processes is based on the distinction between "**preservation**" and "flavor only – not for **preservation**." As of the date of this publication, neither FDA nor USDA have published an official definition for "**preservation**." However, a working definition is derived from applicable sections of the Food Code.

[38] https://www.fda.gov/files/food/published/Job-Aid--Time-and-Temperature-Control-for-Safety-Foods.pdf

- **TCS** ready-to-eat foods, as defined in the Food Code and in Section 1 of this manual, require either hot holding above 135°F. or cold holding at or below 41°F., with a date mark of 7 days or less for safety. (See the definition of **TCS** food, and Paragraphs 3-501.16 and 3-501.17 of the Food Code.)

- Working definition: Preservation means Formulating, processing or packaging a time/temperature control for safety food in a manner that either extends the shelf life of the ready-to-eat product beyond the 7 days allowed under ¶ 3-501.17 of the Food Code, or that renders the final product shelf stable, or both.

Examples of direct acidification processes that are not for preservation include:

- Preparation of ceviche, carpaccio, and similar products from raw, ready-to-eat proteins with the addition of an acid such as lemon or lime juice along with other ingredients. Such products may be prepared and served immediately per customer order, or may be marinated up to one or two days under refrigeration, and served or discarded within one to three additional days storage under refrigeration.

- Preparation of refrigerator pickles, in which a cold pickling brine is added to non-**TCS** vegetables, such as sliced raw cucumbers. The product is stored under refrigeration for quality. Because the non-heat treated vegetable is not defined by the Food Code as **TCS**, and it is not specifically listed as a **TCS** food (as are sprouts, cut melons, "heat-treated plant food" and cut tomatoes), this product has not been preserved and date marking for safety is not applicable.

Examples of direct acidification processes that constitute preservation include:

- Acidification of sushi rice is a common practice in many retail food establishments. Acidification allows extended holding time of the cooked (TCS) rice at room temperature. For complete guidance, see the Conference for Food Protection document "Guidance Document for Retail Sushi HACCP Standardization."[39]

- Be aware when preparing salsa, pico de gallo, sauces containing tomatoes, and similar products – many tomatoes have a pH above 4.6. For this reason, products containing tomato as a major ingredient must be acidified, typically with vinegar (acetic acid) or a citrus juice (citric acid). The choice of acid component is often directed by the desired flavor profile. Testing may be required to determine if the product can be classified as acidified and if it may be considered **shelf stable** or have its shelf life extended.

- Hot-brined pickles, bottled according to a validated process from a recognized **processing authority** or other academic source and tested to confirm pH of 4.6 or lower, are **shelf stable** and are not subject to date marking. Refrigeration is only necessary after opening the first time in the establishment or by the consumer.

- Barbeque sauces, ketchup, mustard, mayonnaise, and many non-vinaigrette salad dressings are typically acidified foods. These must be formulated and tested to confirm non-**TCS** pH, and must be packaged according to guidelines from a **processing authority**. Hot-fill and cold-fill processes are possible. When prepared and packaged according to

[39] http://www.foodprotect.org/media/guide/final-doc-cfp-c3-sushi-rice-standardization-5-2023.pdf

processing authority guidelines, these products are **shelf stable** until opened in the establishment or by the consumer, following which they should be refrigerated.

- Pickled eggs are acidified with vinegar (acetic acid) with added salt. The pH of eggs is above 6.0, but when properly acidified to pH below 4.2, they require no temperature **control** or date mark.

- Bottled garlic-in-oil mixtures must be acidified to prevent spore germination and toxin formation by *Clostridium botulinum*. The oil provides the oxygen-free environment needed by *Clostridium botulinum* for growth and toxin formation. Acidification with vinegar (vinaigrette dressings) or citric acid to pH below 4.6 **controls** this potential **hazard**.

- When held without temperature **control** for longer than four hours, acidified sushi rice requires a product pH below 4.2 to prevent growth and toxin formation by *Bacillus cereus*. The cooked rice is a **TCS** ready-to-eat food once cooked, so without acidification, temperature **control** is required to maintain the safety of the cooked product. Once properly acidified, the non-**TCS** product may be help at room temperature without limiting the allowed time.

*NOTE: When using organic acids such as citric acid, it may be more appropriate to have the product tested for titratable acidity either instead of, or along with, pH. Always consult a **processing authority** for guidance on this important decision and the required level of acidity.*

Acidified foods which will be held without refrigeration (**shelf stable**) and which are packaged with a validated thermal process (heating to a specified temperature, bottled hot and held at the required temperature for the specified time) must reach an equilibrium pH of 4.6 or lower. The operator responsible for these processes must present certification from the FDA "Better Process Control" course for acidified foods. This describes a true canning process for pickled or acidified vegetables. Because the final product has a pH of 4.6 or lower and has been thermally processed and packaged, the product meets the Food Code definition for a non-**TCS** food, and therefore is not subject to date marking for safety. Any date mark used will be a quality date (best by). The retail operator must maintain records for calibration of the pH meter on each day of use, and for testing each batch to confirm the required pH of 4.6 or lower has been met. Products in this category include pickles (unless a true cold pickling process is used with no **TCS** ingredients such as cut tomatoes or watermelon). **See page 240 for instructions on pH meter calibration and product pH testing.**

Other acidified products include salsas, chow chow, relishes, and hot sauces prepared with vinegar or another acidic major ingredient.

Products that have been acidified, which may or may not be heat-treated according to a validated thermal process but which will be held refrigerated at all times, must reach an equilibrium pH less than 4.2 (e.g., 4.1 or lower). Refrigeration serves as a second hurdle in place of the prescribed thermal process for **shelf stable** products.

In some cases, the **processing authority** may allow for a cold-fill and hold process rather than hot-filling. In a cold-fill process, the product must be held for a specified minimum time under required temperature conditions before it can be released for sale and consumption. In this case, the producer's records must document the hold time and ambient holding temperatures until the time the product can be released for sale.

Whether hot-filled or cold-filled, products with a final equilibrium pH less than 4.2 meet the Food Code definition for a non-**TCS** food based on Interaction Table B (definition of **TCS** food). These products are therefore not subject to date marking for safety. Any date mark used will be a quality date ("best by"). The retail operator must maintain records for calibration of the pH meter on each day of use, and for testing each batch to confirm the required pH less than 4.2 has been met.

Guidelines for Validating Direct Acidification HACCP Plans

Prerequisites and Standard Operating Procedure(s) (SOPs)

Written procedures and other documentation include the following **controls**:

- **Approved** supplier documentation for all products that will be processed, and product labeled for traceability.
- 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.
- 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.
- Access to processing equipment limited to trained personnel.
- Cleaning and sanitizing procedures for food contact surfaces delineated.
- All ingredients are as fresh as possible.
- Mason jar lids may not be re-used – new lids are required for each process batch.
- Glass jars may be reused, but must be inspected before each use to ensure they are free of cracks and chips. Glass fragments should be identified as a potential physical **hazard**.
- All produce is inspected for damage, bruises and other defects before washing and processing.
- All ingredients must be chopped, sliced or otherwise processed to consistent dimensions to ensure proper acidification.
- Acidification must follow a recipe in which ingredients are added in consistent proportions which, once **approved**, may not be changed without obtaining re-approval.
- **Hazard analysis** Includes pathogenic growth, particularly *Staphylococcus aureus, Listeria monocytogenes*, and *Clostridium botulinum* as significant **hazards**, with the appropriate thermal process and pH measurement as CCPs. Other significant biological **hazards** may vary according to the food items processed, but all should be **controlled** by the validated process.
- Depending on the foods processed, certain chemical **hazards** may be considered significant, such as mycotoxins (molds associated with certain produce commodities), or patulin

associated with apples. Always consult a process expert for guidance regarding significant **hazards** and required **controls**.

- A science-based hot-fill process or cold-fill and hold process must be used for packaging the product. The exact process and recipe must be from a published academic source. Alternatively, a retail establishment's unique recipe must be tested by a **processing authority**, and must follow the thermal process guidance provided in a process letter from the **processing authority**. That process letter must be submitted to the regulatory authority as part of the application package.

- Retail establishments must test each process batch of **shelf stable** canned goods to document meeting the **critical limit** of pH 4.6 or lower. An operator with documented training from a Better Process Control for Acidified Foods course must be in direct **control** of the processing operation at all times.

- Retail establishments that will hold their canned foods under refrigeration at all times must test each process batch of **shelf stable** canned goods to document meeting the **critical limit** of pH less than 4.2 (4.1 or lower). Refrigeration and the lower pH value are required in lieu of the operator having documented training from a Better Process Control for Acidified Foods course.

- When additives are used to preserve foods by means other than acidification, they must be generally recognized as safe (GRAS) and must be used in compliance with FDA restrictions and specifications for concentration in the final product.

Monitoring Procedures Identified for pH of Acidified Product

- Each batch measured with a calibrated pH meter
- Procedures for preparing product for testing using blender if necessary
- Person(s) identified for **monitoring** pH

Corrective Actions and Documentation Procedures Identified

- pH of fermented product
- Continue fermentation if within allowed time
- Discard product if not within allowed time
- Record on **corrective action** logs
- Determine cause of **deviation** – may require guidance from **processing authority** or regulatory authority

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
- pH meter calibrated before each use

Records Identified for Thermal Process and pH of Acidified Product

- Process batch log to document processing temperature/time and final pH
- pH meter calibration log (sample log provided)
- **Corrective Action** records

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**
- Record-keeping requirements

Jams, Jellies, and Preserves

Jams, jellies, and preserves made from acidic fruits using the standard recipe of fruit, sugar, and pectin benefit from acidic pH and low water activity values. The combination of these two values renders these products **shelf stable** (non-**TCS** food) until opened by the consumer, and in most cases, the pH alone is sufficiently low that these are non-**TCS** foods. Acidic fruits include blackberries, blueberries, raspberries, cherries, peaches, pears, plums, and citrus fruits. Such products may not require approval from the regulatory authority, and do not require a date mark for safety. If an acidic ingredient such as citric acid is added, this does not constitute an acidification process unless the final pH is at least 0.4 pH units lower than the pH of the major fruit ingredient.

Use of sugar substitutes or low-sugar recipes results in very little reduction of water activity. These recipes may require a **product assessment** to determine whether the final pH alone is low enough to render the product non-**TCS**, and may require regulatory approval, depending on the policy of your regulatory authority.

Jams, jellies, or preserves of the following low-acid fruits or vegetables require addition of an acid for **preservation**, and will require **product assessment** for pH and water activity: elderberries, figs, mint, and peppers. The same is potentially true of jams, jellies, or preserves made from acidic fruits as listed above, but which also contain additional low-acid ingredients such as elderberries, figs, mint, or peppers. For these products, a **product assessment** for water activity and pH, as well as a **variance** and **HACCP plan** with regulatory authority approval, will be required.

Using Additives for Preservation

Additives used for **preservation** include acids or acidulants such as vinegar, citric acid, or ascorbic acid, or others used to inhibit spoilage organisms such as sodium citrate and potassium sorbate. All additives must be used in compliance with applicable FDA restrictions on use, maximum allowed limits, and in some cases, combinations specified in federal regulations. Subparagraph 3-502.11(C) of the Food Code requires a regulatory **variance** and a **HACCP plan** when additives are used by retail **food establishments** to preserve food, or to render a food so it is a non-**TCS** product. Always consult your retail food regulatory authority for guidance when considering use of food additives for **preservation** of foods.

Fermentation of foods, unlike direct acidification processes, uses acid formation by microorganisms to preserve the food and to create unique flavor profiles. The next section provides information and guidance on a variety of fermentation processes.

Fermentation Processes

Fermentation is the process of transforming a food through the **controlled** growth of microorganisms, either native or an added starter culture, to produce a desired by-product that changes the food. During the fermentation process, native or added microorganisms convert sugars in the food to acid, alcohol, and/or gas. The acid or alcohol produced prevents other microorganisms from surviving and growing. Humans have fermented foods since ancient times to preserve foods, to transform one food into another, and to enhance the flavor and nutrition profiles of a product.

Vegetable Fermentations

Common fermented vegetable products include kimchi, sauerkraut, and pickled cucumbers. Vegetable fermentation typically occurs through a natural fermentation process, in which salt or brine is applied to a vegetable, creating an environment that allows native bacteria to ferment for days to weeks, and produce acid. The acid and sequential growth of fermenting microorganisms contributes to vegetable tartness and helps prevent the growth of pathogenic and spoilage microorganisms.

The vegetable fermentation process must occur at temperatures between 41°F. and 135°F. to allow the fermenters to grow and thrive, therefore allowing for the possibility of growth of pathogenic bacteria. The ideal fermentation temperature for most vegetable fermentations is between 60°F. and 78°F. A temperature at the lower end of that range will ferment more slowly, resulting in more complex flavors and a higher quality product, while vegetable fermentations at higher temperatures will ferment in less time, which results in less complex flavors and increases the chance of spoilage.

The length of time required for fermentation can also vary depending on the type of fermentation. Science-based recipes for common vegetable fermentations establish these approximate time parameters based on the temperatures outlined above:

Sauerkraut	21 days
Kimchi	4 days
Pickles	2 to 4 weeks

Operators should develop an SOP establishing the expected time/temperature combination to achieve fermentation, with options for next steps in the case of a slower fermentation than expected or in the event of spoilage.

Salt plays an important role in fermentations; it is important to follow validated recipes and to measure ingredients carefully. With low amounts of salt, the growth of more fermenting bacteria and faster acid production is favored, but it can result in a softer textured product, off-flavors, and mold growth. With high amounts of salt, it can result in crisper vegetables and reduce the likelihood of mold growth, but it favors the growth of only some fermenting bacteria, resulting in less complex flavor development.

Because acid is not added in these fermentations, the pH will not immediately be at a level to **control** growth. **Hazards** of concern include both pathogenic microorganisms present on the vegetables such as *Salmonella* species and *Escherichia coli (E. coli)*, and environmental contamination that can occur from *Staphylococcus aureus* and *Listeria monocytogenes*. Only

products grown with good food safety practices should be used for vegetable fermentations, in addition to adhering to sanitary practices during production detailed below.

Dairy Fermentations

Fermented dairy products include yogurt, crème fraiche, and kefir. In dairy fermentation, the lactic acid is formed as a by-product of a starter culture. Since pasteurization of the milk is necessary to kill microorganisms that would compete with the starter culture, the **hazards** of concern are pathogens that could come from environmental contamination, both *S. aureus* and *Listeria monocytogenes*. Incubation and growth of the starter culture must take place at temperatures between 90°F. to 110°F., and if the pH does not drop quickly enough, heat-stable *S. aureus* toxin can be produced. Because of this toxin formation **risk**, the pH should drop below 5.3 within 10 hours, and ultimately below 4.2 for safety. Specific time/temperature combinations may vary slightly based on the recipe and the product. The starter culture packaging will provide guidance on specific temperature and time for the fermentation. Maintaining a consistent temperature for the fermentation is very important, so warming in a hot water bath incubator is recommended. The table below outlines several university Extension recommendations for dairy fermentations.

Publication	Product	Temperature	Time
Utah State University Extension, 2010	Kefir	109°F.	18 hours
Colorado State University Extension, 2020	Kefir	65°F. - 85°F.	18-24 hours
Utah State University Extension, 2010	Crème Fraiche	108°F.	Not specified
Washington State University Extension, 2015	Yogurt	108°F. - 112°F.	4-8 hours

The flavor of a product can be manipulated using temperature. For example, when producing yogurt, one type of lactic acid bacteria is favored to grow at a temperature of approximately 111°F., resulting in a milkier and creamier product; a lower temperature around 100°F. favors a different type of lactic acid bacteria growth and results in a more acidic flavor.

In the case of dairy fermentation, additives, ingredients, and starter cultures must be from an **approved** source. Because *E. coli* can be acid tolerant, it is vital that a new commercial starter culture is used for each batch of fermented dairy. Using yogurt that was prepared in a previous batch as the starter culture for a new batch, known as backslopping, could result in *E. coli* growth during fermentation.

Storage of the starter culture can impact the life of the starter culture, and guidance varies depending on the type of starter culture. Any special handling instructions specified by the manufacturer regarding frozen or refrigerated storage and other factors such as preparation of the culture for use should be observed. New starter cultures should be stored separately from older starter cultures.

If the pH drop is not achieved within the required time, that batch must be discarded. It's possible that the temperature is not remaining within the appropriate range. If the temperature is too low or too high, fermenters will not be able to grow, ultimately interfering with the ability to reduce the pH.

Other Fermentation Examples

There are several types of fermented products that have been increasing in popularity recently in the United States. These will be explored in more detail in this section.

Kombucha is a fermented tea beverage made by combining a symbiotic culture of bacteria and yeast (SCOBY) with black tea and sugar. Kombucha is typically fermented at room temperature (68°F. to 72°F). The pH should drop below 4.2 in 7 days, and the final pH is approximately 2.5. If allowed to progress beyond 10 days, acetic acid levels may reach dangerous levels, so the fermentation should be restarted if 10 days is reached and the pH has not dropped below 4.2.

It is possible for the SCOBY to become contaminated by yeasts, bacteria, molds, or pests during the fermentation process. If this occurs, the SCOBY and liquid should be discarded, followed by a thorough cleaning and sanitizing process before the next use. To avoid contamination, good SOPs should be followed and the SCOBY stored in a way to prevent airborne contamination (such as a fine-weave cloth covering the fermentation container).

A major **risk** of kombucha production is that overfermentation can result in alcohol content of 0.5% or higher. When the 0.5% alcohol by volume (ABV) is reached or exceeded, the product is classified as an alcoholic beverage, in which case the product falls under different regulatory jurisdiction. Because of the low threshold for alcohol content permitted in kombucha, a very accurate method for testing the alcohol content is required. Headspace gas chromatography is the recommended method for testing alcohol content in kombucha, in combination with flame ionization detection or mass spectrometry. These measurements must be performed by a third-party laboratory. The regulatory authority may have a specific required method and may require periodic testing by an **approved** laboratory to confirm alcohol content.

Mold Fermentations

Fermentations can also occur by adding molds, such as *Rhizopus* or *Aspergillus*, to foods to achieve a desired flavor and texture. Examples include tempeh, miso, and koji.

Tempeh is a fermented soybean product that is produced through two types of fermentation. Soybeans are soaked and lactic acid fermentation occurs naturally for less than one day, which lowers the pH to less than 4.6, reducing the **risk** of *B. cereus* and *S. aureus* growth. The soybeans are drained, boiled, mashed, and then inoculated with the *Rhizopus* mold. The mixture ferments for 1 to 2 days between 72°F. and 100°F. The mold produces enzymes which create the desired flavor and texture. The mold also releases ammonia, which results in a pH increase.

Unpasteurized tempeh allows pathogens to grow and has been associated in foodborne outbreaks, as *Salmonella* can grow during the tempeh production process and has been linked to the fungal starter culture. Starter culture should be defined by species and a Certificate of Assurance (CoA) provided; this starter culture should be stored at refrigerated temperatures to maintain quality. Recommendations also advise that the soaking and boiling steps be done in acidified water to ensure that the pH stays below 4.6, reducing **risk** of *B. cereus* and *Staph aureus* toxin formation. Knives, cutting boards, and other food contact surfaces must be cleaned and sanitized frequently in addition to adherence to other good SOPs. Pasteurization (cooking to an internal temperature of 176°F.) and refrigeration of the product to be sold within 7 days are other critical **control** steps. If sold unpasteurized, there should be instructions on the package advising the consumer not to eat the product raw and to cook fully before consumption.

Koji is made by fermenting soybeans, rice, or wheat with *Aspergillus*. Koji is then used in other brine-fermented products such as miso and soy sauce. The first fermentation occurs at 85°F. to 100°F. for 48 hours, followed by the addition of salt and a secondary fermentation at room temperature for 7 days.

Control points include:

- Soaking of rice should be done in such a way to avoid the development of toxins by spore-forming *Bacillus cereus* (i.e., under refrigeration).

- Rice should be cooled following requirements of the FDA Food Code:

    - Must cool from 135°F. to 70°F. or below within the first two hours; and

    - Must cool from 70°F. to 41°F. or below within an additional four hours or less; total cooling time must not exceed 6 hours.

- Starter culture should be defined by species and a Certificate of Assurance (CoA) provided. Backslopping should not occur.

- pH and water activity should be obtained for this product.

Fermentation Containers

The container where the fermentation occurs is another important component in the process. The type of container may vary based on the size of the operation, but it must always be food grade. Size should also be considered, because full submersion of the vegetables approximately 1 to 2 inches below the liquid line is important. Materials such as plastic, glass, or ceramic are commonly used. If ceramic is used, the ceramic should not contain lead, a common component in ceramic crocks made before the 1970s, as lead can leach into the food. It is advised to avoid plastics containing phthalate and bisphenol, given the product will be in the container for weeks. The container should be easy to clean, with no scratches, chips, or pits and should be washed in hot soapy water before using. It is important that the equipment used in the fermentation is smooth and easily cleanable, and has been properly cleaned and sanitized before use. Strict cleaning and sanitizing SOPs, along with policies prohibiting bare-hand contact with ready-to-eat food, will reduce **hazards** associated with environmental contamination.

Monitoring pH of acidified foods (direct acidification or fermentation)

If the fermented food is to be considered a non-**TCS** food, the pH of the product must be below 4.2 after fermentation within the allowed fermentation time. A calibrated pH meter with accuracy to ±0.01 must be used to measure the pH of the food as the CCP. Both fermented and canned vegetables must be pureed with distilled or de-ionized water to create a uniform slurry to be tested.

Calibration of the pH meter

A correctly calibrated pH meter is essential to obtaining accurate measurements of pH in your product samples. All standard buffers and product samples for testing should be stabilized at room temperature before testing. It is essential that the pH meter be calibrated on each day of use. For detailed instructions, see "**Calibration of pH Meters and pH testing procedure" on p. 240.**

Test Sample Preparation Instructions

Yogurt and similar products

1. Gently shake jars to disperse product.

2. Empty some product into a small container.

3. Submerge bottom of probe into the product. Be sure that the probe is not touching the bottom of the container and is completely covered by product.

4. Slowly stir pH meter in product until pH is stabilized.

5. After taking the reading, rinse with deionized water into a waste container. Be sure that no clumps of product are caught underneath the plastic guard.

6. Blot with lint-free, soft tissue.

Vegetable products such as kimchi, sauerkraut, hot sauces

1. Mash up or blend vegetable, adding small amounts of deionized water as needed until a thin paste is made. Take pH in container it was mashed/blended in.

2. Submerge bottom of probe into the product probe into the product. Be sure that the probe is not touching the bottom of the container and is completely covered by-product.

3. Slowly stir pH probe in vegetable paste until pH is stabilized.

4. After taking the reading, rinse with deionized water into a waste container. Be sure that no clumps are caught underneath the plastic guard.

5. Blot with lint-free, soft tissue.

Guidelines for Validating Fermentation 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.

- 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.

- Access to processing equipment limited to trained personnel.

- Cleaning and sanitizing procedures for food contact surfaces delineated.

- All produce is inspected for damage, bruises, and other defects before washing and processing.

- All ingredients must be chopped, sliced, or otherwise processed to consistent dimensions to ensure uniform fermentation.

- Acidification must follow a recipe in which ingredients are added in consistent proportions which, once **approved**, may not be changed without obtaining re-approval.

- Procedures for storage and use of starter cultures are provided.

- **Hazard analysis** includes pathogenic growth, particularly *Staphylococcus aureus* and *Listeria monocytogenes,* and *Clostridium botulinum* if fermentation is done in anaerobic environment.

- CCP identified.

- pH less than 4.2 of fermented product is **critical limit.**

- Time allowed for fermentation depends on product, temperature, and other factors that affect rate of pathogenic growth.

Monitoring Procedures Identified pH of Fermented Product

- Each batch measured with a calibrated pH meter
- Procedures for preparing product for testing using blender if necessary
- Person(s) identified for **monitoring** pH

Corrective Actions and Documentation Procedures Identified

If pH of fermented product has not reached 4.2 or lower, possible **corrective actions** include:

- Continue fermentation if within allowed time.
- Discard product if allowed time has passed.

Record on corrective action log; determine reason for failure – may require guidance from processing authority or regulatory authority.

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
- pH meter calibrated before each use

Records Identified pH of fermented product

- pH logs (sample log provided)
- pH meter calibration log (sample log provided)
- **Corrective Action** records

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**
- Record-keeping requirements

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Additional resources and science-based recipes for canning processes can be found at National Center for Home Food Preservation. https://nchfp.uga.edu/how/can_home.html#gsc.tab=0

HACCP Requirements for Sprouting at Retail

Sprouts are defined as the young shoots of plants shortly after they emerge from the germinated seed or bean. Types of sprouts commonly consumed in the United States include alfalfa, broccoli, various beans including mung, kidney, pinto and soy; radish, sunflower, mustard, dill, wheat berries (wheat grass), and red clover. Sprouts differ from microgreens, in that microgreens consist of a whole baby leaf cut from the stem. Sprouts have been associated with many foodborne illness outbreaks in recent years, and for this reason, they are specifically included in the FDA definition of **time/temperature control for safety** food (**TCS** food, formerly known as potentially hazardous food). The sprout consists of a new stem, often with the beginnings of a leaf at the top. Microgreens are not classified as **TCS** food.

Widely considered a health food, sprouts are rich in a number of vitamins and minerals, and are excellent sources of antioxidants, essential amino acids, and fiber. Sprouts are also commonly labeled as functional foods because in addition to basic nutritional value, they may also provide specific benefits to health, and may also reduce **risk** of certain diseases. Sprouts are commonly consumed either raw or only cooked lightly, so destruction of foodborne pathogens during food preparation is not to be relied upon. Despite their potential health benefits, sprouts are considered a high-**risk** food by the U.S. Food and Drug Administration (FDA). Those at higher **risk** of infection, such as children, the elderly, pregnant women, and persons undergoing medical treatments that compromise the immune system, are advised to avoid consuming raw or lightly cooked sprouts.

Within the U.S. alone, 58 foodborne illness outbreaks were traced to consumption of raw or lightly cooked sprouts between 1998 and 2018, with over 1,900 reported illnesses. As with all foodborne outbreaks, mild cases of illness often are undiagnosed, so there could potentially be many more illnesses that went unreported. Internationally, some of the most noteworthy outbreaks associated with consumption of sprouts include:

- *E. coli* O104:H4, from May through July 2011: 4,075 illnesses and 44 deaths reported in Germany, traced to bean sprouts
- *Salmonella*, from October through December 2005: 648 illnesses in Ontario province, Canada, associated with mung bean sprouts
- *Listeria monocytogenes*, in March 2008: 20 illnesses reported in a multi-state U.S. outbreak, associated with unspecified sprouts

Pathogens of concern and their sources

The pathogens of concern related to sprouts are pathogenic *E. coli* (Enterohemorrhagic *E. coli*, or EHEC, including serotypes O157, O104, O121, O26, and three others); *Salmonella* species, *Listeria monocytogenes,* and the toxin- and spore-forming *Bacillus cereus.* The conditions under which seeds are germinated to produce the sprouts are by far the leading contributor to the food safety **risk**; rarely have processing sanitation or worker hygienic practices in an establishment been identified as contributing to a foodborne outbreak traced to sprouts. Contaminated seed is the most likely source of pathogen contamination. Some types of seeds have a rough surface texture that provides niches where bacteria hide and attach easily, and are able to grow under favorable conditions. Seeds are often harvested from crops not grown for production of seed for sprouting.

These seeds commonly become contaminated as the parent plant is growing, acquiring contamination from sources such as wild animals, manure, or contaminated compost, irrigation water, or unsanitary harvesting practices or equipment. Post-harvest contamination can result from farm vehicles, transportation containers, processing equipment, pests, or workers. Pathogen contamination levels on the seeds are typically low. However, the warm, moist, nutrient-rich conditions under which the seeds are sprouted, pH, and nutrients present from the seeds provide ideal conditions for explosive growth of pathogens such as *Salmonella* or *E. coli*. Additionally, biofilms formed on the sprouts during germination provide cover for pathogen cells, making their removal during frequent irrigation or by disinfection unlikely. As the pathogen population multiplies in the growing chamber, bacterial cells can be taken up through the root systems into certain types of sprouts, making their removal by disinfection impossible.

Critical controls

Given the nature of the sprouts and the high levels of bacteria present after sprouting is completed, the National Advisory Council on Microbiological Criteria for Foods (NACMCF) has recommended disinfection of the seed before sprouting to provide 5-log (100,000 + counts) pathogen population reduction for food safety. Compared with sprouts, seeds tolerate the disinfection treatment better, and there is less organic residue or biofilm that would reduce the effectiveness of the disinfection treatment. Disinfection methods **approved** for use by seed producers include irradiation as specified in 21 CFR Part 179.26(b)(10), and treatment with 20,000 ppm calcium hypochlorite. The U.S. Environmental Protection Agency (EPA) must approve chemical disinfection methods for seeds; currently, only calcium hypochlorite is **approved** for this purpose. A ratio of 4.1 ounces of calcium hypochlorite granules to 1 gallon of warm water is used to prepare the disinfection solution. (*Do not add water to calcium hypochlorite!*) Disinfection solution is poured over the seed after soaking the seed in potable water as described below. After 20 minutes of disinfection, the seed is rinsed thoroughly before being placed into the sprouting tank or chamber.

NOTE: OSHA requires the use of personal protective equipment (respirators, gloves) and adequate ventilation when handling calcium hypochlorite.

HACCP critical **controls** include:

- Retail establishments may purchase seed for sprouting from a reputable supplier that has applied a disinfection process validated to achieve a 5-log reduction in pathogen population. Each seed lot should be accompanied by a supplier certification specifying the disinfection method used, and that the disinfection method used for the purchased lot meets these criteria.

- Retail establishments may choose to use untreated seed as received from the supplier, and perform the recommended calcium hypochlorite pretreatment in-house.

- Testing of irrigation water 1 to 2 days before harvesting.

- Sprouts are rinsed upon harvesting with cold, chlorinated potable water, and then chilled to 41^{o}F. or below within four hours of harvesting.

- If seed is not disinfected before sprouting, it is recommended that sprouts be fully cooked before serving and consumption. If packaged for retail sale, safe handling instructions must include requirements to keep refrigerated and to cook thoroughly before consuming.

Additional preventive control measures:

- All purchased seed should be received with all relevant traceback information. Retail establishment should maintain records of sprouting batches by seed lot number for traceability, without comingling of seed lots.

- All bags or containers of seeds should be inspected visually for water damage, mold, tears, rodent damage, etc. Black lights (shortwave ultraviolet) are used to detect rodent evidence (urine stains).

- Seeds must be protected from rodents, insects, and filth while in storage.

- Before disinfection, it is recommended that seed be soaked in potable water for 2 to 4 hours at 90°F.-95°F. (32°C.-35°C.), or overnight at 68°F.-72°F. (20°C.-22°C.). This soaking step softens the seed hull, allowing more effective penetration by the disinfection solution.

- Irrigation and rinsing water must be of potable quality. If the water is from a source other than a public water system, the water must be treated in a manner that meets public water standards.

- After disinfection and regularly throughout the germination process, the seeds should be drained, rinsed, and irrigated regularly with cool, chlorinated water to reduce bacterial load and buildup of germination waste. Germination takes an average of 4 to 7 days, but can vary between 2 and 14 days. Regular irrigation also keeps the sprouts from overheating.

HACCP Plan and Regulatory Requirements (Variance)

The FDA Food Code, Subparagraph 3-502.11(H) requires that when sprouts are produced in a retail **food establishment** for direct sales or service to consumers, the **food establishment** must obtain a **variance** from the regulatory authority based on an **approved HACCP plan**. The **HACCP plan** must provide specific **controls** to ensure the safety of the sprouts for consumption. Paragraph 8-201.14 of the 2022 Food Code requires the following elements to be included in the **HACCP plan**:

- List the types of sprouts the **food establishment** will produce.

- Provide a flow diagram or chart reflecting the steps of the production process, from receiving of seed to sale or service of the sprouts, listing the **critical control points** (CCPs) and **critical limits**, **control measures**, the methods and frequencies for **monitoring** the CCPs, management **verification** procedures, **corrective actions** to be taken in the event that a **critical limit** is not met, and identifying the records to be maintained to document compliance with the **HACCP plan**.

- Management and food worker training on safe sprouting practices and food safety issues of concern must be provided and documented.

- Identifying the treatment methods used to achieve reduction of pathogen load in the seeds, and showing how the irrigation water from each batch is to be tested. Flushing and replacing irrigation water every 1 to 2 days reduces the bacterial load present during germination. Spent irrigation water testing for *E. coli* O157:H7 and *Salmonella* one to two days before harvest provides essential information on the pathogen load in the batch. Since sprouts are classified as **TCS** ready-to-eat food, there is zero tolerance for these pathogens in the finished product.

Sprouts are classified by the FDA Food Code as **time/temperature control for safety** (**TCS**) food. As ready-to-eat **TCS** food, refrigeration (¶ 3-501.16) and date marking with a shelf life of 7 days or less (¶ 3-501.17) for safety are required. Subparagraph 3-301.11(B) requires that **food establishments** prohibit bare-hands contact with ready-to-eat **TCS** food. Employee health and hygiene practices are essential **preventive measures** to prevent cross contamination of the sprouts by potentially infected food workers. Rigorous cleaning and sanitizing of the growing chamber and processing equipment is equally essential in preventing environmental contaminants such as *Listeria monocytogenes* from being accidentally introduced into the sprouts.

Observations During Inspection

Sprouting at retail typically takes place in buckets, bins, or beds. The presence of bulk sprouts in coolers or refrigerators, or consumer-portioned packages for sale, may indicate production of sprouts in a retail establishment. The presence of menu items with sprouts as ingredients may also indicate sprout production in a retail establishment – especially in establishments specializing in health foods or advertising "house-grown" or "locally sourced" sprouts.

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HACCP Requirements for Bottling Juices at Retail

The FDA Food Code requires fresh fruit or vegetable juices that are packaged at retail to be processed under a **HACCP plan** with a 5-log reduction in pathogens of concern. Unpasteurized juices packaged at retail must bear a warning statement as specified in the FDA 2022 Model Food Code, Subparagraph 3-404.11(B) and in 21 CFR Section 101.17(g). That statement: "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," must appear on the container of unpasteurized juice itself. **Food establishments** that serve a highly susceptible population (e.g., assisted living facilities, child/adult care facilities, hospitals/nursing homes, senior centers, etc.) cannot serve prepackaged juice that bears the warning label; only pasteurized juice may be served. For juice only, this population includes children age 9 or younger who receive food in a school, daycare setting, or similar facility providing custodial care.

Observations During Inspection

The following are indications that a retail establishment may be packaging juices:

- Easy access to large volumes of fruit of vegetable (e.g., orchard on-site) with a retail sales area
- House-brand packaged juice or cider
- Signs present for "Custom Processing" of juice or cider
- Bottled house-branded juices or smoothie mixes displayed in a merchandising unit

Any of these observations should lead inspectors to ask questions to determine whether the establishment is packaging juices requiring process approval.

Definitions

5-log reduction performance standard – Process treatment of juice (or citrus fruit if using surface treatments) that will achieve at least a 100,000-fold decrease in the number of microorganisms. Juice processors must apply **controls** (e.g., heat or other validated processing methods) to achieve the 5-log reduction required by the regulation.

Approved source – A source that is acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health. Acceptable standards include Good Agricultural Practices (GAP), Current Good Manufacturing Practices (21 CFR Part 117), and the FSMA Produce Safety Regulation (21 CFR Part 112). Compliance with these and other relevant standards is required to provide control not only of biological hazards, but also of chemical hazards, such as agricultural chemicals and other chemical contaminants such as arsenic.

Fresh, untreated juice product - A juice product that has not been processed to prevent, reduce, or eliminate hazards.

Food hazard – Any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its **control**.

Identifiable (approved) source - Can include the name and address of the immediate supplier and the actual source or location of the supplies.

Juice - Refers to both beverages that are composed exclusively of an aqueous liquid or liquids extracted from one or more fruits or vegetables, and to the juice ingredient in those beverages that contain other ingredients in addition to juice. "Juice" does not include, for purposes of HACCP, liquids, purees, or concentrates that are not used as beverages or ingredients of beverages.

Pasteurization - The process or treatment (usually heat) applied to reduce the most resistant microorganism of public health significance to a level not likely to present a public health risk in the food.

Patulin - A mycotoxin that is produced by certain types of molds (*Penicillium, Aspergillus*, and *Byssochylamys)* that may grow on apples and pears.

Sanitation Standard Operating Procedures (SSOPs) - The cross-contamination **control** strategies and sanitation practices for an operation. SSOPs state how things will be cleaned, how often, with what cleaning agents and sanitizers and at what concentration. This includes all surfaces (tables, cutting boards), as well as all pieces of equipment and utensils required for making the product.

Time and Temperature Control for Safety (TCS) food - Food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. By regulatory definition, **TCS** foods include 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.

Potential Hazards

Biological Hazards

E. coli O157:H7 and other Shiga-toxin producing *E. coli* (STECs) can be found on incoming produce. If not eliminated prior to the preparation step, and if growth is not prevented by holding products that support growth at proper temperatures, these bacteria may cause serious illness. Acid-tolerant strains of this pathogen have been associated with outbreaks of illness related to fruit juices. *E. coli* O157:H7 and other Shiga-toxin producing *E. coli* (STECs) have also been associated with certain fruit and vegetable products. Apple cider **controls** include the use of produce from identifiable, **approved** sources and washing apples with potable water and/or **approved** food grade sanitizer.

Salmonella species can be found on incoming produce. If not eliminated prior to the preparation step, and if growth is not prevented by holding products that support growth at proper temperatures, may cause serious illness. *Salmonella* contamination has been reported in numerous types of vegetables as well as in acidic fruits, such as peaches. Orange juice **controls** include the use of produce from identifiable, **approved** sources and washing the oranges with potable water and/or **approved** food grade sanitizer.

Clostridium botulinum may be a rare occurrence but has been found in homemade carrot juice. Vegetable products such as used in smoothie mixes, cocktail mixers, etc. (carrots, kale, tomatoes, and others), which have low acidity (pH values above 4.6) are at greater **risk** for growth and formation of botulism toxin. **Control** is maintained through strict temperature **control** of 41°F. (5°C.) or below to **control** growth.

Listeria monocytogenes is a pathogen that may be found both in the growing environment of fruits and vegetables, and in processing facilities and retail **food establishment** kitchens. Failures in sanitation at any level of harvesting, packaging, transportation, or processing, including at the retail level, may result in contamination of finished products. Refrigeration alone is not sufficient to **control** growth of *Listeria*, and for this reason, date marking of finished products is required. In pasteurized acidic or acidified juices, date marks may exceed 7 days shelf life, but **product assessment** should be used to determine allowable shelf life. Low-acid juices (having pH greater than 4.6 – such as virtually all vegetable juices) must either be acidified according to regulatory authority requirements and held under refrigeration, or must be date marked with shelf life not exceeding 7 days.

Viruses such as Norovirus and Hepatitis A do not occur as environmental contaminants, but instead are traced to an ill individual, such as a farmworker or food handler. Thus, contamination of juice by viruses is not likely to occur in a processing facility that **controls** employee health and hygiene

conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces.

Cryptosporidium parvum and *Giardia lamblia* are parasites which can be found on contaminated produce or in contaminated water and could infect consumers. For all produce, **control** may be maintained through purchase agreements with producers that confirm compliance with FSMA Produce Rule or GAP principles and guidelines (**approved** suppliers). Produce should be cleaned, sanitized, and sorted to remove defects that could harbor contamination. Potable water should be used for cleaning, washing, and/or sanitizing.

Chemical Hazards

Patulin is a mycotoxin (mold) that is produced by fungi commonly found on apples. High levels of patulin can be produced in rotting or moldy apples and pose a health **hazard**. If fallen fruit; moldy, rotten, bruised, or damaged apples; or improperly stored apples are used to make juice, high levels of patulin may occur in the juice, including pasteurized juice, because thermal processing does not destroy patulin. More information on patulin is available from FDA.[40]

Processing Operations

Receiving

All products, including fruits, vegetables, and other juice components (e.g., health food supplements, wheat germ), are to be obtained from identifiable, **approved** sources. If juice components are provided from a source outside the fresh juice operations, this source must be **approved**, identifiable, and must be able to provide processing records that demonstrate compliance with Good Manufacturing Practices, GAP/FSMA Produce Rule and/or HACCP programs as recommended in the FDA guidelines for fresh juice operations.[41] The information and prior agreements of suppliers with the fresh juice operation provide controls to prevent potential problems due to safety concerns associated with these products. Obtaining signed grower/supplier agreements or Letters of Guaranty can assure the retail processor that the fruits or vegetables used to make juice products are grown and harvested in a safe and acceptable manner. All **TCS** food components are to be delivered at appropriate temperatures.

Each processor must be aware of the specific requirements for the types of products they will be receiving. The retail establishment should actively manage a program for routine inspection of incoming products for **approved** sources, product condition and temperature as necessary, integrity of packaging and proper label information, and document product acceptance or rejection with dates, times, and the initials or name of the receiving individual, plus any necessary comments. All employees, including workers involved in loading and unloading of food products before and after transport, should adhere to strict personal hygiene practices.

[40] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first#:~:text=Exposure%20over%20time%20to%20high,reconstituted%20single%20strength%20app

[41] www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first

Food Storage

Storage includes temperature **control** units used to hold **TCS** foods. These foods can include raw ingredients and/or finished juice products. These types of foods can be stored in separate units or segregated with protection in the same unit. Display counters are not considered storage units and should not be used to store raw ingredients. Foodborne pathogens may be introduced or allowed to grow and multiply in or on food items during storage or while in transit. Produce should be protected from potential contamination by microorganisms, insects, chemicals, rodents, waste products, toxic material, unclean equipment, unnecessary handling, or other agents of public health significance at all times.

The following guidelines for storage of produce intended for juice products should be observed:

- Maintain storage area in clean and sanitary manner.
- Bottles, caps and packaging materials should be stored in a clean, dry, pest-free area. Ensure that storage areas are free of insects and rodents and constructed to prevent the entrance and harborage of insects and rodents.
- Refrigeration unit(s) operate in a manner that ensures **TCS** food can be maintained at the appropriate temperature for the particular product.
- When storage conditions allow for product internal temperature above 41°F. (5°C.) (or other pre-determined temperature limit) are detected, an evaluation is conducted of all **TCS** foods stored in the unit. The evaluations will document the actual temperature of the products and duration of exposure. **Corrective action** is taken and documented and any suspect product is discarded.
- The storage unit(s) is clean and orderly.
- Products are contained and/or covered for protection.
- Products are marked for identity and duration in storage (dated), as appropriate.
- Packaged products, ready-for-display, are segregated from products that require further handling or processing.
- Products are not being stacked without adequate support and prevention of any leakage between products.
- Drippage into or onto packaged products due to condensation, cooler pan leaks, or other wet sources is prevented.
- Products are stored above the floor (approx. 6 inches) and away from walls and the ceiling. The schedule for product rotation should use a first-in, first-out (FIFO) rule.

Preparation

Washing whole fruits or vegetables to be juiced is one of the most important processing steps. Almost all products can be washed under cold running potable water. This washing is designed to remove soil and any debris that may be present on the produce, and it improves not only the safety and quality, but also the product shelf life.

Once they are washed, fruit and vegetables are selected, rejecting those that might alter the quality of the final product. This includes any produce that is unclean or containing blemishes, bruising, or damage.

The preparation work area, facilities, and utensils should be designated and/or dedicated to the fresh juice operations. If it is necessary to share work space and facilities, segregate from other processing activities, have a defined schedule of operations, and clean and sanitize work area between operations to prevent potential cross contamination of the fresh juice products. All food contact equipment shall be easily cleanable and stored under sanitary conditions to prevent contamination. All equipment and food contact surfaces shall be maintained in clean and sanitary condition.

Food safety practices that are critical to safely preparing raw juices include the implementation and maintenance of a Sanitation Standard Operating Procedure (SSOP) that emphasizes:

- Pathogen reduction of microbes that an establishment identifies as microorganisms of concern through cleaning or pasteurization
- Prevention of cross contamination
- Temperature **control** throughout the flow of service
- Employee hygiene program
- Purchasing from an **approved** source
- Avoiding premixing different types of juices, but rather mix on order

HACCP Plan and Regulatory Requirements

Thermal Processing Conditions

Pasteurization is one of the most efficient and reliable ways to obtain a 5-log reduction for perishable beverages that include fruit and vegetable juices. The time and temperature pasteurization process used must be a validated process from a process authority (such as 160^{o}F. for 6 seconds for apple juice or 160^{o}F. for 6 seconds for orange juice). Additional processes for apple juice at pH values of 4.0 or less include:

- 165°F. for 2.8 seconds,
- 170°F. for 1.3 seconds,
- 175°F. for 0.6 seconds,
- 180°F. for 0.3 seconds

Thermal process recommendations for other products should be obtained from an FDA-recognized Process Authority. In lieu of treating or pasteurizing juice under a **HACCP plan**, a retail establishment offering packaged on-site juice has the option of placing a consumer warning on the label. That warning should state:

“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.”

There are special requirements for establishments that serve high-**risk** populations. These include:

- Juices that bear the warning label and have not been processed per ¶ 3-404.11 to reduce or eliminate pathogens may not be served or sold.

- Unpackaged juices prepared on premise for sale or service in ready-to-eat form shall be processed under a **HACCP Plan** as specified under Subparagraph 8-201.14 (B-E).

Using Alternate Processing Methods to Achieve 5-Log Pathogen Reduction

Pasteurization of juices with ultraviolet irradiation (UV) is a potential alternative to thermal pasteurization. Ultraviolet irradiation can be successfully applied to reduce the microbial load in different fruit juices and nectars. A clear juice such as apple juice needs a lower UV dose to achieve effective microbial reduction, whereas orange juice, which contains a greater amount of suspended matter such as cells and fiber, needs higher UV dosage levels to achieve the microbial reductions needed. This type of treatment is effective in inactivating microorganisms without producing undesirable by-products and changing sensory properties. If a retailer chooses to utilize ultraviolet irradiation for nonthermal treatment of juices, approval from a **processing authority** will be required to do so. According to the FDA Small Entity Compliance Guidance: Juice HACCP,[42] all juices may be processed using ultraviolet light instead of thermal pasteurization, but will require alternate labeling indicating that the juice has been treated with UV light to **control** pathogens. Products treated with UV light rather than thermal pasteurization may not be labeled as "pasteurized" or as "fresh."

Surface disinfection of citrus fruits may be achieved using a series of surface sanitization treatments and an extraction process that limits juice/peel contact as provided for under 21 CFR 120.24 (b). These treatments must consistently achieve at least 5-log reduction in the "pertinent microorganism" – e.g., *E. coli* O157:H7. Multiple processing steps, such as a series of surface sanitization treatments for citrus fruit, may be used to achieve the 5-log reduction. However, under 21 CFR 120.24 (b) and (c), all of the processing steps you perform to meet the 5-log pathogen reduction requirement must be carried out in a single production facility. Treatments with boiling water and with certain chemical applications have been found effective. Use of a surface disinfection method prescribed and validated by a recognized **processing authority** is required.

Process Controls – Bottling Cold-Pressed Juice

In the absence of pasteurization, juices bottled at retail pose a greater **risk** to the consumer. Processing and bottling of cold-pressed juices at retail has become a trend in recent years. Because of that trend, it is essential to use process **controls** to manage the **risk**. The following guidelines are for all squeezed and cold-pressed juices, smoothie mixes, and fruit and/or vegetable-based cocktail mixers bottled for retail (direct-to-consumer) sales.

1. All produce should be sourced from **approved** suppliers, as documented by annual Letters of Guaranty or purchase specifications stipulating compliance with good agricultural practices (GAPs) or the Produce Safety Rule, including harvesting and irrigation practices.

[42] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-juice-haccp

2. All produce must be inspected for damage, bruises, rot, and must be as fresh as possible to minimize **risk** of harborage of pathogens.

3. Use of an antimicrobial produce wash prior to processing is helpful to reduce the potential for pathogens as well as spoilage bacteria in the final products. Except as described above for surface disinfection of citrus fruits, antimicrobial washing is not **approved** to replace pasteurization as the preventive **control** method for achieving the required 5-log reduction of pathogens in other fruits.

4. Juices which contain ingredients classified by the Food Code as **TCS** foods (cut melons, cut leafy greens, cut tomatoes) and in which pH is not **controlled** to below 4.2 must be refrigerated at or below 41°F. and must be consumed or discarded within 7 days, *including the day of production*.

5. All juices not covered under #4 also should be refrigerated at or below 41°F. and consumed or discarded within 7 days, including the day of production, to prevent potential growth of any acid-tolerant pathogens and spoilage organisms.

6. The consumer label on each product bottle must include the following information:

    - "Keep refrigerated."

    - "Consume or discard by (*mm/dd/yy*)" – this date is to not exceed 7 days *including the day of production*.

    - As required by the FDA Food Code, Subparagraph 3-404.11(B), the following consumer advisory: "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."

7. General requirements for label content from Food Code Paragraphs 3-601.12 and 3-602.11 include:

    - Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.

    - The common name of the food or, absent a common name, an adequately descriptive identity statement;

    - The name and place of business of the manufacturer, packer, or distributor; and

    - The name of the food source for each major food allergen contained in the food or a disclaimer that any major food allergen may be contained in the food.

8. Despite the numerous popular claims, no health claims are allowed. See the following FDA resources for guidance regarding health, nutritional, and structural/functional claims:

    - Label Claims for Conventional Foods and Dietary Supplements, FDA 3/7/22, https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements#:~:text=Among%20the%20claims%20that%20can,%2C%20and%20structure%2Ffunction%20claims.

- Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages, FDA 9/16/2018, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-distinguishing-liquid-dietary-supplements-beverages

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Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, 1st Edition, U.S. FDA, March 2004, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first

Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices, U.S. FDA, June 2007, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-refrigerated-carrot-juice-and-other-refrigerated-low-acid-juices

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Small Entity Compliance Guide: Juice HACCP, U.S. FDA, last update April 2003, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-juice-haccp

HACCP Requirements for Custom Processing

Custom processing at retail provides hunters, farmers/ranchers, and others the opportunity to have their animals/carcasses processed to their specifications. The primary concern (**hazards**) regarding custom processing of **meat** for personal use is that the animals may be carriers of bacteria, parasites, and viruses that can cause serious, sometimes fatal illness in humans. Custom processors must be aware that cross contamination of products can occur, and they must take appropriate measures to protect inspected **meats** intended for retail sale.

In-Facility Observations
The following are examples of observations in a retail facility that should prompt inspectors to ask questions to determine whether the facility is engaging in custom processing:

1. Signs outside or inside advertising “custom slaughter” or “custom processing and packaging.”

2. Hanging animal carcasses, sides, or quarters – particularly if the sizes or shapes are unfamiliar.

3. Stored packages of fresh or frozen meat labeled “not for sale.”

4. Heads, feet, hides and/or other nonedible animal parts in various buckets or barrels in a cooler or freezer; possibly labeled as “offal,” “condemned,” etc.

5. Tools associated with slaughter observed inside or outside the back of the facility.

Custom slaughter/custom processing: The Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) require all **meat** and **poultry** products intended for sale to be slaughtered and processed in a facility operating under inspection by the United States Department

of Agriculture's Food Safety and Inspection Service (USDA/FSIS). The FMIA and PPIA do not apply in cases where a personal exemption exists. When an individual raises, prepares, and transports an animal, he or she can slaughter and process the animal without an inspection so long as the **meat** and resulting **meat** products are used exclusively by him or her, the members of his or her household, and his or her non-paying guests and employees.

Custom exempt slaughter/custom exempt processing: A retail custom processing provider is exempt from requirements of the FMIA when he or she slaughters and/or processes a **meat** product for the personal use of an individual. The animal must be owned by that individual prior to slaughter. The carcasses, parts, **meat,** and **meat** products of the animal must be used exclusively by the individual owner and members of the owner's household, non-paying guests, and employees. The retail service provider does not act as the purchasing agent of the live animal and does not sell the **meat**. That retail service provider is merely providing a service for hire.

Under the PPIA, there is an exemption for firms processing 20,000 head of **poultry** per year. However, this does not mean the **poultry** products may be sold without inspection. A federal, state, or local agency will be responsible for inspection. In these cases, jurisdiction typically passes to the state or local jurisdiction. In most jurisdictions, the non-**meat** inspection program at state or local level assumes responsibility for the safety of all human foods that are exempt from federal or state **meat** inspection programs. Federal and state **meat** inspection programs are confined to amenable species only. Any other **meat** product (non-amenable species) is inspected by other food safety programs.

Examples of amenable species:

Meats subject to inspection under the FMIA include products prepared from domesticated food animals: cattle, sheep, swine, goats, horses, mules, and other equine species. **Poultry** products subject to inspection under the PPIA are produced from domesticated chickens, turkeys, ducks, guineas, geese, ratites (flightless birds), and squabs (young pigeons). In October, 2021 USDA added a number of exotic species[43] that may be processed under voluntary inspection.

Non-amenable species:

"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, as **poultry** in 9 CFR 381, or as **fish** as defined under Subpart 1 -201.10(B) of the Food and Drug Administration 2022 Food Code. Examples of game animals include mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

Captive game food animals include bison, white-tailed deer, and other normally wild-type animals that are produced in captivity for slaughter and consumption. Likewise, captive game birds are also produced in captivity for slaughter and consumption. They include farm-raised game birds such as pheasants, quail, wild turkeys, waterfowl, and exotic birds. Ratites such as ostrich, emu, and rhea are not considered game birds.

Examples of wild game animals include antelope, bear, bison, boars, elk, moose, rabbit, racoon, squirrel, pheasants, quail, wild deer, and wild birds such as pheasants, quail, and turkey.

[43] www.fsis.usda.gov/policy/fsis-notice/46-21

Hazards Associated with Custom Processing Wild Game

The primary concern regarding custom processing of **meat** for personal use is that the animals may be carriers of bacteria, parasites, and viruses that can cause serious and sometimes fatal illness in humans. These pathogens may be acquired from the natural foraging habits and areas frequented by these animals. Poor sanitation practices by hunters and/or processors can result in contamination with certain pathogens, as well. The following table summarizes major **hazards** of concern with their sources.

Pathogen	Type	Hazard	Animal Types Affected	Sources
Salmonella spp.	Bacteria	Biological	Mammals, birds	Fecal; unsanitary handling
E. coli O157:H7/STEC	Bacteria	Biological	Warm-blooded animals	Fecal; unsanitary handling
Yersinia pestis	Bacteria	Biological	Carnivorous mammals	Consumption of infected prey
Listeria monocytogenes	Bacteria	Biological	Cattle, sheep, goats, deer, birds	Environmental; contaminated feed
Campylobacter spp.	Bacteria	Biological	Cattle, sheep, goats, birds	Fecal; unsanitary handling
Brucella abortus	Bacteria	Biological	Ruminants, wild pigs/ boars, bison, elk	Animal waste; contaminated feed
Trichinella spiralis	Parasite	Biological	Wild pigs, boars, bears, seals	Consumption of infected meat or garbage
Bullets/fragments	Foreign object	Physical	Game animals	Hunting activity

Healthy wild game can easily be contaminated during the kill, depending on the location of the wound. Wild game may also be contaminated during the field dressing process. Damage to the intestinal tract can lead to fecal contamination of the **meat**. The knowledge and skill of the hunter are key factors in preventing fecal contamination of the **meat**.

Temperature is an important issue in the processing of wild game. Often, it may be hours before the hunter can deliver the carcass to the processing facility to be put into refrigeration. Processors may be inundated with wild game carcasses during hunting season, which may further delay refrigeration or even result in inadequate refrigeration. This overflow of carcasses can also give way to cross contamination, in the event that several kills are waiting to be processed and are kept in the same unrefrigerated area.

In some areas of the country, a custom processing facility may operate only during the hunting season. These seasonal facilities may lack potable water, electricity, sewage disposal, enclosure, and refrigeration. There may also be little organization to the process, which can lead to cross contamination and pest **control** issues.

Cross contamination is always a concern when processing **meat**. The custom processing of wild game in a retail **food establishment** puts the inspected **meat** and other foods at even greater **risk** for contamination. The safety of donated **meat**, or even the sale of wild game that is not inspected, should be suspect. Hunters' organizations often promote the donation of wild game **meat** to the needy. Although the intentions of donating this **meat** are good, the populations receiving the donated, uninspected **meat** may be the most susceptible to foodborne illness.

When state or local law allows field-dressed wild game to be donated, the carcass must receive a post-mortem inspection by an **approved** veterinarian, wildlife biologist, or other individual knowledgeable about wild game diseases. Field dressing, transportation, and processing guidelines developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program (e.g., DNR and Public Health) should be followed. In practice, these guidelines should be developed and delivered to the hunters or hunters' organizations before hunting season begins.

Recommended Control Measures to Ensure the Safety of Custom Processed Meat for Personal Use

Receiving: Each carcass received must contain the following information, and the custom process operator should maintain a log of the following information:

- Name and address of the owner
- Species
- Date received
- Dressed weight
- Assigned designated carcass number on the tag (traceable to the above record)
- Records must be kept onsite for two years after December 31 of the year in which the record was made. All carcasses *intended for donation* must have a documented record of post-mortem inspection, which must also be maintained for at two years.

Processing: Retail **food establishments** intending to custom process **meats** must have an **approved HACCP plan** and obtain a **variance** from the regulatory authority, as required under Subparagraph 3-502.11(F) of the FDA Food Code. The **HACCP plan** and **variance** are required to ensure that the animals intended for personal use do not inadvertently enter the retail food supply, as these animals are considered an **unapproved** food source. All equipment, utensils, refrigeration units, etc. used for both inspected and uninspected **meats** must be completely cleaned and sanitized between uses. Inspected and uninspected **meats** must be kept completely separate, both in storage and in processing. This includes carcasses and final **meat** products. Custom processed **meat** products must be marked/tagged with the words "Not for Sale." The carcass number relating to the owner of the product should also be included.

Wild game species that are legally hunted may be custom processed for personal use only, and may not be sold. However, wild game species such as bison, elk, deer, pheasant, etc., that are commercially farm raised under appropriate regulations generally may be sold. Paragraph 3-201.17 of the 2022 FDA Model Food Code allows products processed under voluntary inspection to be classified as from an **approved** source.

HACCP Plan, Regulatory Requirements (Variance) and Field Verification

- "Not for Sale" tag/label with corresponding record number from the original tag/label provided for shelves or containers holding custom processed meats or meat products
- Separate storage areas in cold storage units for custom processed meat products

- Records (carcass tags identified, written list, receiving log, and times when animals were processed)

- Program (procedures and policies) to protect custom processed product from contamination – biological, chemical, and physical – as well as to maintain separation between custom processed products and retail products during processing and storage (sanitation and cross-contamination **control** procedures)

Example scenario:

Custom processing requires a **HACCP plan** and **variance** under Subparagraph 3-502.11(F) of the FDA Food Code. In this example, the facility in question has requested to be permitted as a retail processor of cured and smoked hams, and smoked turkeys, as well as custom processor of game animals. Curing and smoking hams requires a **HACCP plan** and **variance** under Subparagraph 3-502.11 (A and B). Smoking turkeys may also require a **HACCP plan** and **variance** under Subparagraph 3-502.11(A) if the intent of smoking is for **preservation**. There are 11 employees. The owner wants to equip a separate room in the same facility for custom processing amenable and non-amenable species. Numerous questions and concerns relating to curing and custom processing must be addressed in the **HACCP plan** content, as relevant, for approval of the required retail **variance**. The items in **bold text** are more immediate questions to determine the best initial guidance. All relevant concerns must be covered in the **HACCP plan** or in the supporting procedures requested below.

1. For the proposed retail operation, do the written sanitation plan/procedures and schedule adequately define how cross contamination will be prevented through facility sanitation, processing, and storage practices?

2. **How will the sanitation procedures ensure no cross contamination from the custom processing area into the retail processing area? This plan must address both sanitation and separation procedures.**

3. Are the custom processing facility construction and design adequate for this application?

4. Will there be designated employees assigned to work only in either a custom processing area or the retail processing area? If not, what mandatory controls will be in place to prevent employee-transported cross contamination into the retail space?

5. What will be the labeling requirements for the custom processed game animals? Will the final package be labeled “Not for Sale”?

6. What records will be maintained, and for how long must those records be maintained?

Regarding production of smoked hams and smoked turkeys for retail:

1. Identify source or sources for the hams and turkeys, or provide a supplier approval policy/procedure.

2. How will stored raw game for custom processing be separated from raw pork and turkeys for retail, and from finished retail food products?

3. Describe the preparation process (separately) for the hams and the turkeys. Specifically,

- Will retail processing and custom processing occur at the same time in different rooms, or will the two processes be separated by time (such as production scheduling) and sanitation?

- **Will the hams be cured or uncured?**

- **Will the hams be considered shelf stable or non-shelf stable?**

- If dry-cured, how will the hams be aged to achieve the minimum 18% weight loss required by USDA?

- **Will the hams and turkeys be considered ready-to-eat as sold to the customer? Or will final cooking be required by the consumer?**

- **If shared equipment will be used to process both custom processed product and retail product, such as for cooking, how will production scheduling and sanitation be used to maintain the required separation?**

- Will the hams and turkeys be sold intact, or sliced?

- How will the finished products be packaged? Vacuum packaged?

4. How will the finished products be displayed or held for sale, or distributed/delivered to customers?

5. What will be the labeling requirements for the retail hams and turkeys?

6. **What shelf life is proposed for the finished retail products?**

7. Does the facility have the following prerequisite programs written to support the HACCP **plan**?

    - Employee health and hygiene policies
    - Thermometer calibration procedure
    - Food worker training plan
    - HACCP plan maintenance policy

References:

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Connecticut Department of Agriculture. Farmers Guide to the Rules of Processing and Selling Meat and Poultry in Connecticut. Available as of January 22, 2022, https://portal.ct.gov/-/media/DOAG/Marketing_files/2016/FarmersGuidetotherulesofProcessingandSellingMeatorPoultryinConnecticut2016.pdf?la=en

Rounds J.M. Rigdon, L.J. Muhl, et al. Non-0157 Shiga toxin producing Escherichia coli Associated With Venison. *Emerging Infectious Diseases*, Vol. 18, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3310449/ as of January 22, 2022.

Cornell University. Guide to Direct Marketing Livestock and Poultry, https://smallfarms.cornell.edu/wp-content/uploads/2020/05/Marketing-Livestock-Guide-2020.pdf as of January 22, 2022.

FSIS Guideline to Assist with the Donation of Eligible Meat & Poultry Products to Non-Profit Organizations, as of September 26, 2022, https://www.fsis.usda.gov/sites/default/files/media_file/2021-01/FSIS-Guideline-Food-Donation.pdf

Other Processing Methods Requiring a Variance

At times, retail food operators may want to use methods to produce food that are not typically used in retail **food establishments**. Additionally, ethnic types of foods may be produced which are unfamiliar to the regulatory authority that oversees the retail operation. These techniques often require specialized equipment, ingredients, or technology, and are not specifically addressed in the Food Code. Because of an increased potential health **risk**, specialized processes in retail **food establishments** must be conducted under strict operational procedures. Attention must always be given to the science associated with special processes to ensure that all safety concerns are fully addressed. Before engaging in novel processes, operators should always consult the regulatory authority for guidance specific to their proposed process. At the regulator's discretion, academic experts may be needed to provide science-based guidance, and an **approved HACCP plan,** and a **variance** may be required based on Subparagraph 3-502.11(G) of the Food Code.

While for purposes of this guidance document it is not possible to anticipate all possible processes that may be presented for consideration, two example processes that could be presented would be production of cheese, and mold fermentations to produce products such as miso, koji, and shoyu. While not an exhaustive list, here are concerns that should be considered in evaluating the process to determine need for a **HACCP plan** and a **variance**:

About the food product:

- List and describe the ingredients.
- Are all ingredients Generally Recognized as Safe (GRAS)[44,45]

[44] https://www.fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-terms#:~:text=Food%20Additive%20%2D%20A%20food%20additive,substance%20intended%20for%20use%20in

[45] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-182

- Are all ingredients from an **approved** source?
- Is the product intended to be **TCS** food, or non-**TCS**?
- What are the intended storage conditions and shelf life?
- Describe the intended consumer and the method(s) of distribution.
- Describe the packaging and labeling of the product.

About the production process:

- What type of process will be used?
- Are there steps in the process with **control** parameters outside of Food Code requirements? This includes steps such as:
    - Holding **TCS** food for more than four hours at temperatures between 41°F. and 135°F. (5°C. and 57°C.).
    - Cooking at a lower temperature and/or for less time than required by the Food Code.
    - Using additives[46] as defined by FDA, especially if the intent is to preserve the food.
    - Using cultures (bacterial, yeast, mold, or a combination) to reduce pH or to otherwise modify the food from its original characteristics.
- What **controls** will be substituted for Food Code **controls** to ensure that the safety of the final product will be at or greater than the level provided by Food Code **controls**?
- Is there scientific support for the proposed **controls**?
- At what steps in the process are certain **control measures** critical for safety?
- Are there federal regulations that relate to the process details?
- Has a detailed set of production instructions been developed, including specifications for **control measures** for review?
- Are there comparable processes used in the U.S. food industry for which data may be available for comparison?
- Is **validation** available or needed for the process, such as from a **processing authority**, or from testing data?
- If testing or a process letter is required, what process parameters or testing requirements must be addressed?

[46] www.fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-terms#:~:text=Food%20Additive%20%2D%20A%20food%20additive,substance%20intended%20for%20use%20in

References:

"Cultural Foods Safety App" for smartphones and tablets – University of Tennessee, Center for Agriculture and Food Safety and Preparedness, http://www.vet.utk.edu/cafsp/apps.php

SECTION 8: HACCP TEMPLATES BY PROCESS TYPE

This section provides a list of process types that may be covered under a **HACCP** Food Safety Program. Each separate processing type requires a **hazard analysis** and **HACCP plan** specific to the process steps and **controls** for that type of processing.

It is essential to communicate openly with your regulatory authority for assistance and guidance on determining the process types planned to take place in your establishment. Getting the process types right at the beginning is essential groundwork so your **hazard analysis** is properly conducted and your **HACCP plan** is accurately developed.

Using **meat preservation** processes as an example, "cooking" may involve smoking, grilling, or another method of cooking. Additionally, any of these processing types may or may not include an additional processing type such as use of curing salt (nitrite). These processing types may be used to group specific products when preparing a **hazard analysis**.

Each **HACCP plan** must be specific to an establishment's facilities, equipment, products, and processes. For example, the template for a cured whole muscle process with no cook step could be modified to replace an alternative pathogen reduction step with a cooking step. Any and all parts of these model plans must be edited or modified, therefore, to reflect the specific equipment, products, and processes used in your establishment. It is essential that every routine and alternate or occasional step in a process be represented and evaluated and that proper measures be implemented to **control** all potential significant **hazards**. It is solely the responsibility of each establishment to produce a safe product, properly packaged and labeled for the consumer when necessary.

The use of occasional or alternate steps in a process may require modification of the template. Certain proteins may also require modification from the normal process. For example, reduced oxygen packaging (ROP) of raw **fish** may use the template for ROP storage of raw **meat** and **poultry**. However, freezing instructions will be required before the ROP packaging step; the cold storage must be frozen rather than refrigerated; and a thawing step or instructions must be provided to ensure the **fish** is removed from the ROP package before thawing. **Fish** can also be included in that same ROP plan with other proteins, but the instructions described above must be included as alternate instructions specific to **fish**.

Below is a list of process types covered as special processes under the Food Code. This is not intended to be a complete list. The product list for each **HACCP** process must be complete and specific to your operation.

Reduced Oxygen Packaging

- Raw **meats**, raw **poultry**, or cheeses sold to consumers
- Raw **meats**, raw **poultry**, or cheeses used in RFE
- Raw **fish**, frozen before, during, and after packaging
- Sous vide cooking
- Cook-chill
- **Meats** cured in retail establishment – include nitrite
- Commercially cured **meats** or deli **meats** repacked in retail establishment
- Modified atmosphere packaging
- **Controlled** atmosphere packaging

Preserved and Cured Meats

Jerky Products: Fully Cooked –Shelf Stable (specify if cured)

- Beef jerky
- Pork jerky
- Turkey jerky
- Chicken jerky

Sausage Products: Fully Cooked – Not Shelf Stable (specify if cured)

- Ring bologna
- Summer sausage
- Smoked bratwurst
- Polish sausage
- Beef sticks
- Pork links

Fermented Sausage Products: Not Cooked, Shelf Stable or Non-Shelf Stable (specify if cured)

- Salumi
- Pepperoni
- Prosciutto
- Mortadella

Whole Muscle Products: Fully Cooked – Not Shelf Stable (specify if cured)

- Bone-in ham and loin
- Dried beef

Whole Muscle Products: <u>Not</u> Fully Cooked – Not Shelf Stable (specify if cured)

- Bacon
- Parma
- Tasso

Smoking food (For preservation rather than as a method of flavor enhancement. Specify if cured.)

Hot Smoking Fish for Preservation

Other Processes

Preserving, Acidified, or Acidic Foods (Using food additives or adding components such as vinegar as a method of food preservation rather than flavor enhancement, or to render a food so it is non-TCS.)

- Sushi rice
- Pickles
- Chow chow

- Barbeque sauce
- Vinaigrette dressings

Fermenting non-meat foods

- Yogurt
- Kimchi
- Sauerkraut
- Hot sauce

Templates

The following pages provide templates for the core of a Retail **HACCP Plan** (seven principles and the standard operating procedure), intended to *guide* establishments in developing a **HACCP plan** that meets the requirements of the FDA Food Code. Each template is a suggested format only, and use of the provided format is not required to receive plan approval. However, each template identifies required content for the **HACCP plan** represented. A proper **hazard analysis** and CCP Summary are mandatory elements of every **HACCP plan**. These templates are to be viewed only as a starting point. *The **hazards** identified and the **controls** provided, must reflect the specific process for which the plan is being written*. The information provided in each **HACCP plan** must include the specific details relevant to each establishment's process. Use of these model documents, however, will facilitate the process of writing a **HACCP plan**, as well as regulatory review, approval, and **verification** of an establishment's **HACCP plan** by the regulatory authority. The red text in each template provides guidance as to the minimum information that must be completed specific to each retail **food establishment**. Each template includes the **hazard analysis** table, the **HACCP** Summary (CCP Audit Summary) table, the Standard Operating Procedure section, and references providing **validation** for the plan based on contents of the template.

Each template assumes a certain generic process. The **hazard analysis** must accurately reflect all steps of the process, including occasional or alternate steps, so modification may be required. Certain proteins may also require modification from the normal process. For example, reduced oxygen packaging (ROP) of raw **fish** may use the template for ROP storage of raw **meat** and **poultry**. However, freezing instructions will be required before the ROP packaging step; the cold storage must be frozen rather than refrigerated; and a thawing step or instructions must be provided to ensure the **fish** is removed from the ROP package before thawing.

It is essential to seek guidance from your regulatory authority to be sure your process details are handled correctly.

Process: Reduced Oxygen Packaging for Storage of Raw Meats and Poultry for Sale to Consumers

Hazard Analysis Table: Reduced Oxygen Packaging for Storage of Raw Meats and Poultry for Sale to Consumers

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Meats & Poultry (1)	**B:** Multiplication of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*; *Trichinella*, etc.	No	Fresh meat, poultry are known to contain these pathogens – controlled in later steps	- Approved suppliers, Letters of Guaranty - Inspected at receiving for proper temperature; undamaged	No
	C: None identified				
	P: None identified				
Receiving Packaging Materials (2)	**C:** Deleterious Chemicals	No	Approved supplier, purchase specifications, inspection upon receipt provide control	- Approved suppliers; Letters of Guaranty; inspected at receiving - undamaged	No
	P: Foreign Material	No			
	B: None identified				
Cold Storage of Raw Meats & Poultry (3)	**B:** Multiplication or cross contamination: Pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, etc.	No	Potential for growth and/or cross contamination from improper refrigeration and storage controlled by storage SOP and SSOP	- All meat, poultry stored immediately in cooler or freezer upon delivery; SSOP; proper storage procedures	No
	C: None identified				
	P: None identified				
Dry Storage of Packaging Materials (4)	**B:** Biological	No	Proper storage, SSOP are followed and provide proper control	- Proper storage procedures - SSOP	No
	P: Foreign Material	No			
	C: None identified				

Preparation #1, Vacuum Packing & Labeling (5)	**B:** Multiplication or cross contamination: *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria monocytogenes*; *Shigella, Staph,* Norovirus, Hepatitis A	Yes	Short handling time limits potential growth of pathogens; hazard is controlled by proper cooking as directed by safe handling instructions (consumer label). Employee Health/Hygiene Policies provide control over worker-transmitted contamination. Improper labeling results in outdated & potentially unsafe products	- Minimize time product is in the temp. danger zone - SSOP, Employee Health & Hygienic Practices - Subsequent kill step - all but *Clostridium* spores - Label product: name; date packed; use-by date; and storage, handling, and cooking instructions for consumer	Yes CCP 1
	C: None identified				
	P: None identified				
Cold Storage for Sale (6)	**B:** Multiplication of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, *Clostridium* botulinum, etc.	Yes	Potential growth of pathogens, spores and possible toxin formation *(C. Bot*) if proper temperatures are not maintained. Controlled in-house by proper refrigeration or freezing; requires safe handling and storage instructions on consumer product label.	- Monitor use-by dates and - Proper cold holding - SSOP, Proper storage procedures	Yes CCP 2
	C: Botulinum toxin formation	Yes			
	P: None identified				

HACCP Summary Table: Reduced Oxygen Packaging for Storage of Raw Meats and Poultry for Sale to Consumers

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Product Labeling	Pathogens	Use-by date, safe handling, storage, and cooking instructions present on label	Label contents	Visual inspection	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 2a, 2b Frozen/ Cold Storage	Pathogens	<41˚F.	Cooler temperature	Stem thermometer in cooler	2x daily, a.m. and p.m.	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
		Product date mark not expired	Date mark	Examine label	Each package				

Approved by:_____ Date:_____

Standard Operating Procedures: Reduced Oxygen Packaging for Storage of Raw Meats and Poultry for Sale to Consumers

Establishment Name: _____

Only food establishment employees trained in the use of this process and who have a thorough understanding of the HACCP plan shall conduct this process.

1. **Receiving Raw Meats:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider temperature at receipt as well as the condition of the packages? For what reasons would a shipment be rejected?

2. **Receiving Non-Refrigerated Ingredients and Packaging Materials:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients, and packaging materials to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider condition of the packages. For what reasons would a shipment be rejected?

3. **Cold Storage:** What are the required storage procedures to ensure the food is properly refrigerated and protected from contamination?

4. **Dry Storage:** What are the required procedures to ensure materials are properly stored and protected from contamination?

5. **Preparation #1, Vacuum Packaging & Labeling (CCP 1):** Label content must include safe storage, handling, and cooking instructions for the consumer. Provide instructions for an employee to follow as they are preparing to vacuum package a product. How will they package/seal appropriately, control time and temperature, label the product, determine the expiration date, and any other concerns you may have for this process?

    - Critical Limit: What critical limits must be monitored and met at this step to keep the product safe? If product will be sold for consumer use, what safe storage, handling, and cooking instructions will be provided on the label for consumers?

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits? *Provide a copy of the consumer label to the regulatory authority with this HACCP plan for review.*

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

6. **Cold Storage for Sale to Consumer (CCP 2a, 2b):** What are the instructions for properly storing the vacuum packaged products? Consider temperature abuse and cross contamination.

    - Critical Limit: What critical limits must be monitored and met at this step to keep the product safe?

- Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

- Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

Process: Reduced Oxygen Packaging for Storage of Raw Meats and Poultry

Hazard Analysis Table: Reduced Oxygen Packaging for Storage of Raw Meats and Poultry

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Meats & Poultry (1)	**B:** Multiplication of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Trichinella*, etc.	No	Fresh meat, poultry are known to contain these pathogens – controlled in later steps	- Approved suppliers, Letters of Guaranty - Inspected at receiving for proper temperature; undamaged	No
	C: None identified				
	P: None identified				
Receiving Packaging Materials (2)	**C:** Deleterious Chemicals	No	Approved supplier, purchase specifications, inspection upon receipt provide control	- Approved suppliers; Letters of Guaranty; inspected at receiving - undamaged	No
	P: Foreign Material	No			
	B: None identified				
Cold Storage of Raw Meats & Poultry (3)	**B:** Multiplication or cross contamination: Pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, etc.	No	Potential for growth and/or cross contamination from improper refrigeration and storage controlled by storage SOP and SSOP	- All meat, poultry stored immediately in cooler or freezer upon delivery; SSOP; proper storage procedures	No
	C: None identified				
	P: None identified				
Dry Storage of Packaging Materials (4)	**B:** Biological	No	Proper storage, SSOP are followed and provide proper control	- Proper storage procedures - SSOP	No
	P: Foreign Material	No			
	C: None identified				

Preparation #1, Vacuum Packing & Labeling (5)	**B:** Multiplication or cross contamination: *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria monocytogenes*; *Shigella, Staph,* Norovirus, Hepatitis A	No	- Short handling time limits potential growth of pathogens; hazard is controlled by cooking (in-house) at later step, or by safe handling instructions (consumer label). - Employee Health/Hygiene Policies provide control over worker-transmitted contamination. - Improperly labeling results in outdated & potentially unsafe products.	- Minimize time product is in the temp. danger zone - Label product: name, date packed, 'use-by' date - SSOP, Employee Health & Hygienic Practices - Subsequent kill step - all but *Clostridium* spores - Use-by date and storage, handling and cooking instructions if sold for home use	No
	C: None identified				
	P: None identified				
Cold Storage (6)	**B:** Multiplication of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, *Clostridium* botulinum, etc.	Yes	- Improper cold holding can result in pathogen growth/toxin formation. - Holding past expiration can result in *Listeria* growth - Potential cross contamination controlled by SSOP, proper storage SOP	- Monitor use-by dates and - Proper cold holding - SSOP, Proper storage procedures	Yes CCP 1a, 1b
	C: Botulinum toxin formation	Yes			
	P: None identified				
Preparation #2 (7)	**B:** Cross contamination: pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, *Shigella*, *Staph,* Norovirus, Hepatitis A	No	Subsequent cook step destroys pathogens; Health/Hygiene Policies prevent contamination	- ROP packaging will be opened prior to cooking; minimize time product will be in the temp. danger zone - SSOP, Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Cooking (8)	**B:** Survival or recontamination: Pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, *Shigella*, Norovirus, Hepatitis A	Yes	Pathogen survival, if products are not cooked to correct internal temperatures; recontamination possible after cooking if Health/Hygiene policies and SSOP are not followed	- Monitor use-by dates - Cook to required minimum internal temperatures - SSOP, Employee Health & Hygienic Practices	Yes CCP 2
Service (9)	**B:** Cross contamination: *Salmonella*, *E. coli* O157:H7, *Listeria*, *Shigella*, Norovirus, Hepatitis A	No	Potential recontamination from improper handling controlled by SSOP, Employee Health/Hygiene policies	- Employee health and hygiene policies - SSOP	No

HACCP Summary Table: Reduced Oxygen Packaging for Storage of Raw Meats and Poultry

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1a, 1b Frozen/ cold Storage	Pathogens	<41°F.	Cooler temperature	Stem thermometer in cooler	2x daily, a.m. and p.m.	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
		Product date mark not expired	Date mark	Examine label	Daily				
CCP 2 Cooking	Pathogens	Cook to internal temps: Whole muscle beef, pork 145°F./15 seconds	Internal product temperature	Calibrated stem thermometer	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
		Ground beef, pork 155°F./17 seconds							
		Poultry 165°F.							

Approved by:_____ Date:_____

Standard Operating Procedures: Reduced Oxygen Packaging for Storage of Raw Meats and Poultry

Establishment Name: _____

Only food establishment employees trained in the use of this process and who have a thorough understanding of the HACCP plan shall conduct this process.

1. **Receiving Raw Meat/Poultry:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider temperature at receipt as well as the condition of the packages? For what reasons would a shipment be rejected?

2. **Receiving Non-Refrigerated Ingredients and Packaging Materials:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients, and packaging materials to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider condition of the packages? For what reasons would a shipment be rejected?

3. **Cold Storage:** What are the required storage procedures to ensure the food is properly refrigerated and protected from contamination?

4. **Dry Storage:** What are the required procedures to ensure materials are properly stored and protected from contamination?

5. **Preparation #1, Vacuum Packaging & Labeling:** *If ROP packaged products are to be sold to consumers for home use, or if this is an option, label content must include safe storage, handling and cooking instructions for the consumer as a Critical Control Point (CCP)*. Provide instructions for an employee to follow as they are preparing to vacuum package a product. How will they package/seal appropriately, control time and temperature, label the product, determine the expiration date, and any other concern you may have for this process.

6. **Cold Storage (CCP 1a, 1b):** What are the instructions for properly storing the vacuum packaged products? Consider temperature abuse and cross contamination.

    - Critical Limit: What critical limits must be monitored and met at this step to keep the product safe?

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

7. **Preparation #2:** If ROP-packaged product may be used in-house or sold to consumers for home use, Step 5 will be a Critical Control Point (CCP) for labeling. If ROP-packaged product will only

be sold for consumers' home use, steps 7-9 should be deleted. What instructions are to be followed for final preparation of the product before it is cooked and served?

8. **Cooking (CCP 2):** What equipment will be used to cook the product? If the instruction is different for different products, provide a list of products here for each piece of cooking equipment, refer to the recipe card for each product, or give other general instructions as appropriate.

    - Critical Limit: What critical limits (temperatures and time at temperature) must be monitored and met at this step to keep the product safe?

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

9. **Service:** Serve according to menu or recipe guidelines. Careful to avoid recontamination by servers by observing PRPs for Employee Health and Hygiene.

References**:**

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

Process: Sous Vide Cooking Meats, Poultry

Hazard Analysis Table: Sous Vide Cooking Meats, Poultry

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Meats & Poultry (1)	**B:** Multiplication of *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Clostridium perfringens*, *Trichinella*, etc.	No	Fresh meat, poultry are known to contain these pathogens – controlled in later steps	- Approved suppliers, Letters of Guaranty - Inspected at receiving for proper temperature; undamaged	No
	C: None identified				
	P: None identified				
Receive Packaging Materials (2)	**C:** Deleterious Chemicals	No	Approved supplier, purchase specifications, inspection upon receipt provide control	- Approved suppliers; Letters of Guaranty - Inspected at receiving; undamaged	No
	P: Foreign Material	No			
	B: None identified				
Cold Storage of Raw Meats & Poultry (3)	**B:** Multiplication of *Salmonella* and *E. coli* O157:H7, *Campylobacter*, *Clostridium perfringens*, etc.	No	Potential for growth and/or cross contamination from improper refrigeration and storage controlled by storage SOP and SSOP	- All meat, poultry stored immediately in cooler or freezer upon delivery - SSOP - Proper storage procedures	No
	C: None identified				
	P: None identified				
Dry Storage (4)	**B:** Cross contamination in storage with pathogens	No	Proper storage, SSOP are followed and provide proper control	- Proper storage procedures - SSOP	No
	P: Foreign Material	No			
	C: None identified				
Preparation #1, Vacuum Packing (5)	**B:** Contamination with *Salmonella* and *E. coli* O157:H7, *Campylobacter*, *Listeria monocytogenes*; *Shigella*, Norovirus, Hepatitis A	No	Growth of pathogens, spores Cross contamination possible (handling) – controlled by short process time at this step, Employee Health/Hygiene Policies,	- Minimize time product is in the temp. danger zone	No
	C: None identified				

	P: None identified		SSOP; bacterial hazards controlled by cooking (subsequent step)	- SSOP, Employee Health & Hygienic Practices - Subsequent kill step destroys vegetative cells, but not *Clostridium* spores and viruses	
Cooking (6)	**B:** Survival of *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, etc.	Yes	**B, C:** Potential Growth of spores/failure to destroy pathogens if required cooking temperature is not achieved.	- Cook to proper temperature/time per recipe in a pre-warmed water bath	Yes CCP 1
	B, C: *C. botulinum* and C. *perfringens* – growth, toxin & spores	Yes			
	P: None identified				
Shocking/ Cooling (7)	**B and C:** Activation of spores and formation of *C. botulinum*, C. *perfringens* toxins	Yes	Improper cooling can result in spore activation/toxin formation	- Product properly cooled to minimize time in the TDZ - Label and date mark	Yes CCP 2
	P: None identified				
Cold Storage and Date Mark Control (8)	**B:** Contamination with *Listeria*	Yes	**B, C:** Improper cold holding can result in pathogen growth/toxin formation. -Holding past expiration can result in *Listeria* growth - Potential cross contamination controlled by SSOP, proper storage SOP	- Monitor use-by dates and - Proper cold holding - SSOP, Proper storage procedures	Yes CCP3a, 3b
	C: Toxin formation by *C. botulinum*, C. *perfringens*	Yes			
	P: None identified				
Reheat to Hot Hold (9)	**B:** Recontamination with *Salmonella*, *E. coli* O157:H7, *Listeria*; *Shigella, Staph,* Norovirus, Hepatitis A	Yes	**B:** Recontamination from mishandling, unsanitary equipment or ill worker if removed from bag for reheating **C:** Improper reheat time or temp. can result in activation of spores, toxin formation	- Proper reheat procedure (time and temp) - SSOP, Employee Health, Employee Hygiene	Yes CCP 4 *
	B, C: *C. botulinum* and C. *perfringens* activation of spores, toxin formation	Yes			
	P: None identified				
Service (10)	**B:** Recontamination with *Salmonella*, *E. coli* O157:H7, *Listeria*; *Shigella, Staph,* Norovirus, Hepatitis A	No	Potential recontamination from improper handling - controlled by SSOP, Employee Health/Hygiene policies	- Employee health and hygiene policies - SSOP	No
	C: None identified				
	P: None identified				

*This step is not a critical control point if the food is not reheated for hot holding; it is only reheated for immediate service.

HACCP Summary Table: Sous Vide Cooking Meats, Poultry

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Cooking	Pathogens	Cook Temps: Provide required internal cooking temperature and time for each product category	Internal product temperature	Calibrated stem thermometer	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 2 Cooling	Pathogens	Cool from 135°F. to <70°F. in <2 hrs. Total time not to exceed 6 hrs.	Proper rate of cooling	Monitor internal product temperature	Each batch, hourly	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 3a Datemark expiration	Pathogens	Product date has not expired	Use within marked date	Examine label	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 3b Cold Storage	Pathogens	<41°F.	Cooler temperature	Stem thermometer and electronic logger	Check BOTH 2x daily, a.m. and p.m.	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.

CCP 4 Reheat ***to hot hold***	Pathogens	>165°F. for 15 sec. within 2 hrs. after removed from cold holding	Internal product temperature	Calibrated stem thermometer	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.

Approved by:_____ Date:_____

Standard Operating Procedures: Sous Vide Cooking Meats, Poultry

Establishment Name: _____

Only food establishment employees trained in the use of this process and who have a thorough understanding of the HACCP plan shall conduct this process.

1. **Receiving Raw Meat/Poultry:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider temperature at receipt as well as the condition of the packages. For what reasons would a shipment be rejected?

2. **Receiving Non-Refrigerated Ingredients and Packaging Materials:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients, and packaging materials to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider condition of the packages. For what reasons would a shipment be rejected?

3. **Cold Storage:** What are the required storage procedures to ensure the food is properly refrigerated and protected from contamination?

4. **Dry Storage:** What are the required procedures to ensure the food is properly stored and protected from contamination?

5. **Preparation #1 and Vacuum Packaging:** Provide instructions for an employee to follow as they are preparing to vacuum package a product. What ingredients are to be added? (Can refer to recipe for product.) What instructions are to be followed to package/seal appropriately, control time and temperature during preparation, label the product, and any other concerns for this process?

1. **Cooking (CCP 1 – NOT a CCP if the product is always reheated for hot holding):** What instructions are to be followed to properly cook the product? Provide specifications for the product portions to ensure uniform cooking. What is the limit for the number or weight of portions that can be placed in the water bath to allow for proper circulation and heating? Are the cooking times and temperatures found in the recipe for each product? What instructions are to be followed to prepare the water bath for cooking?

    - Critical Limit: Provide a list of *critical temperatures and required time at temperature* for each product or product category (such as whole muscle beef, chicken, or pork). This information can be provided in recipe cards – if so, all recipes must be submitted with this plan for review.

    - Monitoring: What must the employee do to ensure that critical limits for temperature and time have been met? How are product temperatures to be monitored? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: What instructions are to be followed if the critical limit is not met?

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

6. **Cooling/Shocking (CCP 2):** What are the instructions for properly cooling the vacuum packaged products? After cooling, how is the product to be labeled, and what information is required? Explain how the correct date mark is determined.

    - Critical Limit: List the critical limits for the two phases of cooling that must be monitored and met at this step to keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: What corrective actions are allowed in each phase of cooling if the cooling rate required is not being met? If product fails to cool to below 41°F. within 6 hours, what corrective action is required?

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

7. **Cold Storage (CCP 3a, 3b):** What are the instructions for properly storing the vacuum packaged products? Consider temperature abuse and cross contamination.

    - Critical Limits: What critical limits must be monitored and met at this step to keep the product safe?

    - Monitoring: How will temperature measurements be made to ensure that critical limit is being met? How often will temperatures be checked and documented? What records will be maintained to demonstrate compliance with the critical limits? How often will the required *continuous electronic temperature monitoring* system be checked for operation, and what will be done with that data? How will date marks be monitored for rotation and expiration?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

8. **Reheating (CCP 4 – *NOT* a CCP if product is always reheated for immediate service!):** What equipment will be used to reheat the product? If the instruction is different for different products, either provide a list of products here for each piece of cooking equipment, or refer to the recipe card for each product, or give other general instructions as appropriate.

    - Critical Limit: What critical limits must be monitored and met at this step to keep the product safe?

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

- Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

9. **Service:** Serve according to menu or recipe guidelines. Be careful to avoid recontamination by servers by observing policies for Employee Health and Hygiene.

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

FSIS Revised Appendix A, "FSIS Cooking Guideline for Meat and Poultry Products" December 2021, https://www.fsis.usda.gov/wps/wcm/connect/bf3f01a1-a0b7-4902-a2df-a87c73d1b633/Salmonella-Compliance-Guideline-SVSP-RTE-Appendix-A.pdf?MOD=AJPERES#:~:text=FSIS%20Salmonella%20Compliance%20Guidelines%20for%20Small%20and%20Very,use%20to%20produce%20safe%20products%20with%20respect%20to

Process: ROP Cook-Chill Storage of Soups, Stocks, and Prepared Foods

Hazard Analysis Table: ROP Cook-Chill Storage of Soups, Stocks, and Prepared Foods

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards? B: Biological C: Chemical P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Meats & Poultry (1)	**B:** Multiplication of *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Clostridium perfringens*, etc.–C, P - None identified	No	Fresh meat, poultry are known to contain these pathogens – controlled in later steps	- Approved suppliers, Letters of Guaranty; inspected at receiving for proper temperature; undamaged	No
	C: None identified				
	P: None identified				
Receive Packaging Material (2)	**C:** Deleterious chemicals	No	Approved supplier, purchase specifications, inspection upon receipt provide control	- Approved suppliers; Letters of Guaranty; inspected at receiving - undamaged	No
	P: Foreign material	No			
	B: None identified				
Cold Storage of Raw Meats & Poultry (3)	**B:** Multiplication of *Salmonella* and *E. coli* O157:H7, *Campylobacter*, *Clostridium perfringens*, etc.	No	Potential for growth and/or cross contamination from improper refrigeration and storage controlled by storage SOP and SSOP	- All meat, poultry stored immediately in cooler or freezer upon delivery; SSOP; proper storage procedures	No
	C: None identified				
	P: None identified				
Dry Storage (4)	**B:** Cross contamination in storage with pathogens	No	Proper storage, SSOP are followed and provide proper control	- Proper storage procedures - SSOP	No
	P: Foreign material	No			
	C: None identified				
Preparation and Cooking (5)	**B:** Survival of *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, etc.	Yes	Potential production of spores/failure to destroy pathogens if required cooking temperature is not achieved	- Cooking to proper temperature/time per recipe destroys vegetative cells, but not spores or viruses - SSOP, Employee Health & Hygienic Practices	Yes CCP 1
	C: None identified				
	P: None identified				

Bagging and Vacuum Packing (6)	**B:** Recontamination with *Salmonella* and *E. coli* O157:H7, *Campylobacter*, *Listeria monocytogenes*; *Shigella*, Norovirus, Hepatitis A	No	Potential growth of pathogens and cross contamination controlled by subsequent steps; proper handling procedures, SSOP, Employee Health and Hygiene policies	- Minimize time product is in the temp. danger zone - SSOP, Employee Health & Hygienic Practices	No
	B, C: *C. botulinum* and C. *perfringens* – growth, toxin, and spores	No			
	P: None identified				
Shocking/Cooling (7)	**B:** *Listeria*	Yes	Improper cooling can result in spore activation/toxin formation	- Product properly cooled to minimize time in the TDZ - Label and date mark	Yes CCP 2
	B, C: *C. botulinum*, C. *perfringens*	Yes			
	P: None identified				
Cold Storage and Date Mark Control (8)	**B:** *Listeria*	Yes	-Improper cold holding can result in pathogen growth/toxin formation -Holding past expiration can result in *Listeria* growth - Potential cross contamination controlled by SSOP, proper storage SOP	- Monitor use-by dates and - Proper cold holding - SSOP, Proper storage procedures	Yes CCP3a, 3b
	B, C: *C. botulinum*, C. *perfringens*	Yes			
	P: None identified				
Reheat to Hot Hold (9)	**B:** Recontamination with *Salmonella*, *E. coli* O157:H7, *Listeria*; *Shigella, Staph,* Norovirus, Hepatitis A	Yes	-Recontamination may result if Employee Health/Hygiene Policy or SSOP not followed. Improper reheat time or temp. can result in pathogen growth/toxin formation	- Proper reheat procedure (time and temp) - SSOP, Employee Health, Employee Hygiene	Yes CCP 4
	B, C: *C. botulinum* and C. *perfringens* spores and toxin	Yes			
	P: None identified				
Service (10)	**B:** Recontamination with *Salmonella*, *E. coli* O157:H7, *Listeria*; *Shigella, Staph,* Norovirus, Hepatitis A	No	Potential recontamination from improper handling - controlled by SSOP, Employee Health/Hygiene policies	- Employee health and hygiene policies - SSOP	No
	C: None identified				
	P: None identified				

HACCP Summary Table: ROP Cook-Chill Storage of Soups, Stocks, and Prepared Foods

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Cooking	Pathogens	Cook Temps: Provide required internal cooking temperature and time for each product category	Internal product temperature	Calibrated stem thermometer	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 2 Cooling	Pathogens	a. Cool from 135°F. to <70°F. in <2 hrs. ***AND*** b. Cool from 70°F. to <41°F. in <4 hrs. Total time not to exceed 6 hrs.	Proper rate of cooling	Monitor internal product temperature	Each batch, hourly	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 3a Datemark expiration	Pathogens	Product date has not expired	Use within marked date	Examine label	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.

CCP 3b Cold Storage	Pathogens	<41°F	Cooler temperature	Stem thermometer and electronic logger	Check BOTH 2x daily, a.m. and p.m.	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 4 * Reheat ***to hot hold***	Pathogens	>165°F. for 15 sec. within 2 hrs. after removed from cold holding	Internal product temperature	Calibrated stem thermometer	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.

*This step is not a critical control point if the food is not reheated for hot holding; it is only reheated for immediate service.

Approved by:_____ Date:_____

Standard Operating Procedures: ROP Cook-Chill Storage of Soups, Stocks, and Prepared Foods

Establishment Name: _____

Only food establishment employees trained in the use of this process and have a thorough understanding of the HACCP plan shall conduct this process.

1. **Receiving Raw Meat/Poultry:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider temperature at receipt as well as the condition of the packages. For what reasons would a shipment be rejected?

2. **Receiving Non-Refrigerated Ingredients and Packaging Materials:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients, and packaging materials to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider condition of the packages. For what reasons would a shipment be rejected

3. **Cold Storage:** What are the required storage procedures to ensure the food is properly refrigerated and protected from contamination?

4. **Dry Storage:** What are the required procedures to ensure the food is properly stored and protected from contamination?

5. **Preparation and Cooking (CCP 1 – NOT a CCP if the product is always reheated for hot holding):** What instructions are to be followed to properly prepare and cook the product? Are the cooking times and temperatures found in the recipe for each product?

    - Critical Limit: Provide a list of *critical temperatures and required time at temperature* for each category (such as beef, chicken, or pork). This information can be provided in recipe cards – if so, include all recipes with this plan for review.

    - Monitoring: What must the employee do to ensure that critical limits for temperature and time have been met? How are product temperatures to be monitored? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: What instructions are to be followed if the critical limit is not met?

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

6. **Bagging and Vacuum Packaging:** Product must be bagged at a temperature of at least 135°F. for safety. Provide instructions for an employee to follow as they are bagging and vacuum packaging product. What instructions are to be followed to package/seal appropriately? What information must be included in the product label? How is the expiration date properly determined? Are there other concerns that must be addressed at this step?

7. **Cooling/Shocking (CCP 2):** What are the instructions for properly cooling the vacuum packaged products? Is stacking of packages allowed? After cooling, how is the product to be labeled, and what information is required? Explain how the correct date mark is determined.

- Critical Limit: List the critical limits for the two phases of cooling that must be monitored and met at this step to keep the product safe.

- Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

- Corrective Action: What corrective actions are allowed in each phase of cooling if the cooling rate required is not being met? If product fails to cool to below 41°F. within 6 hours, what corrective action is required?

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

8. **Cold Storage (CCP 3a, 3b):** What are the instructions for properly storing the vacuum packaged products? Consider temperature abuse and cross contamination.

    - Critical Limits: What critical limits must be monitored and met at this step to keep the product safe? (*List all critical limits.*)

    - Monitoring: How will temperature measurements be made, to ensure that critical limit is being met? How often will temperatures be checked and documented? What records will be maintained to demonstrate compliance with the critical limits? *How often will the required electronic temperature monitoring* system be checked for operation, and what will be done with that data? How will date marks be monitored for rotation and expiration?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

9. **Reheating (CCP 4 – *NOT* a CCP if product is always reheated for immediate service!):** What equipment will be used to reheat the product? If the instruction is different for different products, either provide a list of products here for each piece of cooking equipment, or refer to the recipe card for each product, or give other general instructions as appropriate.

    - Critical Limit: What critical limits must be monitored and met at this step to keep the product safe?

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

10. **Service:** Serve according to menu or recipe guidelines. Careful to avoid recontamination by servers by observing policies for Employee Health and Hygiene

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

Process: Uncured, Smoked Jerky

Hazard Analysis Table: Uncured, Smoked Jerky

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Meats & Poultry (1)	**B:** Introduction of pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*, etc.); *Trichinella* (pork only)	No	Fresh meat, poultry are known to contain these pathogens – controlled in later step	- Approved suppliers (Letters of Guaranty) - Inspected at receiving for proper temperature, undamaged	No
	C: None identified				
	P: None identified				
Receiving Packaging Materials (2)	**B:** None identified		Use of approved supplier, purchase specifications, inspection upon receipt will control/prevent hazard	- Approved suppliers (Letters of Guaranty) - Receiving inspection	No
	C: Introduction of Deleterious Chemicals	No			
	P: Introduction of Foreign Material	No			
Cold Storage of Raw Meats & Poultry (3)	**B:** Growth of pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*, etc.)	No	Proper refrigeration, sanitation, and storage will prevent growth and/or cross contamination	- Proper storage - Proper refrigeration - SSOP	No
	C: None identified				
	P: None identified				
Dry Storage of Non-Meat Ingredients (4)	**B:** None identified		Proper storage and sanitation will prevent growth and/or cross contamination	- Proper storage - SSOP	No
	C: None identified				
	P: Introduction of Foreign Material	No			

Assemble & Weigh Meat & Ingredients (5)	**B:** Cross contamination of pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*, etc.)	No	Growth of pathogens (temp. abuse) & cross contamination possible (handling) controlled by Employee Health & Hygiene policies, SOP, SSOP	- Minimize time product is in the temp. danger zone - Follow SOP - SSOP - Employee Health & Hygiene	No
	C: None identified				
	P: None identified				
Marinate (6)	**B:** Cross contamination of pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*, etc.)	No	Pathogen destruction is provided at later step (cooking); additional control provided by Employee Health & Hygiene policies, SOP, SSOP	- Follow SOP – temperature control - Employee Health /Hygiene - SSOP	No
	C: None identified				
	P: None identified				
Smoke/Cook (7)	**B:** Survival of pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*, etc.)	Yes	Cooking is critical at this step to destroy pathogens Potential recontamination after cooking/smoking controlled by SSOP, Employee Health/Hygiene Policies	- Cook to required temperature and time. - SSOP, Employee Health & Hygienic Practices	Yes CCP 1
	C: None identified				
	P: None identified				
Cooling (8)	**B:** Germination of spores and growth of *Clostridial* species	Yes	Improper cooling can result in activation of spores, toxin formation; potential recontamination controlled by other policies/procedures Oxygen present in air is barrier to *C. botulinum* toxin formation	- -Proper cooling per procedure - SSOP, Employee Health & Hygienic Practices	Yes CCP 2
	C: None identified				
	P: None identified				
Dehydrate (9)	**B:** Growth and survival of pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*, etc.)	Yes	Improper drying can allow growth of pathogens Potential recontamination controlled by other policies/procedures	- Dry according to SOP to required weight loss - SSOP	Yes CCP 3
Package & Label (10)	**B:** Introduction of pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*, etc.)	No	Potential recontamination controlled by SSOP, Employee Health and Hygiene Policies	- Process SOP - SSOP - Employee Health & Hygienic Practices	No
	C: Botulinum toxin	No	*C. botulinum* activity, growth of other pathogens, and toxin formation prevented by low water activity		

	C: Allergens	No	No allergens present in any of the ingredients		
	P: None identified				
Sale or Service (11)	**B:** None identified		Packaging of product at previous step prevents possibility of recontamination, and low water activity prevents growth of any pathogens that may have survived or been introduced at previous steps	- Packaging and storage SOPs - SSOP	No
	C: None identified				
	P: None identified				

HACCP Summary Table: Uncured, Smoked Jerky

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Smoke / Cook	Pathogens	Cook temperature: **Whole muscle** beef, pork 145°F./15 seconds Ground beef, pork 145°F./15 seconds Poultry 165°F.	Temperature	Calibrated probe thermometer	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 2 Cooling	Pathogens	Cooling rate: From 135°F. to 70°F. in <2 hrs. And from 70°F. to <41°F. in < 4 hrs. from reaching 70°F.	Cooling rate (temp/time)	Calibrated probe thermometer	Time intervals throughout cooling; each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 3 De-hydrating	Pathogens	Weight loss	Product weight loss – Green weight and final weight	Calibrated scale	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step

Approved by:_____ Date:_____

Standard Operating Procedures: Uncured, Smoked Jerky

Establishment Name: _____

Only food establishment employees trained in the use of this process and who have a thorough understanding of the HACCP plan shall conduct this process.

1. **Receiving Raw Meat/Poultry:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider temperature at receipt as well as the condition of the packages. For what reasons would a shipment be rejected?

2. **Receiving Non-Refrigerated Ingredients and Packaging Materials:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients, and packaging materials to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider condition of the packages. For what reasons would a shipment be rejected?

3. **Cold Storage:** What are the required storage procedures to ensure the food is properly refrigerated and protected from contamination?

4. **Dry Storage:** What are the required procedures to ensure the food is properly stored and protected from contamination?

5. **Assemble and weigh meat, ingredients:** What instructions should an employee follow as they are preparing this product? Are the recipe(s) available for use during preparation? Are there requirements for time and temperature control? What is required for size of the pieces of meat to ensure uniform drying?

6. **Marination:** How is the marinade prepared? What containers are to be used for marinating? Where will the product be held? Is there a required temperature? How long will the product be marinated?

7. **Cooking or Smoking (CCP 1):** What equipment will be used to cook or smoke the product? Are humidity controls required? If the instructions are different for different products, either provide instructions for each product category with a list of category products, or refer to the recipe card for each product, or give other general instructions as appropriate.

    - Critical Limit: List the critical limits that must be monitored and met to keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

8. **Cooling (CCP 2):** What procedure will be used for cooling? How will each batch be cooled properly for safety?

    - Critical Limit: List the critical limits that must be monitored and met to keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

9. **Dehydrating (CCP 3):** What equipment will be used to dehydrate the product? What operating parameters (temperature and humidity) must be controlled for proper drying, to ensure the product will be safe? How will these operating conditions be monitored and controlled?

    - Critical Limit: List the critical limits that must be monitored and met to keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

10. **Package and Label:** How will the finished product be packaged? Is the atmosphere in the package modified in any manner (vacuum packaging or use of oxygen scrubber pillows)? Where will the product be held? Is there a required temperature? What is the shelf life? If date marking is required, how are the required days to be counted?

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

Use of Cure Agent (nitrite):9 CFR Part 424, https://www.ecfr.gov/current/title-9/chapter-III/subchapter-E/part-424

USDA FSIS document "Cured Meat and Poultry Product Operations, https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/fplic-5a-cured-meat-and-poultry-operations.pdf

"FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) December, 2021" (lethality and alternative lethality requirements based on temperature and humidity): https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf

"Processing Procedures- Dried Meats" (surface pH reduction): , https://www.academia.edu/42833096/PROCESSING_PROCEDURES_DRIED_MEATS

Quick Guide on Processing Jerky (International HACCP Alliance): http://www.haccpalliance.org/sub/food-safety/compliance_guideline_jerky.pdf

Process: Curing & Smoking Sausage, Non-Shelf Stable, ROP Packaged

Hazard Analysis Table: Curing & Smoking Sausage, Non-Shelf Stable, ROP Packaged

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Meats & Poultry (1)	**B:** *E. coli* (STECs), *Salmonella*; Parasites in pork (*Trichinella spiralis*, *Toxoplasma gondii*)	No	Approved supplier must ensure parasite-free pork; receiving procedure	- Approved suppliers (Letters of Guaranty) - Inspected at receiving (temperature, damage)	No
	C: None identified				
	P: None identified				
Receiving Non-Meat Ingredients (2)	**B:** Pathogens	No	Approved supplier, purchase specifications, inspection upon receipt	- Approved suppliers (Letters of Guaranty) - Inspected at receiving (temperature, damage)	No
	C: Deleterious Chemicals	No			
	P: Foreign Material	No			
Cold Storage of Raw Meats & Poultry (3)	**B:** Growth of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*	No	Controlled by proper refrigeration, sanitation, and storage procedures	- Proper storage - Proper refrigeration - SSOP	No
	C: None identified				
	P: None identified				
Dry/Cold Storage of Non-Meat Ingredients (4)	**B:** None identified		Controlled by proper refrigeration, sanitation, and storage procedures	- Proper storage (cure salt in secure location; other ingredients dry storage) - SSOP	No
	P: Introduction of Foreign Material	No			
	C: None identified				
Tempering of Meat (5)	**B:** Growth or cross contamination with pathogens: *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*	No	Improper refrigeration and storage can result in growth and/or cross contamination – controlled by SOPs	- Minimize time product is in the temp. danger zone - SSOP	No
	C: None identified				
	P: None identified				

Assemble Ingredients (6)	**B:** Cross contamination with *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*; Norovirus, Hepatitis A	No	Time/temperature control prevents growth of pathogens; potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- Follow SOP, recipe - SSOP, cross-contamination controls - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Cut or Grind Meat (7)	**B:** Cross contamination with *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*; Norovirus, Hepatitis A	No	**B:** Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies **P:** Controlled by SSOP	- SSOP - Employee Health & Hygienic Practices - Operating SOP	No
	C: None identified				
	P: Introduction of foreign material (metal fragments)	No			
Weigh Meat (8)	**B:** Cross contamination with *Salmonella*, *E. coli* O157:H7, *Campylobacter*, *Listeria*; Norovirus, Hepatitis A	No	Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Weigh Ingredients and Cure (9)	**B:** Cross contamination with *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*; Norovirus, Hepatitis A	No	Failure to follow recipe, procedures can result in contamination Inaccurate weighing can result in toxic level of nitrite or growth & toxin formation by *C. botulinum*	- SSOP; Scale Calibration; Recipe/SOP - Employee Health & Hygienic Practices - Correct weight of nitrite cure per pound of meat	YES CCP 1
	C: Excessive Nitrite; botulism toxin formation	Yes			
	P: None identified				
Mix Meat, Ingredients, Cure (10)	**B:** Cross contamination with *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*; Norovirus, Hepatitis A	No	Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- SSOP - Employee Health & Hygienic Practices - Process SOP	No
	C: None identified				
	P: None identified				
Stuff (11)	**B:** Cross contamination with Pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, *Staph;* human-transmitted viruses	No	Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- Follow SOP (casing diameter and use of mold) - SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				

Smoke/Cook (12)	**B:** Survival of pathogens: *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, *Staph* **C:** None identified **P:** None identified	Yes	Undercooking may result in survival of pathogens	- Cook or smoke to required temperature per SOP - Temperature, Humidity controls - SSOP - Process SOP	YES CCP 2
ROP Packaging & Labeling (13)	**B:** Multiplication or cross contamination: *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria monocytogenes*; *Shigella*, Norovirus, Hepatitis A **C:** None identified **P:** None identified	No	Short handling time limits potential growth of pathogens; hazard is controlled by cooking (in-house) at later step Improperly Labeling results in outdated & potentially unsafe products	- Minimize time product is in the temp. danger zone - Label product: name, date packed, 'Use-By' date - SSOP, Employee Health & Hygienic Practices - Subsequent kill step - all but *Clostridium* spores - Use-by date and storage, handling, and cooking instructions if sold for home use	No
Cool (14)	**B:** Germination of Clostridia spp. spores **C:** Botulism toxin formation **P:** None identified	Yes No	Bacterial spores can activate if not cooled properly, resulting in toxin formation. Product is RTE, potential is higher for recontamination Activity and toxin formation by C. bot controlled by presence of nitrite	- Cool within allowed time (per SOP) - SSOP - Employee Health & Hygienic Practices	No CCP 3
Cold Hold (15)	**B:** Cross contamination with pathogens if not properly protected: *Salmonella*, and *E. coli* O157:H7, *Listeria* **C:** None identified **P:** None identified	No	Recontamination by improper storage of RTE food could result in recontamination – controlled by Employee health and hygiene policies, storage SOP, SSOP	- Monitor date marks for expiration and proper rotation - Maintain temperature at or below 41oF. - SSOP and storage SOP - Employee Health & Hygienic Practices	YES CCP 4
Service or Consumer Sale (16)	**B:** Recontamination with pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, *Staph;* human-transmitted viruses **C:** None identified **P:** None identified	No	Recontamination by improper handling of RTE food prevented by following SSOP, Employee Health and Hygiene Policies, and proper handling or serving procedures	- Controlled by - SSOP - Employee Health and Hygiene Practices	No

HACCP Summary Table: Curing & Smoking Sausage, Non-Shelf Stable, ROP Packaged

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Weight of Cure (nitrite)	**C:** Excessive Nitrite; Botulinum toxin formation	(##) oz. pink salt /(##) lbs. of meat	Weight of cure (per recipe)	Calibrated scale	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 2 Smoke / Cook	**B:** Destruction of pathogens	Whole muscle beef, pork 145°F./15 seconds Ground beef, pork 145°F./15 seconds Poultry 165°F.	Internal temperature	Calibrated probe thermometer	Each batch	Who is responsible for monitoring the critical limit at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 3 Cooling	**B:** Spore-forming pathogens	a. Cool from 135°F. to <70°F. in < 2 hrs.; & b. Cool from 70°F. to 41°F. or lower in <4 hrs.	Internal temperature (cooling rate)	Calibrated probe thermometer	3 sausages per batch, each batch	Who is responsible for monitoring the critical limit at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 4 Cold holding / date mark expiration	**B:** *Listeria* and other pathogens	Hold at 41°F. or lower	Cooler temperature	Calibrated thermometer & temp data logger	2x daily	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
		Not to exceed 7 days shelf life	Date mark expiration	Visual – examine labels	Daily				

Approved by:_____ Date:_____

Standard Operating Procedures: Curing & Smoking Sausage, Non-Shelf Stable, ROP Packaged

Establishment Name: _____

Only food establishment employees trained in the use of this process and who have a thorough understanding of the HACCP plan shall conduct this process.

1. **Receiving Raw Meat/Poultry:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider temperature at receipt as well as the condition of the packages. For what reasons would a shipment be rejected?

2. **Receiving Restricted and Non-Restricted Ingredients, Casings:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients, and packaging materials to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider condition of the packages. For what reasons would a shipment be rejected?

3. **Cold Storage:** What are the required storage procedures to ensure the food is properly refrigerated and protected from contamination?

4. **Dry Storage:** What are the required procedures to ensure the ingredients, casings, and packaging are properly stored and protected from contamination?

5. **Tempering of Meat:** Where will the meat be held for tempering before preparing and mixing? What temperature is required for safe tempering?

1. **Assemble Ingredients:** What work area is to be used for staging and weighing ingredients? Is this area separated from other workspaces in order to prevent possible cross contamination? Are the recipes available for use during preparation? What batch record will be maintained for this step and the remaining steps?

2. **Cut or Grind Meat:** For whole muscle sausages, how is the meat to be cut to ensure uniform curing? For comminuted sausages, what grinding instructions are to be followed? Refer to the recipe card for each product, and give other general instructions as appropriate.

3. **Weigh Meat:** Give weighing instructions. What is used to hold the meat for weighing? Is calibration of the scale necessary? Refer to the recipe card and scale calibration procedure as appropriate.

4. **Weigh Ingredients and Cure (CCP 1):** What is to be used to hold the ingredients for weighing? Is calibration of the scale necessary? Provide specific instructions for weighing the exact amount of pink salt to be used for the batch. What curing salt product is used? Refer to the recipe card and scale calibration procedure as appropriate.

    - Critical Limit: List the critical limits that must be monitored and met to keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

- Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

5. **Mix Meat, Ingredients, and Cure:** How will the meat and other ingredients be mixed? What equipment is required?

6. **Stuffing:** What type and diameter of casing is to be used? How are the sausages for this batch to be identified? Provide other instructions as necessary to properly perform this step.

7. **Smoking/Cooking (CCP2):** Provide instructions for operation of the smokehouse. How will product temperatures be monitored? What temperature and humidity controls are required?

    - Critical Limit: List the critical limits that must be monitored and met to make and keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? Where are instructions to be found for calibration and use of instruments for monitoring? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

8. **ROP Packaging and Labeling (*CCP if sold for consumer use):** Provide instructions for an **employee** to follow as they are preparing to vacuum package a product. Provide instructions for operation of the vacuum packaging machine. How should an employee package/seal appropriately, label the product, determine the expiration date, and any other requirements or concerns related to this step? If product will be sold for consumer use, what safe storage, handling, and cooking instructions will be provided on the label for consumers?

9. **Cooling (CCP 3):** What procedure will be used for cooling? How will the batch be cooled properly for safety?

    - Critical Limit: List the critical limits that must be monitored and met to keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

10. **Cold Holding (CCP 4):** Where will finished product be stored for future use or sale? How is product to be stored to protect from cross contamination?

    - Critical Limit: List the critical limits that must be monitored and met to make and keep the product safe. Note that this is an ROP cook-chill process, which requires continuous electronic temperature monitoring; the logging device must be inspected twice daily for operation.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the Critical Limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

11. **Service**: Serve according to menu or recipe guidelines. Be careful to avoid recontamination by servers by observing PRPs for Employee Health and Hygiene.

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

Cooking, cooling, and cold storage/shelf life: FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

Use of Cure Agent (nitrite):9 CFR Part 424, https://www.ecfr.gov/current/title-9/chapter-III/subchapter-E/part-424

USDA FSIS document "Cured Meat and Poultry Product Operations, https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/fplic-5a-cured-meat-and-poultry-operations.pdf

"Sausages and Food Safety" (shelf life of cured sausages and deli meats): https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation/sausages-and-food-safety/ct_index

Process: Curing & Fermenting Dry, Shelf-Stable or Semi-Dry, Non-Shelf Stable Sausages, ROP Packaged

Hazard Analysis Table: Curing & Fermenting Dry, Shelf-Stable or Semi-Dry, Non-Shelf Stable Sausages, ROP Packaged

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Meat & Poultry (1)	**B:** Pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*; *Trichinella*, *Toxoplasma gondii*)	No	Approved supplier must ensure parasite-free pork; Receiving procedure	- Approved suppliers (Letters of Guaranty) - Inspected at receiving (temperature, damage)	No
	C: None identified				
	P: None identified				
Receiving Restricted & Non-Restricted Ingredients (2)	**B:** Introduction of pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Approved supplier, purchase specifications, inspection upon receipt	- Approved suppliers (Letters of Guaranty) - Inspected at receiving (temperature, damage)	No
	C: Presence of deleterious chemicals	No			
	P: Presence of foreign material	No			
Cold Storage (3)	**B:** Growth of pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*)	No	Controlled by proper refrigeration, sanitation, and storage procedures	- -Proper storage - -Proper refrigeration - -SSOP	No
	C: None identified				
	P: None identified				
Dry/Cold Storage of Non-Meat Ingredients, Cultures (4)	**B:** Growth of *Listeria*	No	Controlled by proper refrigeration, sanitation and storage procedures	- -Proper storage (cure salt in secure location; cultures stored according to supplier procedures; other ingredients dry storage) - -SSOP	No
	C: None identified				
	P: Introduction of Foreign Material	No			
Tempering (5)	**B:** Growth or cross contamination with pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Improper refrigeration and storage can result in growth and/or cross contamination – controlled by SOPs	- Minimize time product is in the temp. danger zone - SSOP	No
	C: None identified				

	P: None identified				
Assemble Ingredients, Prepare Cultures (6)	**B:** Growth or cross contamination with pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Time/temperature control prevents growth of pathogens; potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- Follow culture prep instructions, recipe and SOP - SSOP, cross-contamination controls - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Cut or Grind Meat (7)	**B:** Growth or cross contamination with Pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	B) Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies P) controlled by SSOP	- SSOP - Employee Health & Hygienic Practices - Operating SOP	No
	C: None identified				
	P: Introduction of Metal	No			
Weigh Meat (8)	**B:** Growth or cross contamination with pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- Follow recipe and SOP - SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Weigh Ingredients and Cure (9)	**B:** None identified		Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies Accurate weighing prevents toxic level of nitrite, and prevents growth & toxin formation by *C. botulinum*	- SSOP; Scale Calibration; Recipe/SOP - Employee Health & Hygienic Practices - Correct Weight of cure salt per pound of meat	YES CCP 1
	C: Excess Nitrite	Yes			
	P: None identified				
Mix Meat, Ingredients, Cure (10)	**B:** Growth or cross contamination with pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- SSOP - Employee Health & Hygienic Practices - Process SOP	No
	C: None identified				
	P: None identified				
Stuff (11a) Apply Mold (11b)	**B:** Growth or cross contamination with pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- Process SOP (casing diameter and use of mold) - SSOP	No
	C: None identified				

	P: None identified			- Employee Health & Hygienic Practices	
Ferment (12)	**B:** Growth of pathogens and toxin formation (*Staphylococcus aureus*)	Yes	pH must drop quickly to prevent growth of pathogens – especially *Staph;* high humidity + temperature help control or destroy other pathogens	- Reduce pH within allowed degree-hours - Temperature, Humidity controls - SSOP - Process SOP	YES CCP 2
	C: None identified				
	P: None identified				
Weigh (13)	**B:** Growth or cross contamination with pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- Process SOP - SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Dry (14)	**B:** Cross contamination and survival of *Salmonella*, and *E. coli* O157:H7, *Listeria*	Yes	Product must be dried to achieve safe level of water activity to prevent growth of pathogens; drying at high humidity and helps eliminate *E. coli* O157:H7	- Reduce weight to targeted % weight loss per SOP - Temperature, Humidity controls - SSOP - Employee Health & Hygienic Practices	YES CCP 3
	C: None identified				
	P: None identified				
Vac Pac and Labeling (15)	**B:** Growth or cross contamination with pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Short handling time limits potential growth of pathogens; hazard is controlled by cooking (in-house) at later step Improperly Labeling results in outdated & potentially unsafe products	- Minimize time product is in the temp. danger zone - Label product: name, date packed, 'Use-By' date - SSOP, Employee Health & Hygienic Practices - Subsequent kill step - all but *Clostridium* spores - Use-By date and storage, handling and cooking instructions if sold for home use	No
	C: None identified				
	P: None identified				
Storage (16)	**B:** Growth of *Listeria monocytogenes*	No	Potential for recontamination from environment or cross contamination limited by proper storage procedures, SSOP	- SSOP - Storage procedures - *CCP (temp. & date mark) only if non-shelf stable; may affect step 18	No
	C: None identified				
	P: None identified				
Prepare (17a) or	**B:** Growth or cross contamination with pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Potential recontamination from handling - controlled by other policies/SOPs	- SSOP - Employee Health & Hygienic Practices	No

Sale to customer (17b)	**C:** None identified				
	P: None identified				
Cook (18) (Optional step)	**B:** Growth or cross contamination with pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Dry sausages do not require cooking to be safe; but when included in recipes with other foods, proper cooking, handling, and clean/sanitary equipment are required to prevent contaminating RTE food CCP is not required for this product unless sausage is semi-dry (NRTE)	- Proper cooking according to recipe & SC Reg. 61-25 - SSOP, Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Service (19)	**B:** Growth or cross contamination with pathogens (*Salmonella*, and *E. coli* O157:H7, *Campylobacter*)	No	Potential recontamination from handling - controlled by other policies/SOPs	- SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				

HACCP Summary Table: Curing & Fermenting Dry, Shelf-Stable or Semi-Dry, Non-Shelf Stable Sausages, ROP Packaged

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Weight of Cure (nitrite)	**B:** Pathogens **C:** Nitrite	(##) oz. pink salt/(##) lbs. of meat	Weight of cure (per recipe)	Calibrated scale	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 2 Ferment	**B:** *Listeria*; *Staph*	pH <5.3 within (allowed no. of hours)	pH and time	Calibrated pH meter	Each batch	Who is responsible for monitoring the critical limit at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 3 Drying	Pathogens	Lose at least 30% of green weight	Initial weight & final weight of min. of 3 sausages	Calibrated scale	3 sausages per batch, each batch	Who is responsible for monitoring the critical limit at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.

Approved by:_____ Date:_____

Standard Operating Procedures: Curing & Fermenting Dry, Shelf-Stable or Semi-Dry, Non-Shelf Stable Sausages, ROP Packaged

Only food establishment employees trained in the use of this process and who have a thorough understanding of the HACCP plan shall conduct this process.

1. **Receiving Raw Meat/Poultry:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider temperature at receipt as well as the condition of the packages. For what reasons would a shipment be rejected?

2. **Receiving Restricted and Non-Restricted Ingredients, Casings:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients, and packaging materials to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider condition of the packages. For what reasons would a shipment be rejected?

3. **Cold Storage:** What are the required storage procedures to ensure the food is properly refrigerated and protected from contamination?

4. **Dry Storage:** What are the required procedures to ensure the ingredients, casings, and packaging are properly stored and protected from contamination? How and where are fermentation and mold cultures to be stored? Frozen, refrigerated, or ambient?

5. **Tempering of Meat:** Where will the meat be held for tempering before preparing and mixing? What temperature is required for safe tempering?

6. **Assemble Ingredients, Prepare Cultures:** What work area is to be used for staging and weighing ingredients? Is this area separated from other workspace in order to prevent possible cross contamination? Are the recipes available for use during preparation? How are the fermentation and mold cultures to be prepared for use? (Provide detailed instructions.) What batch record will be maintained for this step and the remaining steps?

7. **Cut or Grind Meat:** For whole muscle sausages, how is the meat to be cut to ensure uniform curing? For comminuted sausages, what grinding instructions are to be followed? Refer to the recipe card for each product, and give other general instructions as appropriate.

8. **Weigh Meat:** Give weighing instructions. What is used to hold the meat for weighing? Is calibration of the scale necessary? Refer to the recipe card and scale calibration procedure as appropriate.

9. **Weigh Ingredients and Cure (CCP 1):** What is to be used to hold the ingredients for weighing? Is calibration of the scale necessary? Provide specific instructions for weighing the exact amount of pink salt to be used for the batch. Which specific curing salt product is used? Refer to the recipe card and scale calibration procedure as appropriate.

    - Critical Limit: List the critical limits that must be monitored and met to keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

- Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

10. **Mix Meat, Ingredients, and Cure:** How will the meat and other ingredients be mixed? What equipment is required?

11. **a. Stuffing:** What type and diameter of casing is to be used? How are the sausages for this batch to be identified? Provide other instructions as necessary to properly perform this step.

    b. Apply mold culture: How is the mold culture prepared and applied? Provide other instructions as necessary to properly perform this step. Refer to the recipe, as appropriate.

12. **Fermenting (CCP2):** Provide instructions for the fermentation step. What fermentation temperature and humidity are required to achieve proper fermentation? What is the GOAL for time to reach the required pH? What is the maximum time allowed to reach the required pH? How many "test" portions of product are designated for required monitoring? How are the test portions to be marked? Is there a system that must be followed to properly organize batches of sausages in the fermentation chamber?

    - Critical Limit: What is the pH target for fermentation, and what is the maximum number of hours allowed to reach that target? Note that the allowed time in degree-hours is dependent on the fermentation temperature.

    - Monitoring: What procedure is to be followed to test the sausage pH? Where are instructions to be found for calibration and use of the pH meter? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

13. **Initial Weighing:** How many sausages from each batch will be weighed (green weight) to monitor drying? How are these sausages marked for monitoring? Where is this data recorded? Which scale is to be used?

14. **Drying (CCP 3):** Provide instructions for monitoring weight loss as sausages are dried.

    Percent weight loss = Subtract dried weight (DW) from green weight (GW). Multiply the result by 100. Then divide by the green weight (GW) to determine percent weight loss.

    $$\text{Percent weight loss} = \frac{(GW - DW) \times 100}{GW}$$

    - Critical Limit: List the weight loss target for each product, as a percent of the green weight.

- Monitoring: How will measurements be made to ensure that each critical limit has been met? What scale is to be used? What records will be maintained to demonstrate compliance with the critical limits?

- Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

15. **Vacuum Packaging & Labeling:** Provide instructions for an employee to follow as they are preparing to vacuum package a product. Provide instructions for operation of the vacuum packaging machine. How should an employee package/seal appropriately, label the product, determine the expiration date, and any other requirements or concerns related to this step?

16. **Storage or Merchandising finished product:** What are the instructions for properly storing the vacuum packaged, dry cured products? Where will product be stored for in-house use or for merchandising display?

17. **Preparation #2:** What instructions are to be followed for final preparation of the product before it is cooked and served?

18. **Cooking:** Cooking is not normally required for fermented dry sausages. However, if the sausage is used in a recipe with other ingredients that require cooking, refer to the recipes here for each sausage product used in this manner. All recipes are to be cooked to appropriate temperatures as required by state or local regulations.

19. **Service**: Serve according to menu or recipe guidelines. Careful to avoid recontamination by servers by observing PRPs for Employee Health and Hygiene.

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

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Use of Cure Agent (nitrite):9 CFR Part 424, https://www.ecfr.gov/current/title-9/chapter-III/subchapter-E/part-424

USDA FSIS document "Cured Meat and Poultry Product Operations, https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/fplic-5a-cured-meat-and-poultry-operations.pdf

"FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) December, 2021" (lethality and alternative lethality requirements based on temperature and humidity), https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf

Processing Procedures- Dried Meats:
https://www.academia.edu/42833096/PROCESSING_PROCEDURES_DRIED_MEATS

Good Manufacturing Practices For Fermented Dry & Semi-Dry Sausage Products (pH requirements, degree-hours requirements):
https://meathaccp.wisc.edu/Model_Haccp_Plans/assets/GMP%20Dry%20Sausage.pdf

“Sausages and Food Safety” (shelf life of cured sausages and deli meats):
https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation/sausages-and-food-safety/ct_index

Process: Cured & Cooked Whole Muscle

Hazard Analysis Table: Cured & Cooked Whole Muscle

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Meats & Poultry (1)	**B:** ***E. coli***/STECs; *Salmonella*; *Trichinella*, *Toxoplasma gondii* in pork	No	Approved supplier must ensure parasite-free pork; Receiving procedure	- Approved suppliers (Letters of Guaranty) - Inspected at receiving for proper temperature, undamaged	No
	C: None identified				
	P: None identified				
Receiving Packaging Materials (2)	**B:** None identified		Approved supplier, purchase specifications, inspection upon receipt	- Approved suppliers (Letters of Guaranty) - Receiving inspection	No
	C: Deleterious Chemicals	No			
	P: Foreign Material	No			
Cold Storage of Raw Meats & Poultry (3)	**B:** Growth of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*	No	Improper refrigeration and storage can result in growth and/or cross contamination – controlled by SOPs	- Proper storage - Proper refrigeration - SSOP	No
	C: None identified				
	P: None identified				
Dry Storage of Non-Meat Ingredients (4)	**B:** *Listeria*	No	Cross contamination possible from improper storage or unsanitary storage controlled by SOPs	- Proper storage - SSOP	No
	C: None identified				
	P: Foreign Material	No			
Assemble & Weigh Meat & Ingredients (5)	**B:** Introduction of *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, human-transmitted viruses	No	Growth of pathogens, spores (temp. abuse) & cross contamination possible	- Minimize time in the temp. danger zone - SSOP	Yes CCP 1

	C: Nitrate	Yes	(handling) controlled by Employee Health & Hygiene policies, SSOP Too much or too little nitrite is potentially hazardous	- Employee Health & Hygiene - Follow SOP/recipe; calibrated scale to weigh ingredients – ratio of cure to protein per recipe	
	P: None identified				
Mix & Marinate – "Curing" (6)	**B:** Introduction of human-transmitted pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, etc.	No	Growth of pathogens, spores (temp. abuse) & cross contamination possible (handling) controlled by Employee Health & Hygiene policies, SSOP	- Temperature control - Process SOP - SSOP	No
	C: None identified				
	P: None identified				
Rinse (7)	**B:** Introduction of human-transmitted pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, human-transmitted viruses	No	Growth of pathogens, spores (temp. abuse) & cross contamination possible (handling) controlled by Employee Health & Hygiene policies, SSOP	- Process SOP - SSOP, Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Cooking (8)	**B:** Survival of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, etc.	Yes	Cooking to proper temp/time required to destroy parasites and vegetative pathogens	- Proper cooking per SOP and recipe - Process SOP - SSOP, Employee Health & Hygienic Practices	Yes CCP 2
	C: None identified				
	P: None identified				
Package (optional) & Label (9)	**B:** Introduction of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, human-transmitted viruses	No	Potential recontamination controlled by SSOP, Employee Health and Hygiene Policies	- Process SOP - SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Cooling (10)	**B:** Growth of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, *Clostridium perfringens*.	Yes	Improper cooling can result in activation of spores, toxin formation; potential recontamination controlled by other policies/procedures	- Proper cooling per SOP - SSOP	Yes CCP 3
	C: None identified				
	P: None identified				

Storage (11)	**B:** *Listeria*; other pathogens	Yes	Potential for recontamination from environment or cross contamination limited by packaging; proper temperature control and date marking control potential growth of pathogens re-introduced after cooking	- Controlled by proper refrigerated storage, date marking and sanitation procedures (SSOP)	Yes CCP 4
	C: None identified				
	P: None identified				
Service (12)	**B:** Introduction of *Salmonella***,** and *E. coli* O157:H7, *Campylobacter*, *Listeria*, human-transmitted viruses	No	Potential recontamination from handling - controlled by other policies/SOPs	- SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				

HACCP Summary Table: Cured & Cooked Whole Muscle

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Assembling and weighing ingredients and cure	**C:** Nitrite	Amt of cure #1 per Kg protein (applied according to recipe)	Weight ratio of cure to protein	Calibrated scale	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 2 Cooking	**B:** Survival of Pathogens	Cook temps: List required temps and times here.	Internal product temperature	Calibrated stem thermometer	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 3 Cooling	**B:** Growth of Pathogens	Cooling from: ambient to 135°F. to 70°F. <2 hrs. and 135°F. to <41°F. in < 6 hrs. total time	Cooling rate (temp/time)	Calibrated probe thermometer	Time intervals throughout cooling; each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if the critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 4 Cold Storage	**B:** Growth of Pathogens	<41°F.	Cooler temperature	Stem thermometer	Check 2x daily, a.m. and p.m.	Who is responsible for monitor the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.

Approved by:_____ Date:_____

Standard Operating Procedures: Cured & Cooked Whole Muscle

Establishment Name: _____

Only food establishment employees trained in the use of this process and who have a thorough understanding of the HACCP plan shall conduct this process.

1. **Receiving Raw Meat/Poultry:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider temperature at receipt as well as the condition of the packages. For what reasons would a shipment be rejected?

2. **Receiving Non-Refrigerated Ingredients and Packaging Materials:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients, and packaging materials to ensure that they are acceptable for use, i.e., safe and not contaminated? Consider condition of the packages? For what reasons would a shipment be rejected?

3. **Cold Storage:** What are the required storage procedures to ensure the food is properly refrigerated and protected from contamination?

4. **Dry Storage:** What are the required procedures to ensure the unrestricted and restricted ingredients and materials are properly stored and protected from contamination?

5. **Assemble and weigh meat, ingredients (CCP 1):** What instructions should an employee follow as they are preparing this product for curing? How is the meat prepared before applying brine or marinade? Are there requirements for time and temperature control? Are the recipe(s) available for use during preparation? What is the strength of the nitrite (and nitrate if applicable) in the cure salt? If a dry rub, will the cure mixture be applied more than once, and if so, at what frequency? What containers are to be used for marinating? Do these containers allow for drainage of the meat juices during the cure process? **Refer to product recipes as needed.**

    - Critical Limit: List the critical limits (weight of cure salt or cure mixture applied to protein) that must be monitored and met to keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For each critical limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

6. **Curing:** How will the cure be applied to the product? Where will the product be held? What is the required temperature? How long will the product be cured? Refer to product recipe as needed.

7. **Rinsing:** After cure is completed, will the product be rinsed before moving to the cooking step? Provide instructions for how and where the rinsing will be accomplished.

8. **Cooking (CCP 2):** What procedure will be used for cooking? Refer to product recipes as needed.

    - Critical Limit: What is the required minimum internal cooking temperature for each type of product?

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For the critical limit at each phase of cooling, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

9. **Vacuum Package (optional) and Label:** How will the finished product be packaged? (NOTE: **If the cooked product will be vacuum packaged, the product must be packaged while still above 135°F.)** What handling and sanitary controls are necessary? Where will the product be held? Is there a required temperature? Does the product require a date mark? If date marking is required, how are the required days to be counted?

10. **Cooling (CCP 3):** What procedure will be used for cooling?

    - Critical Limit: What is the critical rate of cooling that must be monitored and met to keep the product safe? (How much time is allowed to cool from 135°F. to <41°F.?)

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

    - Corrective Action: For the critical limit at each phase of cooling, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

11. **Cold Storage (CCP 4):** Where will the finished products be stored? Is there a dedicated space for these items?

    - Critical Limit: What is the required storage temperature? What is the maximum shelf life of each product?

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the critical limits?

- Corrective Action: For each critical limit, what instructions are to be followed if the critical limit is not met? Is there more than one option for corrective action? If so, list the options.

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

12. **Service**: Serve according to menu or recipe guidelines. Be careful to avoid recontamination by servers by observing PRPs for Employee Health and Hygiene.

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

Use of Cure Agent (nitrite):9 CFR Part 424, https://www.ecfr.gov/current/title-9/chapter-III/subchapter-E/part-424

USDA FSIS document "Cured Meat and Poultry Product Operations, https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/fplic-5a-cured-meat-and-poultry-operations.pdf

"FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) December, 2021" (lethality and alternative lethality requirements based on temperature and humidity): https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf

Processing Procedures- Dried Meats: https://www.academia.edu/42833096/PROCESSING_PROCEDURES_DRIED_MEATS

Table of Safe and Suitable Ingredients: Antimicrobial Update 5/25/2017, FSIS Directive 7120.1 (use of acid rinse in lieu of lethality cooking step), https://www.fsis.usda.gov/wps/wcm/connect/24346cbd-ad28-4223-8db1-55f067ce3879/7120.1-Antimicrobials.pdf?MOD=AJPERES

Hams and Food Safety (required weight loss; shelf life) – USDA Food Safety and Inspection Service Fact Sheet, 1/7/2016, https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation/ham-and-food-safety/ct_index

Process: Curing & Drying Whole Muscle (No-Cook Process)

Hazard Analysis Table: Curing & Drying Whole Muscle (No-Cook Process)

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Meats & Poultry (1)	**B:** *E. coli*/STECs; *Salmonella*; *Trichinella*, *Toxoplasma gondii* in pork	Yes	Approved supplier must ensure parasite-free pork; receiving procedure; potential biological hazards are controlled by later process steps	- Approved suppliers (Letters of Guaranty) - Inspected at receiving for proper temperature, undamaged	No
	C: None identified				
	P: None identified				
Receiving Packaging Materials (2)	**B:** None identified		Approved supplier, purchase specifications, inspection upon receipt	- Approved suppliers (Letters of Guaranty) - Receiving inspection	No
	C: Deleterious Chemicals				
	P: Foreign Material				
Cold Storage of Raw Meats & Poultry (3)	**B:** Growth of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*	Yes	Improper refrigeration and storage can result in growth and/or cross contamination – controlled by SOPs	- Proper storage - Proper refrigeration - SSOP	No
	C: None identified				
	P: None identified				
Dry Storage of Non-Meat Ingredients (4)	**B:** *Listeria*	No	Cross contamination possible from improper storage or unsanitary storage controlled by SOPs	- Proper storage - SSOP	No
	C: None identified				
	P: Foreign Material				
Assemble & Weigh Meat & Ingredients (5)	**B:** Introduction of *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, human-transmitted viruses	No	Growth of pathogens, spores (temp. abuse) & cross contamination possible	- Minimize time in the temp. danger zone - SSOP	Yes CCP 1

	C: Nitrite	Yes	(handling) – controlled by Employee Health & Hygiene policies, SSOP Too much or too little nitrite is potentially hazardous	- Employee Health & Hygiene - Follow SOP/recipe; calibrated scale to weigh ingredients – ratio of cure to protein per recipe	
	P: None identified				
Prepare Acid Rinse/Dip (6)	**B:** None identified		Preparation at excessive concentration may result in toxicity in finished product – controlled by SOP	- Follow SOP, allowed strength as prescribed by regulation, and manufacturer instructions	No
	C: Preparation at concentration higher than allowed by regulation	Yes			
	P: None identified				
Acid Treatment of Meat Surface (7)	**B:** None identified		Acid rinse or dip serves to reduce or eliminate surface population of potential pathogens	- Follow SOP	No
	C: None identified				
	P: None identified				
Mix & Marinate – "Curing" (8)	**B:** Introduction of human-transmitted pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, etc.	No	Growth of pathogens, spores (temp. abuse) & cross contamination possible (handling) – controlled by Employee Health & Hygiene policies, SSOP	- Temperature control - Process SOP – 14-day curing process reduces likelihood of pathogen survival - SSOP	No
	C: None identified				
	P: None identified				
Prepare, Weigh, Hang (9)	**B:** Introduction of human-transmitted pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, human-transmitted viruses	No	Growth of pathogens, spores (temp. abuse) & cross contamination possible (handling) – controlled by Employee Health & Hygiene policies, SSOP	- Process SOP - SSOP, Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Smoking (10a) (OPTIONAL STEP)	**B:** Growth of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, etc.	No	Excessive time in temperature danger zone can result in spore activation, pathogen growth, toxin formation	- Process SOP - SSOP, Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Cooling (10b) (REQUIRED if smoked)	**B:** Growth of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, *Clostridium perfringens*	Yes	Improper cooling can result in activation of spores, toxin formation	- Proper cooling per SOP - SSOP	Yes CCP 2

	C: None identified		Potential recontamination controlled by other policies/procedures		
	P: None identified				
Dehydrate (11)	**B:** Growth of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*	Yes	Improper drying can allow growth of pathogens Potential recontamination controlled by other policies/procedures	- Dry according to SOP to required weight loss - SSOP	Yes CCP 3
	C: None identified				
	P: None identified				
Package & Label (12)	**B:** Introduction of pathogens, *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, human-transmitted viruses	No	Potential recontamination controlled by SSOP, Employee Health and Hygiene Policies	- Process SOP - SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Storage (13)	**B:** *Listeria*; other pathogens?	No	Potential for recontamination from environment or cross contamination limited by packaging	- Controlled by proper storage procedures and sanitation procedures (SSOP)	No
	C: None identified				
	P: None identified				
Service (14)	**B:** Introduction of *Salmonella*, and *E. coli* O157:H7, *Campylobacter*, *Listeria*, human-transmitted viruses	No	Potential recontamination from handling – controlled by other policies/SOPs	- SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				

HACCP Summary Table: Curing & Drying Whole Muscle (No-Cook Process)

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Assembling and weighing ingredients	**C:** Nitrite	Amt of Cure #1 per Kg protein (applied as dry rub)	Weight ratio of cure to protein	Calibrated scale	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 2 Cooling	**B:** Growth of Pathogens	Cooling from: Ambient to 70°F. to <41°F. in < 4 hrs.	Cooling rate (temp/time)	Calibrated probe thermometer	Time intervals throughout cooling; each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if the critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 3 De-hydrating	**B:** Growth of Pathogens	Minimum of 30% weight loss from green weight	Difference in product weight from green weight, as percent	Calibrated scale	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.

Approved by:_____ Date:_____

Standard Operating Procedures: Curing & Drying Whole Muscle (No-Cook Process)

Establishment Name: _____

Only food establishment employees trained in the use of this process and have a thorough understanding of the HACCP plan shall conduct this process.

1. **Receiving Raw Meat/Poultry:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use – safe and not contaminated? Consider temperature at receipt as well as the condition of the packages? For what reasons would a shipment be rejected?

2. **Receiving Non-Refrigerated Ingredients and Packaging Materials:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients and packaging materials to ensure that they are acceptable for use – safe and not contaminated? Consider condition of the packages? For what reasons would a shipment be rejected?

3. **Cold Storage:** What are the required storage procedures to ensure the food is properly refrigerated and protected from contamination?

4. **Dry Storage:** What are the required procedures to ensure the unrestricted and restricted ingredients and materials are properly stored and protected from contamination?

5. **Assemble and weigh meat, ingredients (CCP 1):** What instructions should an employee follow as they are preparing this product for curing? How is the meat prepared before applying brine or marinade? Are there requirements for time and temperature control? Are the recipe(s) available for use during preparation? Refer to product recipes as needed. What is the strength of the nitrite (and nitrate if applicable) in the cure salt?

    - Critical Limit: List the critical limits (weight of cure salt or cure mixture applied to protein) that must be monitored and met to keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the Critical Limits?

    - Corrective Action: For each Critical Limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

6. **Preparation of Acid Rinse/Dip:** What product will be used (trade name and chemical name)? What is the strength of that product? How much of that acid will be added per gallon of water? Refer to FSIS Directive 7120.1[47] for specific approved products and required strengths.

[47] https://www.fsis.usda.gov/wps/wcm/connect/24346cbd-ad28-4223-8db1-55f067ce3879/7120.1-Antimicrobials.pdf?MOD=AJPERES

7. **Acid Treatment of Meat Surface:** Is the acid solution applied as a rinse, or is the product dipped into the solution? If dipped, how long will the product remain in the solution? How is excess acid solution removed from product surface – is it allowed to drain? Patted dry?

8. **Mixing and Marination:** How is the marinade prepared? If a dry rub, will the cure mixture be applied more than once, and if so, at what frequency? What containers are to be used for marinating? Do these containers allow for drainage of the meat juices during the cure process? Where will the product be held? What is the required temperature? How long will the product be marinated? Refer to product recipes as needed.

9. **Prepare for dehydration and smoking:** Will the cured (marinated) product require rinsing? How much time is allowed for this step, or how will temperature control be maintained? What instructions are to be followed to prepare the product for dehydration (and for cold smoking, if applicable)? Refer to product recipes as needed.

10. **(OPTIONAL) Smoking (10a) and Cooling (10b, CCP 2):** What procedure will be used for cooling? How will each batch be cooled properly for safety?

    - Critical Limit: What is the critical rate of cooling that must be monitored and met to keep the product safe? (How much time is allowed to cool from ambient or smoking temperature to <41°F.?)

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the Critical Limits?

    - Corrective Action: For the Critical Limit at each phase of cooling, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

11. **Dehydrating (CCP 3):** What equipment will be used to dehydrate the product? What are the required temperature and humidity settings, to ensure a safe and uniformly dried product? How will these operating conditions be monitored and controlled? (NOTE: A hygrometer or other equivalent instrument is necessary for monitoring relative humidity.) What is the weight loss target value for desired quality?

    - Critical Limit: What is the critical limit for minimum weight loss percentage that must be monitored and met to keep the product safe?

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the Critical Limits?

    - Corrective Action: What instructions are to be followed if the critical limit is not met?

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective? Who is responsible, and how often will this activity occur?

12. **Package and Label:** How will the finished product be packaged? What handling and sanitary controls are necessary? Where will the product be held? Is there a required temperature? Does the product require a date mark? If date marking is required, how are the required days to be counted?

13. **Storage:** What storage conditions are required for storage of products from this process? What equipment is used for storing these products?

14. **Service**: Serve according to menu or recipe guidelines. Careful to avoid recontamination by servers by observing PRPs for Employee Health and Hygiene.

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

Use of Cure Agent (nitrite): 9 CFR Part 424 and USDA FSIS document "Cured Meat and Poultry Product Operations," https://www.ecfr.gov/current/title-9/chapter-III/subchapter-E/part-424, https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/fplic-5a-cured-meat-and-poultry-operations.pdf

"FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) December, 2021" (lethality and alternative lethality requirements based on temperature and humidity): https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf

Processing Procedures- Dried Meats: https://www.academia.edu/42833096/PROCESSING_PROCEDURES_DRIED_MEATS

Table of Safe and Suitable Ingredients: Antimicrobial Update 5/25/2017, FSIS Directive 7120.1 (use of acid rinse in lieu of lethality cooking step), https://www.fsis.usda.gov/wps/wcm/connect/24346cbd-ad28-4223-8db1-55f067ce3879/7120.1-Antimicrobials.pdf?MOD=AJPERES

Hams and Food Safety (required weight loss; shelf life) – USDA Food Safety and Inspection Service Fact Sheet, 1/7/2016, https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation/ham-and-food-safety/ct_index

Process: Preserving Fish by Hot Smoking

Hazard Analysis Table: Preserving Fish by Hot Smoking

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards? B: Biological C: Chemical P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Fish (scombroid & non-scombroid species) (1)	**B:** Pathogenic bacteria; parasites	No	Smoking/cooking controls bacteria Freezing destroys parasites Use mercury-free species only Use headed & gutted fish only	- Approved suppliers (Letters of Guaranty) - Inspected at receiving (temperature, damage)	No
	C: Mercury	No			
	P: None identified				
Receiving Non-Meat Ingredients (2)	**B:** Pathogens	No	Approved supplier, purchase specifications, inspection upon receipt	- Approved suppliers (Letters of Guaranty) - Inspected at receiving (temperature, damage) - Use only canners grade (pickling) salt	No
	C: Deleterious Chemicals	No			
	P: Foreign Material	No			
Frozen Storage (3)	**B:** Pathogen growth (*C. botulinum*, *Listeria*)	No	Controlled by freezing, sanitation and storage procedures	- Frozen storage until needed - SSOP	No
	C: None identified				
	P: None identified				
Dry/Cold Storage of Non-Meat Ingredients (4)	**B:** None identified		Controlled by proper sanitation and storage procedures	- Proper storage - SSOP	No
	P: None identified				
	C: None identified)				

Tempering of Fish – Partial Thawing (5)	**B:** Growth or cross contamination with pathogens: *C. botulinum*, *Listeria*	No	Refrigeration control <40°F. and limiting to partial thawing controls potential growth of pathogens. Potential for cross contamination controlled by proper storage and SSOP.	- Product must remain partially frozen at time of butchering - SSOP	No
	C: None identified				
	P: None identified				
Preparation of Brine (6)	**B:** Pathogen growth during smoking and in final product	Yes	Human error or failure to follow recipe or required brining time can result in pathogen growth during smoking or in final product.	- Brine prepared and held cold until needed - SSOP; Scale Calibration; Recipe/SOP - Employee Health & Hygienic Practices -	YES CCP 1A
	C: None identified				
	P: None identified				
Butchering (7)	**B:** Growth or cross contamination with pathogens: *C. botulinum*, *Listeria*; cross contamination with human-transmitted pathogens	No	Cold processing temperature and limited time prevent growth of pathogens. Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- Limit processing time; maintain cool processing environment - SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Rinsing (8)	**B:** Cross contamination with human-transmitted pathogens or *Listeria*	No	Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- Fish rinsed in fresh water at < 70°F. to remove debris - SSOP - Employee Health & Hygienic Practices	No
	C: None identified				
	P: None identified				
Brining (9)	**B:** Pathogen growth during smoking and in final product	Yes	Human error or failure to follow recipe or required brining time can result in pathogen growth during smoking or in final product	- Brine prepared and held cold until needed - SSOP; Scale Calibration; Recipe/SOP - Employee Health & Hygienic Practices	YES CCP 1B
	C: None identified				
	P: None identified				
Rinsing (10)	**B:** Cross contamination with human-transmitted pathogens or *Listeria*	No	Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies	- Fish rinsed in fresh water at < 70°F. to remove surface brine - SSOP - Employee Health & Hygienic Practices - Process SOP	No
	C: None identified				
	P: None identified				

Smoke/Dry/Cook (11)	**B:** Pathogen survival/growth in final product (*C. botulinum*, *Listeria*)	Yes	Undercooking may result in survival of pathogens. Underdrying may result in low water phase salt, which may allow growth and toxin formation by pathogens	- Cook or smoke to required temperature per SOP - Dry for required time based on required brine strength - Process SOP	YES CCP 2
	C: None identified				
	P: None identified				
Cooling (12)	**B:** Cross contamination with human-transmitted pathogens; growth or recontamination with pathogens such as *Listeria*	Yes	Potential growth of pathogens if not properly cooled per Food Code. Potential cross contamination from equipment or mishandling controlled by SSOP, SOP, Employee Health/Hygiene policies.	- Cool per Food Code requirements - SSOP, SOP, Employee Health & Hygienic Practices	Yes CCP 3
	C: None identified				
	P: None identified				
Package and Label (13)	**B:** Pathogen growth in temperature abused product	Yes	Bacterial spores can activate if not cooled properly, resulting in toxin formation. Product is RTE, potential is higher for recontamination Activity and toxin formation by *C. botulinum* controlled by presence of nitrite	- Label must include use-by date and storage, handling and cooking instructions if sold for home use - SSOP - Employee Health & Hygienic Practices	Yes CCP 4
	C: None identified				
	P: None identified				
Cold Storage (15)	**B:** Pathogen growth in temperature abused product	Yes	Growth of pathogens may occur if product is temperature abused and/or if held beyond use-by date, especially if water phase salt is too low	- Monitor date marks for expiration and proper rotation - Maintain temperature at or below 38oF. - SSOP and storage SOP	YES CCP 5
	C: None identified				
	P: None identified				

HACCP Summary: Preserving Fish by Hot Smoking

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Brine recipe and time	**B:** Pathogen growth	Brine recipe per required formulation Brining time	Minimum brine strength and time	Salinometer and in/out time	Each batch	Who is responsible for monitoring the critical limits at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
CCP 2 Smoke/ Dry/Cook	**B:** Pathogen survival	Drying step at least X hours	Drying time required per validated process	In/out times	Each batch	Who is responsible for monitoring the critical limit at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.
		Hold cooking temperature of 145˚F. for minimum 15 seconds	Internal temperature	Calibrated probe thermometer					
CCP 3 Cooling	**B:** Pathogen growth	Cool from 135˚F. to <70˚F. in < 2 hrs. and 135˚F. to < 41˚F. in < 6 hrs. total time	Internal temperature (cooling rate)	Calibrated probe thermometer	Each batch	Who is responsible for monitoring the critical limit at this step?	What actions are required if a critical limit is not met at this step?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate? Who does this, and how often?	List the forms that are used to document monitoring data and verifications at this step.

Approved by:_____ Date:_____

Standard Operating Procedures: Preserving Fish by Hot Smoking

Establishment Name: _____

Only food establishment employees trained in the use of this process and have a thorough understanding of the HACCP plan shall conduct this process.

1. **Receiving Raw Fish:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use – safe and not contaminated? Consider temperature at receipt as well as the condition of the packages? For what reasons would a shipment be rejected?

2. **Receiving Ambient Restricted and Non-Restricted Ingredients:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients and packaging materials to ensure that they are acceptable for use – safe and not contaminated? Consider condition of the packages? For what reasons would a shipment be rejected?

3. **Cold Storage:** What are the required storage procedures to ensure the food is properly refrigerated and protected from contamination?

4. **Dry Storage:** What are the required procedures to ensure the ingredients and packaging are properly stored and protected from contamination?

5. **Tempering of Meat:** Where will the fish be held for tempering before butchering? What **temperature** is required for safe tempering?

6. **Brine Preparation:** What work area is to be used for staging and weighing ingredients? Is this area separated from other workspace in order to prevent possible cross contamination? Are the recipes available for use during preparation? What is the required strength of the brine? What salt product and any other ingredients are to be used? Record the brine preparation at CCP 1 on the batch record.

7. **Butchering:** What are the fabrication instructions (thickness, length/width) for preparing pieces of fish to ensure uniform brining? Refer to the recipe card for each product, and give other general instructions as appropriate.

8. **Rinsing:** How and where is the fish to be rinsed to remove viscera residue and any other contaminants? What should be the maximum temperature of the rinse water?

9. **Brining (CCP 1):** What is to be used to hold the ingredients for weighing? Is calibration of the scale necessary? Provide specific instructions for weighing the exact amount of pink salt to be used for the batch. Refer to the recipe card.

    - Critical Limit: What is the required minimum weight of salt per volume of water? What is the required brining time and temperature?

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the Critical Limits?

- Corrective Action: For each Critical Limit, provide instructions to be followed if the critical limit is not met.

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective. Who is responsible, and how often will this activity occur?

10. **Rinsing:** How and where is the fish to be rinsed to remove surface brine? What should be the maximum temperature of the rinse water?

11. **Smoking/Drying/Cooking (CCP2):** Provide instructions for operation of the smokehouse. How will product temperatures be monitored? What temperature and humidity controls are required? Note that this step includes both the required drying and cooking treatments.

    - Critical Limit: List the critical limits (time and temperature) that must be monitored and met to make and keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? Where are instructions to be found for calibration and use of instruments for monitoring? What records will be maintained to demonstrate compliance with the Critical Limits?

    - Corrective Action: For each Critical Limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective. Who is responsible, and how often will this activity occur?

12. **Cooling (CCP 3):** What procedure will be used for cooling? How will the batch be cooled properly for safety?

    - Critical Limit: List the critical limits that must be monitored and met to keep the product safe.

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the Critical Limits?

    - Corrective Action: For each Critical Limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective. Who is responsible, and how often will this activity occur?

13. **ROP Packaging and Labeling (CCP 4):** Provide instructions for an employee to follow as they are packaging and labeling the product. How should an employee package/seal appropriately? If product will be sold for consumer use, what use-by date, safe storage, handling and (if required) cooking instructions will be provided on the label for consumers? What is the correct way to determine the use-by date?

- Critical Limit: What is the maximum shelf life in days for determining the use-by date?

  What should the required safe handling instructions read on the label?

- Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the Critical Limits?

- Corrective Action: For each Critical Limit, provide instructions to be followed if the critical limit is not met.

- Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective. Who is responsible, and how often will this activity occur?

14. **Cold Holding (CCP 5):** Where will finished product be stored for future use or sale? How is product to be stored to protect from cross contamination?

    - Critical Limit: What is the required storage temperature? What is the maximum shelf life date?

    - Monitoring: What must the employee do, or how will measurements be made, to ensure that each critical limit has been met? What records will be maintained to demonstrate compliance with the Critical Limits?

    - Corrective Action: For each Critical Limit, provide instructions to be followed if the critical limit is not met.

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective. Who is responsible, and how often will this activity occur?

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

Use of Cure Agent (nitrite): 9 CFR Part 424, https://www.ecfr.gov/current/title-9/chapter-III/subchapter-E/part-424,

Model HACCP Plan for Hot Smoked Fish - Oregon Sea Grant Extension Program at https://seagrant.oregonstate.edu/sites/seagrant.oregonstate.edu/files/sgpubs/onlinepubs/i97001.html

https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/fplic-5a-cured-meat-and-poultry-operations.pdfModel HACCP Plan for Hot Smoked Fish

Minneapolis, Minnesota Health Department HACCP Resources webpage:
http://www.minneapolismn.gov/health/inspections/HACCP

Process: Canning or Bottling Acidified or Acidic Foods

Hazard Analysis Table: Canning or Bottling Acidified or Acidic Foods

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Vegetables (1)	**B:** Pathogens: *Salmonella* spp., and shiga toxin-producing *E. coli*, *Listeria monocytogenes*	No	Bacterial pathogens may be present on produce and spices but normally should not be at levels hazardous to public health. Later process step will destroy vegetative pathogen cells. Approved suppliers reduce the likelihood of toxins being present on raw materials.	- Products will be purchased from approved suppliers (Letter of Guaranty may be required) and received at proper temperatures and proper receiving procedures as noted in the SOP.	No
	C: Introduction of toxins such as mycotoxin, patulin, etc.	No			
	P: None identified				
Receiving Ambient Ingredients and Packaging (2)	**B:** None identified		Non-food packaging materials might have been treated/washed with chemicals not suitable for food contact surfaces	- Letters of Guaranty ensuring packaging materials are appropriate for product use will be kept on file. - Proper receiving procedures as noted in SOP.	No
	C: Deleterious Chemicals	No			
	P: Foreign Material	No			
Cold Storage of Raw Vegetables and Herbs (3)	**B:** Growth or cross contamination: pathogens, *Salmonella*, and *E. coli* 0157:H7	No	Potential growth of pathogens and cross contamination are controlled by proper temperature control and preventing cross contamination per SOP, and by SSOP.	- Store as required by SC Reg. 61-25 and SOP - Cleaning and sanitizing SOP - Employee Health and Hygiene SOP - Proper maintenance and recording of refrigeration/freezer and Date Mark log	No
	C: Formation of toxin from yeast & mold	No			
	P: None identified				
Dry Storage of Ambient	**B:** None identified		Foreign material is prevented by proper storage and SSOP	- Proper storage in designated area per SOP	No
	C: None identified				

Ingredients and Packaging (4)	**P:** Introduction of Foreign Material	No		- SSOP	
Preparation of Ingredients (5)	**B:** Cross contamination with pathogens: *E. coli* O157:H7, *Salmonella*, *Shigella*, Norovirus, Hepatitis A virus from handling **C:** None identified **P:** Foreign material	No No	Cross contamination prevented or controlled by SSOP, SOP, Employee Health/Hygiene Policies. Later process step destroys vegetative cells Follow SOP – no broken, cracked or damaged jars will be used.	- Process SOP - SSOP - Employee Health and Hygiene Policies - Process SOP; SSOP	No
Kill Step (6)	**B:** Survival of pathogens: *Salmonella* spp., and shiga toxin-producing *E. coli*, *L. monocytogenes* **C:** None identified **P:** None identified	Yes	Survival of bacteria, yeast, and mold if products are not properly thermally processed to correct temperature and time.	- Follow recommendations from Process Authority, which are Implemented in our SOP, to meet time/temperature requirements at lethality temperature.	Yes CCP 1
Storage (7)	**B:** None identified **C:** Formation of botulinum toxin **P:** None identified	Yes	Proper equilibrium pH of 4.6 or below at subsequent step will prevent formation of botulinum toxin.	- Product stored for time specified by SOP and Process Authority to ensure equilibrium pH of 4.6 or lower is reached.	No
Testing (8)	**B:** None identified **C:** Formation of botulinum toxin **P:** None identified	 Yes 	Finished product pH of 4.6 or below prevents toxin formation	- Finished product pH 4.6 or below per SOP	Yes CCP 2
Storage (9)	**B:** None identified **C:** None identified **P:** None identified	 	Finished product pH of 4.6 or below, storage under sanitary conditions and proper temperature prevents recontamination, pathogen growth and toxin formation	- Product is stored according to SOP requirements - SSOP	No
Serving (10)	**B:** Cross contamination with pathogens: *E. coli* O157:H7, *Salmonella*, *Shigella*, Norovirus, Hepatitis A virus from handling **C:** None identified **P:** None identified	No	Following SSOP, Employee Health and Hygiene policies prevents introduction of pathogens by improper handling during final prep/service, or by infected worker.	- Employee Health and Hygiene - SSOP - Proper serving techniques	No

HACCP Summary Table: Canning or Bottling Acidified or Acidic Foods

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Heat Treatment	**B:** Survival of pathogens: *Salmonella* spp., and shiga toxin-producing *E. coli*, *L. monocytogenes*	What critical limits are provided by the Process Authority letter?	What specific controls must be monitored to ensure the critical limit(s) is/are met?	How will the critical limit(s) be monitored for compliance?	Each batch	Who is responsible for monitoring this critical CCP?	For each critical limit value, what corrective action is required if the critical limit is not met, to bring the process back into control?	What activity is necessary to ensure that workers are following the approved procedure, and that records are complete? Who is responsible? How often? How often is the thermometer calibration checked? Who is responsible?	What log forms are used to record monitoring and verification data for each critical limit and for all verification activities? *List the forms by name.*
CCP 2 Testing	**B:** Pathogens: *C. botulinum* **C:** Botulinum toxin formation	pH of 4.6 or below	pH of finished product	Use a calibrated pH meter Follow SOPs for preparing product slurry, calibrating pH meter, and testing pH	Each batch	BPCS Certified Supervisor	What corrective action is required if this critical limit is not met?	What activity is necessary to ensure that workers are following the approved procedure, and that records are complete? Who is responsible? How often? How often does the pH meter require calibration? Who is responsible?	What log forms are used to record monitoring and verification data for each critical limit and for all verification activities? *List the forms by name.*

Approved by:_____ Date:_____

Standard Operating Procedures: Canning or Bottling Acidified or Acidic Foods

Establishment Name: _____

Only food establishment employees trained and that have a thorough understanding of the HACCP plan shall conduct the Canning of Acidified Foods operations. See notes in Hazard Analysis regarding preventive measures.

1. **Receiving Raw Vegetables:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use – safe and not contaminated? Consider temperature at receipt as well as the condition of the packages? For what reasons would a shipment be rejected?

2. **Receiving Spices, Seasonings, Salt and Sugar and Packaging:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients and packaging materials to ensure that they are acceptable for use – safe and not contaminated? Consider condition of the packages? For what reasons would a shipment be rejected?

3. **Cold Storage:** What storage procedures to ensure the food is properly refrigerated and protected from contamination? What storage temperature is required?

4. **Dry Storage:** What are the required procedures to ensure the food is properly stored and protected from contamination?

5. **Preparation**: Provide instructions for preparing each ingredient. How are the ingredients mixed? What containers will be used for bottling? What other instructions must be followed? How are the bottles or jars to be prepared for filling?

Prepare 1 Test Jar that is the same size as all jars for each batch to be tested and discarded after testing. How is the test jar to be marked?

6. **Kill Step (CCP 1):** Give instructions for the kill step, using the process guidance from the Process Letter provided by the Process Authority. What steps must the employee follow to perform this critical step correctly? What temperatures and times are critical to the safety of this process? Is a test jar necessary for monitoring the critical limits?

    - Critical Limit: List the critical limit values (temperature and time) that must be met to ensure the safety of this process.

    - Monitoring: How is the process monitored to be sure *each critical limit* is met? What records must be maintained to document that the critical limits have been met?

    - Corrective Action: For each critical limit, what corrective actions are required if the critical limit is not met?

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective. Who is responsible, and how often will this activity occur?

7. **Storage:** If specified by the Process Authority, product may need to be held a certain amount of time before testing and release for consumption. How and where will product be stored

before testing? How long must the product be stored? What storage temperature and time are required?

8. **pH Testing (CCP 2):** Provide instructions for the testing step. How is the product in the test jar prepared for analysis to ensure a representative pH value has been reached? What is your quality target for pH, and what is the critical pH value?

   - Critical Limit: What pH target must be met?

   - Monitoring:
     Calibrate pH meter: See procedure below for proper calibration of pH meter.

     - Prepare product slurry:
       - Select the batch test jar from each batch.
       - Place contents of test jar in clear plastic or metal blender cup.
       - Blend the product for approximately 1 minute to create uniform slurry.
     - Test product pH:
       - After calibrating the pH meter according to the procedure below, test the pH of the product slurry. Do not use pH papers or strips.
       - Record product pH in the Acidified Foods Batch Log.
       - Once test is complete, discard test sample.

     What records will be maintained to demonstrate compliance with the Critical Limits?

   - Corrective Action: If the critical limit is not met, what is to be done with the batch of product?

   - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective. Who is responsible, and how often will this activity occur?

9. **Storage of product released for use or sale**: Where is the finished product to be held for service or sale to consumers? How is each jar or bottle to be marked or labeled?

10. **Serving**: What instructions and policies are to be followed to prevent recontamination of the finished product during final preparation and service?

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

Process: Fermenting Vegetables

Hazard Analysis Table: Fermenting Vegetables

Establishment Name: _____

HAZARD ANALYSIS					
Process Step	**What are the potential hazards?** **B: Biological** **C: Chemical** **P: Physical**	**Is this hazard significant at this step?**	**What is the justification of your decision on significance (likelihood/severity)?**	**What preventive measures can be used to control the hazard(s)?**	**Is this step a CCP?**
Receiving Raw Vegetables (1)	**B:** Multiplication of pathogens: *Salmonella* spp., *E. coli* O157:H7/STEC, *Shigella*, *Listeria monocytogenes*; irrigation water-borne parasites	No	Purchasing all ingredients from approved suppliers will provide control over potential for parasites, mycotoxins and agricultural chemicals. Later process steps will destroy vegetative pathogen cells that may be present.	- Approved suppliers – Letters of Guaranty on file - Receiving procedures – temperature, inspection	No
	C: None identified				
	P: None identified				
Receiving Ambient Ingredients and Packaging (2)	**B:** *E. coli* O157:H7/STEC, *Salmonella*	No	Purchasing all ingredients and packaging materials from approved suppliers will control/reduce potential contamination sources to acceptable levels.	- Approved suppliers - Letters of Guaranty on file - Proper receiving procedures as noted in SOP	No
	C: None identified				
	P: None identified				
Cold Storage of Raw Vegetables (3)	**B:** Multiplication of *Salmonella*, *E. coli* O157:H7/STEC, *Shigella*, *Listeria*, etc.	No	Potential growth of pathogens and cross contamination are controlled by proper temperature control and preventing cross contamination per SOP, and by SSOP.	- Store as required by SOP and SC Reg. 61-25 - SSOP - Proper maintenance of cooler	No
	C: Yeast and mold (mycotoxin)	No			
	P: None identified				
Dry Storage of Ambient Ingredients and Packaging (4)	**B:** None identified		Following proper storage procedures and SSOP provide effective control.	- Proper storage in designated area per SOP - SSOP	No
	C: None identified				
	P: Foreign Material	No			

Preparation: washing/inspection and cutting of vegetables, mix with ingredients (5)	**B:** Cross contamination with pathogens: *E. coli* O157:H7, *Salmonella*, *Shigella*, Norovirus, Hepatitis A virus from handling	No	Inspection while preparing produce removes damaged or bruised vegetables that may provide harborage for pathogens Employee Health & Hygiene Policy and SSOP control potential cross contamination including foreign material.	- Process SOP - SSOP - Employee Health and Hygiene Policies - Process SOP; SSOP	No
	P: Foreign Material	No			
	C: None identified				
Fermentation (6)	**B:** Multiplication of pathogens: *Salmonella* spp., and shiga toxin-producing *E. coli*, *L. monocytogenes*, *C. botulinum*	No	Survival/multiplication of pathogens and toxin formation are prevented by following the SOP/recipe and maintaining proper temperature control	- Ingredients and fermentation according to recipe - Maintain proper temperature control* to support safe fermentation; SSOP and proper storage procedures followed to prevent potential recontamination.	No
	C: Toxins: Botulinum toxin, *Staph* toxin	No			
	P: None identified				
Testing (7)	**B:** Multiplication of pathogens: *Salmonella* spp., and shiga toxin-producing *E. coli*, *L. monocytogenes*, *C. botulinum*	Yes	Final pH <4.2 will prevent multiplication of any surviving pathogens, if final product will not be canned. Final destruction and control of vegetative pathogens is achieved at the canning step. Failure to achieve pH 4.6 or lower allows potential toxin formation by *C. botulinum*.	- Test batch at 12-hr. intervals until required pH is achieved. Required pH levels are <4.2 (not canned) or <4.6 (canned).	Yes CCP 1
	C: Formation of botulinum toxin	Yes			
	P: None identified				
Canning (8) (optional)	**C:** Formation of botulinum toxin	Yes	Improper canning may result in formation of botulinum toxin	- Thermal process and procedures for required temperature and time assigned by Process Authority must be followed.	Yes CCP 2
	B: None identified				
	P: None identified				
Storage (9)	**B:** None identified known	No	Canned product pH of 4.6 or below, and storage under sanitary conditions	- Product is stored according to SOP requirements	No
	C: None identified				

	P: None identified		and proper temperature prevent recontamination, pathogen growth, and toxin formation. ****If not canned, product pH <4.2 renders the product non-TCS; refrigeration serves as a second hurdle to prevent growth of any vegetative pathogens.	- SSOP	**Yes Alternate CCP 2
Serving (10)	**B:** Cross contamination with pathogens: *E. coli* O157:H7, *Salmonella*, *Shigella*, Norovirus, Hepatitis A virus from handling	No	Following SSOP, Employee Health and Hygiene policies prevents introduction of pathogens by improper handling during final prep/service, or by infected worker.	- Employee Health and Hygiene - SSOP - Proper serving techniques	No
	C: None identified				
	P: None identified				

HACCP Summary Table: Fermenting Vegetables

Establishment Name: _____

HACCP SUMMARY (CCP Audit Table)									
(1) Critical Control Point	**(2) Hazard Description**	**(3) Critical Limits**	**Monitoring**				**(8) Corrective Action**	**(9) Verification Activities**	**(10) Record Keeping**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
CCP 1 Testing	Pathogens and bacterial toxins	pH of ≤4.6 within (allowed time) if product **will** be canned OR, pH of <4.2 within (allowed time) if product **will not** be canned	pH of finished product	Use a calibrated pH meter Follow SOPs for preparing product slurry, calibrating pH meter, and testing pH	Each batch	Who is responsible to perform this monitoring?	What corrective action is required if the critical limit is not met, to bring the process back into control?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	What log forms are used to record monitoring and verification data for each critical limit and for all verification activities? *List the forms by name.*
CCP 2 Canning (optional step)	Pathogens and bacterial toxins	Time and temperature	Temperature; time	Use a calibrated thermometer and clock or timer	Each batch	Who is responsible to perform this monitoring?	What corrective action is required if the critical limit is not met, to bring the process back into control?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	What log forms are used to record monitoring and verification data for each critical limit and for all verification activities? *List the forms by name.*
CCP 2 Alternate Storage	Pathogens	Refrigerate at 41°F. or lower	Temperature	Use a calibrated thermometer	2x daily	Who is responsible to perform this monitoring?	What corrective action is required if the critical limit is not met, to bring the process back into control?	What actions are taken to ensure procedures are followed, corrective actions are effective, and measurements are accurate at this step? Who does this, and how often?	What log forms are used to record monitoring and verification data for each critical limit and for all verification activities? *List the forms by name.*

Approved by:_____ Date:_____

Standard Operating Procedures: Fermenting Vegetables

Establishment Name: _____

Only food establishment employees trained and that have a thorough understanding of the HACCP plan shall conduct fermentation of vegetables. See notes in Hazard Analysis regarding preventive measures.

1. **Receiving Raw Vegetables:** What must the receiving employee check or look for on each incoming shipment of refrigerated foods to ensure that they are acceptable for use – safe and not contaminated? Consider temperature at receipt as well as the condition of the packages? For what reasons would a shipment be rejected?

2. **Receiving Spices, Seasonings, Salt and Sugar and Packaging:** What must the receiving employee check or look for on each incoming shipment of non-refrigerated foods, ingredients and packaging materials to ensure that they are acceptable for use – safe and not contaminated? Consider condition of the packages? For what reasons would a shipment be rejected?

3. **Cold Storage:** What storage procedures to ensure the food is properly refrigerated and protected from contamination? What storage temperature is required?

4. **Dry Storage:** What are the required procedures to ensure the food is properly stored and protected from contamination?

5. **Preparation**: Provide instructions for preparing each ingredient. Is inspection necessary to ensure no damage or bruising? How are the ingredients mixed? What containers will be used for fermenting? What other instructions must be followed?

6. **Fermenting:** Place covered containers with prepared product in (What dedicated location will be used?) for fermentation. How is the batch to be labeled? Room temperature should be maintained at 70°F. (21.1°C.) to 80°F. (26.7°C.) for proper fermentation. Sample with clean, sanitized ladle every (specify frequency) to test pH until testing demonstrates the required pH has been achieved. How long should the fermentation process take? What actions are required if the fermentation is taking longer than normal?

7. **Testing (CCP 1):** A representative portion of the vegetables and brine is blended using (What equipment is required?) for 1 minute to ensure a uniform mixture. Calibrate the pH meter according to calibration procedure and test the slurry.

    - Critical Limit: The pH of the final product must be less than (state the required pH value) within (specify required time in hours or days).

    - Monitoring: Who is responsible to test each batch at (specify frequency) intervals until critical limit is met? Where is final product pH to be recorded?

    - Corrective Action: What corrective action is required if the required pH value is not reached within the allowed time? Determine cause and resolve issue; retrain employees if failure was result of employee error. Record corrective actions on the Acidified Foods Batch Log.

    - Verification: Who is responsible for data review, at what frequency?

8. **Canning (*optional step*) (CCP 2):** Give instructions for the canning step, using the process guidance from the Process Letter provided by the Process Authority. What steps must the employee follow to perform this critical step correctly? What temperatures and times are critical to the safety of this process? Is a test jar necessary for monitoring the critical limits?

    - Critical Limit: List the critical limit values (temperature and time) that must be met to ensure the safety of this process.

    - Monitoring: How is the process monitored to be sure *each critical limit* is met? What records must be maintained to document that the critical limits have been met?

    - Corrective Action: For each critical limit, what corrective actions are required if the critical limit is not met?

    - Verification: How will management ensure that procedures are being followed correctly, required records are being maintained, and corrective actions are effective. Who is responsible, and how often will this activity occur?

9. **Storage:** If not canned, what are the instructions for properly storing the fermented product? In what type of containers should the product be stored? How is the batch to be labeled? Where is the product to be stored? What temperature is required to properly preserve the characteristics of the finished product?

10. **Serving**: Serve according to menu or recipe guidelines. Be careful to avoid recontamination by servers by observing PRPs for Employee Health and Hygiene.

References:

A Retail Food Establishment Guide for Developing a HACCP Plan, April 2014, Association of Food and Drug Officials, https://ag.utah.gov/documents/Retail_Food_Establishment_Guide_for_Developing_a_HACCP_Plan.pdf

FDA 2022 Model Food Code, https://www.fda.gov/media/164194/download

Special Processes at Retail (FD 312), FDA – Office of Training, Education and Development (OTED)

Recommendations for Safe Production of Fermented Vegetables, University of Wisconsin, July 2009, https://foodsafety.wisc.edu/assets/pdf_Files/Fermented_Vegetables.pdf

Establishment Name
Process Name

Curing Recipe Template

This template is intended for use with cured meats that will be heat-treated (cooked or smoked) as the next step following the "Mixing ingredients and cure with proteins" below. Used with an approved HACCP plan for a reduced oxygen packaging – cook-chill process for cooked products. For fermented sausages, this template may be used with an approved HACCP plan for reduced oxygen packaging for storage of raw and processed meats.

1. **Product name:** (Provide the name of one product here, for which the recipe and instructions will be provided below.)

   NOTE: Flavor variations can be included in a single recipe document, but all potential ingredients must be listed below. For example: Summer sausage – mild and spicy formulations.

2. **Recipe:** Give amounts of all proteins and other ingredients in weight units (ounces, pounds, grams, kilograms. Must include the type of cure salt with the percent of nitrite (and percent of nitrate, if applicable); must also identify the nitrite/nitrate as sodium or potassium salts. A copy of the cure salt label may be submitted to provide this information.

   For brines and dry rubs, provide the weight of cure salt in the cure mixture batch; total batch weight; the weight of dry rub or brine used per batch of protein, and the weight in pounds or kilograms of protein cured in each batch. State whether the cure is applied as dry rub, injection, immersion, or a combination.

3. **Production Instructions:** Insert the step-by-step instructions you follow to prepare this product, up to cooking this product. This recipe refers to the "Preparation" steps in the associated HACCP plan.

4. **Process Step – Assemble ingredients:** Do any ingredients require preparation before they are added to the mixture? Where will these ingredients be staged for production? Do the proteins require preparation, such as tempering or partial freezing, grinding, or chopping?

5. **Process Step – Weighing of Cure:** Provide general instruction: What scale will be used? How accurately must the cure be weighed? Is the cure weighed separately, or together with other ingredients? What is the weight of cure salt used per recipe or per cure mixture batch, and the final prepared weight of dry rub mixture or brine?

   How much cure salt is required per pound of protein, or per pound of dry rub mix, or per pound of brine? For dry rubs and liquid brines, how much is used per pound of protein?

6. **Process Step (CCP) – Mixing ingredients and cure with proteins:** How is the cure combined with the proteins? At what temperature is the product to be held? If holding is required, such as for a dry rub, marination or immersion process, how long is the holding step? Is the product rinsed before proceeding to the next step?

   - Critical Limit: Ratio of cure mix to protein

- Monitoring: Describe the necessary actions to ensure the critical limit is met? How will the measurements of cure, cure mixture and protein be recorded?

- Corrective action: What action will be taken if the critical limit is not met?

- Verification: What actions will be taken, and at what frequency, to verify that the above procedures have been followed correctly? Who is responsible?

Recipe refers back to the appropriate step of the relevant HACCP plan at this point.

Labeling Requirements of the Food Code

Paragraph 3-201.11 of the FDA Food Code provides general labeling requirements for foods packaged and sold at retail:

3-201.11 Compliance with Food Law

(F) MEAT and POULTRY that is not a READY-TO-EAT FOOD and is in a PACKAGED form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in LAW, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

Paragraphs 3-602.11 and 3-602.12 of the FDA Food Code provide the following *labeling guidance* for foods that will be sold to consumers for home use:

3-602.11

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;

(2) If made from two or more ingredients, a list of ingredients and sub-ingredients in descending order of predominance by weight, including a declaration of artificial colors, artificial flavors and chemical preservatives, if contained in the FOOD;

(3) An accurate declaration of the net quantity of contents;

(4) The name and place of business of the manufacturer, packer, or distributor; and

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient.[Pf]

(6) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(q)(3) –(5), nutrition labeling as specified in 21 CFR 101 -Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.

(7) For any salmonid FISH containing canthaxanthin or astaxanthin as a COLOR ADDITIVE, the labeling of the bulk FISH container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.

3-602.12 Other Forms of Information

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT or manufacturers' dating information on FOODS may not be concealed or altered.

(C) The PERMIT HOLDER shall notify CONSUMERS by written notification of the presence of MAJOR FOOD ALLERGENS as an ingredient in unPACKAGED FOOD items that are served or sold to the CONSUMER.

On fresh or non-heat-treated **meat** or **poultry** products, a safe handling statement should be included. USDA provides the following safe handling instruction examples:

- Keep refrigerated or frozen.
- Thaw in refrigerator or microwave.
- Keep raw **meat** and **poultry** separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw **meat** or **poultry**.
- Cook thoroughly.
- Keep hot foods hot. Refrigerate leftovers immediately or discard.

Other specific labeling requirements are directed by the description of the process or the intended use/distribution of the product in the initial pages of the **HACCP plan** ("preliminary steps"). Paragraph 3-502.12 of the Food Code (Reduced Oxygen Packaging) includes specific labeling requirements for ROP processes.

Date Marking of Special Process Products

Scientific Basis for Shelf Life

The shelf life is the life expectancy of a food product. Large food processors and manufacturers operating under federal inspection must comply with strict regulations pertinent to their market sector. They also have stringent sanitation programs that include required **monitoring** activities that demonstrate the effectiveness of their sanitation. The various production, **preservation,** and packaging methods used are validated by various methods, which may include published research, independent testing, or scheduled processes from a Process Authority. For these reasons, shelf-life values stated on commercially-produced food packages purchased at grocery stores are said to be quality dates (use-by, best-by, etc.).

Retail **food establishments** operate under state or local food safety regulations, the majority of which are based on the FDA Model Food Code. For the typical **time/temperature control for safety** (**TCS**) foods produced in retail **food establishments**, FDA has established date marking requirements that are more stringent than those for similar manufactured products. This could be considered a trade-off for less regulatory pressure in the form of retail inspections that occur one to four times yearly. For **TCS ready-to-eat (RTE)** foods such as all cooked foods, cut tomatoes, cut leafy greens, cut melons, and sprouts, the Food Code states a shelf-life expectancy of 7 days, including the day of production. This requirement is based on research involving a wide range of **TCS RTE** foods. *All shelf-life dates for special processes are consume- or discard-by dates for safety*.

To determine shelf-life values, challenge studies are performed in which multiple packages of a food product are inoculated ("challenged") with cultures of the pathogens of greatest concern specific to the food type. Testing is then conducted over a predetermined time that is at least 30 percent longer than the predicted shelf life (for products with a shelf life measured in months), or as much as 50 percent beyond the expected shelf life when the predicted value is as few as 7 days. When any one of the inoculated pathogens multiplies to a level 1 log (10 times) higher than the original concentration in the food, the study is finished. The shelf-life value is then established at the appropriate level, 30% to 50% less than the time it took to reach that 1-log threshold.

All date marks assigned by retail **food establishments** for products produced at retail are considered *safety* dates (consume or discard-by) for regulatory purposes.

Retail establishments using any of the Food Code retail **preservation** methods (smoking, curing, acidification, fermentation, pasteurization of juice) must use one of the following methods to determine the allowed shelf life for their products:

- Follow date marking requirements from local regulations based on the Food Code for ROP processes.

- Obtain independent product testing data for pH, water activity, or other appropriate testing indicated by the regulatory authority to classify the food as **TCS** or non-**TCS**, or to determine the shelf life This would apply to acidified foods, dry or semi-dry sausages and jerky, and other preserved **meats**.

- Precisely follow a USDA or Process Authority published **meat preservation** process for a specific product type, and follow the allowed shelf-life guidance for that product when published USDA guidance is available.

- The chemical properties of certain foods may not be supportive of bacterial growth, even when the pH and water activity indicate the food is a **TCS** product (not **shelf stable**). A challenge study is required in this case to demonstrate that the food cannot support the growth of the pathogens of greatest concern for that particular type of food. Consult with the regulatory authority for guidance, or discuss with an FDA-recognized **Processing Authority** or with an accredited commercial food testing laboratory that has the expertise to perform challenge testing.

Reduced Oxygen Packaging Processes

The Food Code provides the following date marking requirements under ¶ 3-502.12 for various ROP processes at the specified conditions:

Product Category	Storage Temp.	Shelf life (Expiration)	Note
Raw **meat**, **poultry**, vegetables	≤41°F. (≤5°C.)	30 days	
Commercial deli **meats**	≤41°F. (≤5°C.)	7 days	(Repackaged at retail)
Commercially cured meats	≤41°F. (≤5°C.)	30 days	(Repackaged at retail)
Sous vide & ROP cook-chill products	≤41°F. (≤5°C.)	7 days	

Sous vide & ROP cook-chill products	≤34°F. (≤1.1°C.)	30 days	After proper cooling, must cool to ≤34°F. within an additional 48 hrs.
Any of the above, frozen after packaged**	≤32°F. (≤0.0°C.)	Indefinitely	
Raw **fish** (all)***	≤32°F. (≤0.0°C.)	Indefinitely	Must be kept in a frozen state before, during and after packaging. Remove from ROP package to thaw.
Hard & semi-soft cheeses*	≤41°F. (≤5°C.)	30 days, or longer with a **variance**	See FDA Food Code, Annex 3, ¶ 3-501.17.

*Pasteurized process cheese is also classified as a hard cheese, exempt from date marking. Cheeses not listed as exempt from date marking may be considered exempt if the moisture content is less than 40% (hard cheese) or less than 50% (semi-soft cheese). Raw milk cheeses must have been aged at least 60 days and must meet the moisture criteria described above.

**For products frozen immediately after packaging and chilling, shelf life starts when the product is taken out of the freezer to thaw. If stored refrigerated for part of the allowed shelf life, then frozen, then moved back to refrigeration, the date marking must account for all time under refrigeration (excluding freezer time) in total consecutive days including before and after freezing. The shelf life cannot be reset to "day one" when taken out of the freezer.

***__Fish__ as defined by the Food Code must be frozen before ROP packaging and must remain frozen for as long as it remains in the ROP package. **Fish** may be stored indefinitely in a freezer (safety), but must be removed from the ROP bag for thawing.

An alternate type of vacuum packaging film called 10K OTR may be used to store fresh, raw **fish** under refrigeration. This film allows a very high rate of oxygen transmission into the bag, serving as an alternate hurdle to **control** *Clostridium botulinum*. However, spoilage is not **controlled** with this type of film, so shelf life is not extended any more than if the product is not in the 10K OTR bag. This product is only **approved** for raw **fish** with no other ingredients. The 10K OTR bags are not **approved** for any other foods, or for sous vide cooking, storage of cooked **fish** products, or for any process in which the bag would be subjected to heat such as bagging of cooked foods. The use of 10K OTR packaging requires a regulatory **variance** under Subparagraph 3-502.11(D) of the Food Code.

Preservation: Smoking and Curing Processes

Preserved or cured **meats** have a wide range of possible shelf-life values, depending on the type and characteristics of the final products. When the Food Code provides no guidance, there are two options for determining shelf-life values:

- Follow a USDA or FDA protocol for a specific process type, and use the published shelf life for that product. Or,

- Have testing performed by an independent laboratory or process authority, based on guidance from the Regulatory Authority, to determine the shelf life. This testing must be based on an analysis of several batches of product to account for batch-to-batch process variation. Always consult the regulatory authority for guidance before pursuing testing.

Fully cooked, non-**shelf stable sausages** have a shelf life of 7 days including the day of production as **TCS RTE** food, based on ¶ 3-501.17. Some types of cured or preserved **meats**, such as fermented dry sausages, jerky and country (salt-cured) hams, may be **shelf stable** and may have a much longer shelf life. USDA guidance regarding shelf life for sausage **meats** may be found at Sausages and Food Safety (www.fsis.usda.gov/food-safety/safe-food-handling-and-preparation/meat/sausages-and-food-safety). For the shelf life of preserved and cured **meats**, refer to the section of this resource for further guidance.

Preservation: Acidification or Fermentation, and Use of Additives for Preservation

Acidic foods (those with pH values of 4.6 or lower without the addition of an acid) and acidified foods (those to which an acid has been added to reduce the pH by at least 0.4 pH units to pH 4.6 or lower) are classified as non-**TCS** food when the pH is known to meet those criteria. Fermented foods are acidified by the action of acid-producing bacteria. Foods that are classified as non-**TCS**, including acidic and acidified foods and those classified as non-**TCS** based on pH, water activity, or the interaction of the two, have no required safety date for shelf life.

The following **pages provide templates or model policies for the most common PRPs required in retail HACCP plans for the processes previously described. Red text indicates required additional information unique to each establishment that must be provided to complete the policy.**

SECTION 9: PREREQUISITE PROGRAM TEMPLATES AND MODEL POLICIES

Sanitation Standard Operating Procedures (SSOP) - Template

Cleaning and Sanitizing Procedure (Pre-Operational)

Properly cleaned and sanitized food contact surfaces are critical to ensuring a safe, sanitary operation. The use of **approved** cleaners and sanitizers in accordance with the manufacturer's label instructions will reduce levels of pathogenic organisms to prevent cross contamination of the product. Detergent cleaners suspend and help remove various food soils. Chemical sanitizers reduce the number of pathogens and other microorganisms.

The clean-up process must be completed in accordance with the following general procedure. *Be sure to add any specific cleaning, sanitizing, and pre-operational inspection instructions required for the equipment used in your **HACCP** process or processes – such as slicers, grinders, choppers, and stuffers.*

- Pre-cleaning – equipment and utensils shall be pre-flushed, presoaked, or scraped as necessary to eliminate excessive food debris.

- Washing – equipment and utensils shall be effectively washed to remove or completely loosen soils using a manual or mechanical means. Only approved chemicals are to be used in this process. Mix concentration according to the manufacturer's recommendations.

- Rinsing – washed utensils and equipment shall be rinsed to remove abrasives and to remove or dilute cleaning chemicals with water.

- Sanitizing – after being washed and rinsed, equipment and utensils must be sanitized with an approved chemical by immersion, manual swabbing, brushing or pressure spraying methods. Concentration and exposure times are important to ensure the effectiveness of the chemical. Refer to the manufacturer's label for concentrations and times.

- Air drying - all utensils and equipment shall be air dried and inspected to ensure good repair before the next use.

- Ensure that an appropriate chemical test kit such as chlorine, quaternary ammonia, iodine, etc. test strips is available and routinely used to ensure that accurate concentrations of the sanitizing solutions are being used.

Record results/findings/activities including sanitizer strength and corrective actions on Sanitation Log, along with initials of the person who performed cleaning and sanitizing, with date and time. Periodic verification review is to be documented by management.

Frequency of Cleaning (Operational)

Equipment, food contact surfaces, and utensils shall be cleaned in a time frame as follows:

1. Before each use with a different type of raw animal food, including beef, fish, lamb, pork or poultry;

2. Each time there is a change from working with raw foods to working with ready-to-eat foods;

3. Between uses with raw fruits or vegetables and with potentially hazardous foods.

4. At any time during the operation when contamination may have occurred;

5. If used with TCS Foods, throughout the day at least once every four hours;

6. Utensils and equipment used to prepare food must be cleaned at least once every four hours when in use.

7. Slicers, grinders, stuffers, choppers and injectors must be disassembled for cleaning and sanitizing after each use, and must be inspected for any maintenance issues when reassembled for use.

8. Before using or storing a food temperature measuring device;

9. Equipment used for storage of packaged or un-packaged food, including coolers, and the equipment is cleaned at a frequency necessary to eliminate soil residue.

10. For ice bins, at a frequency necessary to preclude accumulation of soil or mold.

11. Cooking equipment shall be cleaned at a frequency to prevent the accumulation of food residues.

12. Non-food-contact surfaces of equipment shall be cleaned at a frequency necessary to prevent the accumulation of soil residues.

Provide a diagram of the kitchen showing where the special process is to be conducted. The concern is to show how the process and product will be protected to prevent cross contamination. It is understood that many retail kitchens may not have dedicated space in which to conduct their special processes, so explanation must be provided to detail how the process and product will be protected from cross contamination through other means such as physical barriers or separation in time and space with sanitation controls from other activities in the kitchen.

Employee Hygienic Practices - Template

1. Hands are to be thoroughly washed for 10 to 15 seconds in a hand sink with soap and water, paying particular attention to the areas underneath the fingernails and between the fingers by scrubbing thoroughly with a fingernail brush. Dry with single-use towels. Hand washing is to be done at the following times:

    - Changing or putting on gloves
    - After using the toilet, in the toilet room
    - After coughing, sneezing, using a tissue, using tobacco, eating or drinking
    - After handling soiled equipment or utensils
    - Immediately before engaging in food preparation activities
    - During food preparation activities necessary to remove soil and prevent cross contamination
    - When switching between raw and ready-to-eat foods
    - Every four hours of continuous use in a single activity
    - Other times as needed to maintain good sanitation

2. Fingernails must be kept trimmed, filed, free of nail polish, and maintained so the edges are cleanable and not rough. Artificial nails are prohibited.

3. Eating and drinking are prohibited in areas where contamination of exposed food, clean equipment, utensils, unwrapped single service and single-use articles could occur. A food employee may drink from a closed beverage container so long as it is handled and stored in a way that prevents contamination.

4. Effective hair restraints and beard covers (as appropriate) must be worn in processing areas.

5. Smoking and other uses of tobacco are prohibited. If smoking is allowed only in a designated location, include the information in this section.

6. Clean outer clothing must be worn each day and changed as often as necessary throughout the day (when moving from a raw food operation to a ready-to-eat food operation.

7. Smocks and aprons used by employees are to be hung in a designated area when not in use. They are not to be worn in the toilet area, eating areas, or locker rooms.

8. Footwear is to be kept clean.

9. No jewelry (except a wedding band or other plain ring) is allowed during the handling of food.

10. Bare-hand contact with ready-to-eat food is prohibited. Employees must use gloved hands, deli paper, tongs, or other appropriate utensils to handle ready-to-eat foods.

11. All employees are required to follow the establishment's Employee Health Policy regarding notification of management when experiencing listed symptoms, diagnoses, or exposures, and regarding required exclusions and restrictions.

THE NEXT TWO PAGES PROVIDE A MODEL EMPLOYEE HEALTH POLICY AGREEMENT WHICH MAY BE USED AS A POSTING AND AS DOCUMENTATION OF EMPLOYEE TRAINING.

Food Employee Health Policy Agreement

(Retail Food Establishment name) is committed to ensuring the health and safety of our employees and customers, and complying with all health department regulations. The purpose of the Food Employee Health Policy is to protect consumers by ensuring that all food employees notify the **person-in-charge (PIC)**, when experiencing any listed condition so that proper steps are taken to prevent the transmission of foodborne illness.

POLICY

All food employees experiencing any of the following symptoms shall report this to their PIC:

- Diarrhea
- Vomiting
- Jaundice
- Sore throat with fever
- Lesions (boils, infected wounds, burns) containing pus on the hand or wrist.

Food employees shall also notify their PIC whenever diagnosed by a healthcare provider with any of the following diseases that can be transmitted through food, or when they have had a significant exposure to any of these illnesses:

- Salmonellosis (non-typhoid *Salmonella*)
- *Salmonella typhi* (typhoid fever)
- Hepatitis A virus
- Shigellosis
- Norovirus
- *Escherichia coli* (EHEC or STEC)

Examples of significant exposures include:

- A member of the employee's household is diagnosed with any of the above illnesses.

- The employee or a member of their household works in, or attended a conference or other setting where there has been a confirmed outbreak of one of the above illnesses.

EXCLUSION, RESTRICTION, AND REINSTATEMENT (RETURN TO WORK)

If a food employee has diarrhea, vomiting, jaundice, or sore throat with fever; or if a food employee has, or has been exposed to Norovirus, *Salmonella typhi (typhoid fever),* non-typhoid Salmonellosis*, Shigella* spp. infection, *E. coli* infection (*Escherichia* coli O157:H7 or other EHEC/STEC infection), or Hepatitis A, the PIC will determine whether to **exclude*** that employee, or to **restrict**** that employee from food-handling duties. The PIC will refer to the FDA's Employee Health and Personal Hygiene Handbook[48] or specific guidance regarding excluding, restricting, and reinstating (return to work). In the case of most of the specified illnesses, an employee who has been excluded or restricted may not return to work until they have been asymptomatic for at least 24 hours, depending on the diagnosis. If an employee has been diagnosed with Hepatitis A, they must provide written clearance from a medical professional prior to returning to work.

[48] https://www.fda.gov/media/77065/download

If a food employee has an infected cut, wound, or lesion containing pus on the hand or wrist, that wound must be covered with an impermeable bandage and a single use glove. If not covered in this manner, the employee will be **restricted**** from work.

**An excluded employee is not allowed to* come *to work.*

***A restricted employee's duties will* not *include handling of food.*

FOOD EMPLOYEE RESPONSIBILITY

All food employees shall follow the reporting requirements specified above involving symptoms, diagnoses and high-risk conditions. All food employees shall comply with any work restrictions or exclusions that are imposed upon them as required by the FDA Model Food Code. Compliance with this health policy, and with good hygienic practices, is vital to protecting the health and safety of our patrons.

PIC RESPONSIBILITY

The PIC will:

1. Ensure that all food employees are informed and reminded of their responsibility to report to management certain symptoms or illnesses that may be transmitted through food; and

2. Take appropriate action as specified in the FDA Model Food Code including exclusion, restriction and/or monitoring of food employees who have reported certain symptoms, or who have been diagnosed with or had significant exposure to certain illnesses that may be transmitted through food.

I have received training on the Food Employee Health Policy, understand my responsibilities regarding the policy, and I will comply.

_____ _____

Employee Signature Date

Special Process Employee Training Plan – Template

All personnel operating parts of the plan will be trained as specified in the HACCP Plan. Management will document the required training for each employee. As an essential, required part of HACCP-related training, food employee and supervisory training must address the food safety issues of concern.

1. Who is to be trained?

2. When does training occur? (Examples: new employee, annual, and quarterly talks on different food safety topics)

3. How is training documented?

4. What is covered in training? Must include relevant food safety issues, and training relevant to the procedures involved in the specialized process and proper corrective actions (those resulting from human error).

HACCP Plan Verification and Maintenance – Template

Verification Procedures - Routine

All monitoring records will be checked for accuracy and completeness prior to sale or service within 24 hours, or as prescribed by the HACCP plan. If discrepancies are noted, corrective action will be documented.

An essential element of routine verification of a HACCP process is the calibration of instruments used to make measurements to monitor critical limits. The following templates provide guidance for the most common monitoring instruments and procedures.

Verifying Accuracy of Thermometers and Thermocouples:

Digital thermometers and probes will be checked for accuracy at least weekly and when accuracy may be questionable, or when dropped or broken. Bimetallic (dial-type) thermometers are less stable than digital thermometers, and for this reason, their calibration should be verified no less than daily. All thermometers and probes will be checked for accuracy using an ice bath or a standard according to manufacturer's recommendations and recorded on the Thermometer/Probe Accuracy Log. To check thermometer calibration using an ice bath, fill a glass with crushed ice; then add enough water to fill the gaps in the ice. Mix well for 30 seconds to a minute, then place the thermometer or thermocouple probe in the center of the ice slush without touching the sides or bottom to the container. Allow the reading to stabilize. Then record the observed temperature on the Thermometer Calibration Log. If the measured temperature is not within 32 $\pm$2 °F. (0 $\pm$1°C.), recalibrate according to manufacturer instructions, or replace the thermometer. The boiling point method should be used to check accuracy of thermometers that are used to measure cooking temperatures. In this method, the water must be at a rolling boil (212 $\pm$2 °F. or 100 $\pm$1°C.). Boiling point elevation correction[49] should be made when appropriate and when required by the regulatory authority.

Verifying Accuracy of Scales:

Scales used to weigh cure will be checked for accuracy each time a product is made. The scale will be checked for accuracy using a reference weight within the same range as the amount of cure to be weighed, according to manufacturer recommendations, and will be recorded on the Scale Accuracy Log. Observed weights for reference weights should agree with the true value to within $\pm$2% of the reference value. Scales must comply with any state or local certification requirements for weights and measures. Scales used for weighing curing salt should weigh accurately to two decimal places. It is essential that the scale be leveled using the leveling sight glass on the scale before each use. Scales should be cleaned after each use to prevent corrosion of the electronics by curing salt dust and must be maintained in a sanitary condition.

Calibration of pH Meters and pH Testing Procedure:

Calibration of pH meters is necessary on each day of use. Calibration points above and below the **critical limit** must be used to ensure accuracy. For purposes of the processes requiring pH **control** covered in this manual, the **critical limits** for pH will be either 4.2, 4.6, 5.3, or 5.8. Calibration points

[49] www.asi.k-state.edu/doc/meat-science/thermometer-calibration-guide-2.pdf

for the pH meter should therefore be 7.0 and 4.0 pH values. Use of a 10.0 pH buffer is optional but not necessary as a third calibration point.

1. Follow the manufacturer's instructions to establish a valid calibration. Typical instructions are as follows:

    - Open up electrode (usually will need to pop a cap or turn the top to expose). This may not apply to some meters.
    - Clear out previous pH slope (may only pertain to some meters) and set meter to calibrate mode.
    - Rinse with deionized water into a waste container.
    - Blot with soft, low-lint tissue – do not wipe!
    - Place electrode into pH 4.0 buffer until it stabilizes (may have to confirm or enter once it stabilizes).
    - Rinse with deionized water into a waste container.
    - Blot with soft, low-lint tissue – do not wipe!
    - Place electrode into pH 7.0 buffer until it stabilizes (may have to confirm or enter once it stabilizes).
    - Some pH meters will display a slope value at this time. The slope should be within the range specified by the manufacturer. If not, recalibrate.
    - Rinse with deionized water into a waste beaker or container.
    - Blot with soft, low-lint tissue – do not wipe!
    - The pH meter may prompt you to accept the calibration – confirm. Other meters will automatically go to testing mode once the calibration is accepted.

2. After establishing the calibration and returning the meter to testing mode, re-read the low pH standard to ensure that it reads within +0.1 pH unit from the true value (for example, 4.0 buffer should read between 3.9 and 4.1 pH units). If this test fails, repeat the calibration procedure above and this step before testing product samples. Record the calibration results on the pH calibration log or on the appropriate batch production log.

3. Now you are ready to take the pH of your product samples!

4. Rinse the probe after every standard buffer or sample using distilled or deionized water, then blot gently with a soft, low-lint tissue.

5. Prepare product samples in a manner that ensures a uniform distribution of acidity. Mix 1 ounce of products such as fermented sausage with four parts of distilled water and blend to ensure a uniform mixture. For products such as chow chow or relish, shake a product sample well, then immediately pour out at least 4 ounces into a small container; use an immersion blender or

blender to homogenize. For products such as pickles, kimchi or sauerkraut, a test jar should be included in every batch. Blend the entire contents of the test jar. After homogenizing the product sample, measure the product pH and record on the appropriate batch log or pH testing log.

6. After every use, clean the pH probe according to manufacturer instructions and gently blot with a soft tissue. Over time, food residue penetrates the probe, resulting in slower readings and more drift in readings. Consult manufacturer instructions for reconditioning the probe, or replace the probe when re-conditioning is no longer effective.

7. The cotton pad in the cap for the pH probe must be kept moistened with fresh 7.0 buffer to keep the probe properly conditioned.

Annual HACCP Plan Reverification and Maintenance

The HACCP plan and related records will be reviewed by the HACCP Team Leader at least annually and when significant modifications are proposed to ensure that procedures are accurate, working as intended, and in compliance with current regulations. A review of receiving, monitoring and training records will include an overview of corrective actions and routine verifications to identify weaknesses in procedures or policies. Adjustments are to be made when required, and retraining of staff must be provided as necessary.

If problems are identified by a team member (such as confusing or incorrect instructions), notify HACCP Team Leader so that the recommended change can be reviewed properly and implemented consistently. Any unapproved modifications to the HACCP plan, and unapproved changes to the procedures, equipment, food suppliers, or foods and ingredients used will invalidate the approval and may result in an uncontrolled food safety hazard.

Timely revisions are necessary to maintain compliance with state regulations and to ensure that HACCP procedures are effective and accurate. Certain situations require a special review:

1. Potential new hazards are identified that may be introduced into the process.
2. New ingredients are added, or when an ingredient supplier is changed.
3. The process steps or procedures are changed.
4. New or different processing equipment is introduced.
5. Production volume changes.
6. Personnel changes.
7. There are changes in the regulations.
8. Consumer complaints or illnesses are associated with a product from the process.
9. Patterns of deviations result in corrective actions.

Maintaining a record of review and revisions provides important documentation of the effective dates of procedures in force at any given time. This information is essential in the event of a food safety problem being traced to food processed using this HACCP process.

Revisions that do not change the process do not require re-approval from the regulatory authority. Changes that directly affect the process, such as changing suppliers, recipes, products, or the food preparation process, do require regulatory review and approval. Whenever the HACCP plan is revised, relevant training of HACCP team members is required; working copies of the previous version must be retracted and archived, and working copies of the new version are made available to the team. Archival original versions of the HACCP plan are maintained according to the retention schedule in the record-keeping policy.

HACCP Plan Record Keeping

The **HACCP system** must include records that are current and maintained, and provided to the regulatory authority upon request. The **HACCP plan** submitted for regulatory approval must include blank copies of each **monitoring** record required by the plan, covering **monitoring** of **critical control points**, instrument calibrations, corrective actions, staff training, and maintenance and reassessment of the plan. **HACCP** records must demonstrate that the following are routinely employed and in compliance with the **approved** plan and with state regulations, as relevant:

- Procedures for **monitoring** the **critical control points**
- Results of **monitoring** of the **critical control points**
- **Verification** of the effectiveness of the operation or process, and
- Necessary corrective actions when a **critical limit** at a **critical control point** is not met

Documents such as supplier Letters of Guaranty and **validation** of critical **control measures** are permanent records and should be retained as long as the **HACCP** process is in use. Records for products of **HACCP** processes that have a short shelf life (such as the 7 days allowed for sous vide products), should be retained for at least six months, or as required by the regulatory authority. Records for products that have a long preparation process and/or shelf life should be retained for at least six months beyond the shelf life of the product batch.

Example Forms and **monitoring** logs are provided in Section 9. Electronic record-keeping systems may be an option your establishment could consider to reduce record-keeping labor. However, all electronic records should provide at least the same information identified in the example forms in Section 9. Additionally, electronic logs should:

- Secure, to prevent tampering with data entries;
- Provide automatic date and time stamping for data entries and management reviews;
- Be routinely backed up to prevent loss of data;
- Provide for documenting management review
- Provide an electronic audit trail.

Local jurisdictions may have additional requirements for electronic record-keeping systems.

SECTION 10: SAMPLE FORMS

Examples of records or monitoring logs used in the **HACCP** Food Safety System are included on the following pages:

- Hazard Analysis Worksheet
- HACCP Summary Table (CCP Audit Table)
- ROP/Vacuum Packaging Batch Log
- Cooking and Reheating Temperature Log
- Cooling Log
- Refrigerator/Freezer Temperatures and Date Mark Check Log
- Corrective Actions Log
- Thermometer Calibration Check Log
- pH Meter Calibration and Product pH Monitoring Log
- Acidic or Acidified Food Cold Fill, Hold/Release Log
- Food Scale Accuracy Log
- Cleaning and Sanitizing Food Contact Surfaces Log
- Employee Training Record
- HACCP Re-Verification and Maintenance Log
- Cured, Cooked Whole Muscle, Non-Shelf Stable Batch Log
- Dry Cured Whole Muscle, No-Cook Process Batch Log
- Fermented Sausage Products Batch Log
- Fully Cooked, Dried Jerky Batch Log
- Fully Cooked, Cured Sausage Non-Shelf Stable Batch Log
- Preserving Fish by Hot Smoking Batch Log

Hazard Analysis Worksheet

Store Name _____

Street Address _____

City _____State _____Zip Code _____

(1) Ingredient/Processing Step	(2) Identify potential hazards introduced, controlled or enhanced at this time.	(3) Are any potential food safety hazards significant? (YES/NO)	(4) What is the justification for your decision for column 3?	(5) What preventive measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (YES/NO)
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				

Developed by: _____Date: _____

HACCP Plan (CCP Audit Table)

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

CCP	Hazard	Critical Limits	Monitoring				Corrective Action(s)	Verification	Records
			What	How	Frequency	Who			

Approved by: _____ Date: _____

ROP/Vacuum Packaging Batch Log

Store Name _____

Street Address _____

City _____State _____Zip Code _____

Instructions: Record product name, time, the temperatures/times taken, and any corrective action taken on this form. The chef or manager will verify that food workers have taken the required cooking temperatures correctly by observing food workers and preparation procedures during the shift, and by reviewing, initialing, and dating the data in this log, including any corrective actions, daily. This log should be maintained for a minimum of 6 months.

Date	Time	Food Item	Correctly Labeled?	Corrective Action Taken	Initials	Verified By

Cooking and Reheating Temperature Log

Store Name _____

Street Address _____

City _____State _____Zip Code _____

Instructions: Record product name, time, the temperatures/times taken, and any corrective action taken on this form. The chef or manager will verify that food workers have taken the required cooking temperatures correctly by observing food workers and preparation procedures during the shift, and by reviewing, initialing, and dating the data in this log, including any corrective actions, daily. This log should be maintained for a minimum of 6 months.

Date	Time	Food Item	Expire Date OK?	Internal Temp	Cook (C) or reheat (R)	Corrective Action Taken	Initials	Verified By

Cooling Temperature Log

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Instructions: Record temperatures every hour during the cooling cycle. Record corrective actions, if applicable. The chef or manager will verify that food workers are cooling food properly by observing food workers and preparation procedures during the shift, and by reviewing, initialing, and dating the data in this log, including any corrective actions, daily. This log should be maintained for a minimum of 6 months.

Date	Food Item	Time/ Temp	Time/ Temp	Time/ Temp	Time/ Temp	Time/ Temp	Time/ Temp	Corrective Actions Taken	Initials	Verified By

Refrigerator/Freezer Temperatures and Date Mark Check Log

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Instructions: The designated food establishment employee must record the location or description of holding unit, date, time, air temperature, corrective action, review of date marks, and initials on this Log daily. *When continuous electronic* monitoring *is required, the food worker monitoring temperatures indicates by signature that the electronic monitoring system has been examined for operation as required*. The designated supervisor must verify that foodservice workers have taken the required temperatures by visually monitoring food workers during their shift, and must review, initial, and date this log daily. This log will be maintained for a minimum of 6 months.

Location/ Unit Description	Date	Time	Temp	Date Marks Checked	Corrective Action	Initials	Verified By

Corrective Action Log

Store Name _____

Street Address _____

City _____State _____Zip Code _____

CCP #	Date	Product	Problem	Disposition of Product	Corrective Actions	Person Responsible	Verified By/Date	Compliance Procedures (Preventive Measures)

Thermometer Calibration Check Log

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Instructions: The designated food establishment employee(s) must record the calibration temperature and corrective action taken each time a thermometer is calibrated. Thermometers intended for measuring hot temperature items must be calibrated in hot water, while those used for cold temperatures must be calibrated in ice water. The designated supervisor must verify and initial that food establishment employees are using and calibrating thermometers properly by making visual observations of employee activities during hours of operation. This log should be maintained for a minimum of 6 months.

Date	Time	Thermometer ID#	Method Used (Ice Slurry/ Boiling Point)	Thermometer Reading	Accurate (Yes /No)	Corrective Action	Initials	Verified By

pH Meter Calibration and Product pH Monitoring Log

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Instructions: The designated food establishment employee(s) must record the calibration of the pH meter and any corrective action taken each time the meter is calibrated. The pH meter must be calibrated daily. Verify that the 4.00 pH buffer solution reads between 3.9 and 4.1 after calibration is complete. The designated supervisor must verify and initial that food establishment employees are using and calibrating pH meter properly by visually observing employee activities during hours of operation. This log should be maintained for a minimum of 6 months.

Date & Initial	pH meter #	Calibrated before use?	pH 4.0 reading after calibration	Accurate within 3.9 – 4.1 (yes/no)	Corrective Action	Product Tested	Product Batch ID	pH value observed	Reviewed By/Date

Acidic or Acidified Food Cold Fill Hold/Release Log

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Instructions: The designated food establishment employee(s) must record the calibration of the pH meter and any corrective action taken each time the meter is calibrated. The pH meter must be calibrated on each day of use. Verify that the 4.00 pH buffer solution reads between 3.9 and 4.1 after calibration is complete. The designated supervisor must verify and initial that food establishment employees are using and calibrating the pH meter properly by visually observing employee activities during hours of operation. This log should be maintained for a minimum of 6 months.

Date & Initial	Product Tested	Prep Time	Hold temp.	pH meter calibrated before use?	pH 4.0 reading *after calibration*	Accurate within 3.9 – 4.1 (yes/no)	Product pH value	Corrective Action	Release Date & Time	Reviewed By/Date

Food Scale Accuracy Log

Store Name _____

Street Address _____

City _____State _____Zip Code _____

Instructions: Scales used to weigh cure will be checked for accuracy each time a product is made. The scale will be checked for accuracy using a standard weight according to manufacturer's recommendation and recorded on the Scale Accuracy Log. The designated supervisor must verify and initial that food establishment employees are verifying accuracy of scales by reviewing and signing this log. This log should be maintained for a minimum of 6 months.

Date/Time	Food Scale Identification	Standard Weight	Scale Reading	Accurate Y/N	Corrective Action(s)	Staff Initial	Verified By (Initials)

Cleaning and Sanitizing Food Contact Surfaces Log

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Instructions: Food establishment employees will observe practices and procedures in accordance with the SSOP and corrective action taken, if applicable. The foodservice manager will verify that food establishment employees are following the SSOP properly by making visual observations of employee activities during all hours of operation and noting any corrective actions taken, or none taken if no violations for the day. The food establishment manager will review and initial the log on a weekly basis. Retain this log for a minimum of 1 year.

Date	Observed Practices in Accordance with SSOP (Y/N)	If No, Violations Observed	Corrective Action	Initials	Manager Initials/Date

Employee Training Record

Store Name _____

Street Address _____

City _____State _____Zip Code _____

I have been provided training on the subject described above. I have read or re-read the relevant policies and procedures, and I have had any questions answered. I understand what is required and will comply with the requirements.		
Name	**Initials**	**Title**

HACCP Re-Verification and Maintenance Log

Store Name _____

Street Address _____

City _____State _____Zip Code _____

Instructions: Each HACCP plan must be reviewed and re-verified at least annually to maintain regulatory compliance and to ensure that the plan is current and effective. Procedures, policies and all records related to the HACCP plan must be reviewed to identify weaknesses or needed corrections and updates. Special reviews prompted by changes in procedures, equipment, recipes, regulations, corrective actions, or supplier issues, may require revision of parts of the HACCP plan. Staff training related to revisions in the HACCP plan may be required. This log should be maintained for a minimum of 3 years.

Manager Initials/Date	Revisions Required? Y/N	If Yes, Affected Section(s):	Reason	Regulatory Review Required? Y/N	Approved by Regulatory? Y/N	Old Version Retracted? Y/N

Batch Log: Cured, Cooked Whole Muscle, Non-Shelf Stable

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

BATCH:

Date:	**Recipe:**	
Produced by:	**Curing Salt Used: Yes No % Nitrite (and nitrate?):**	
Staff initials:	**Weight of Curing Salt Used:**	**Weight of meat used:**
CCP Met? Yes No	**Corrective Action:**	

CURING:

Start date:	**Staff Initials:**	**Finish date:**	**Total Time:**
Raw protein lot#	**Circle one process: Dry rub Immersion brine**		

SMOKING AND COOLING:

Cold smoking times:	**Start:**			**Finish:**			
Cooling: Time:	Start						Finish
Temp:							
Corrective Action:							
CCP Met? Yes No	**Staff Initials:**						

VERIFICATION:

All CCPs Met?	Yes	No	
Corrective Actions:			
Verified by:		**Date:**	

Batch Log: Dry Cured Whole Muscle, No-Cook Process

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

BATCH:

Date:	**Recipe:**	**Curing Salt Used: Yes No**
Produced by:	**Cure Product Name:**	**Lot #**
	Weight of Curing Salt Used:	**Green weight of meat used:**
CCP Met? Yes No	**Staff Initials:**	

CURING/BRINING:

Start Date:	**Staff Initials:**	**Finish date:**	**Total Time:**
CCP Met? Yes No	**Circle one process:**	**Dry rub**	**Immersion brine**
Corrective Action:			

COLD SMOKING AND COOLING:

Cold smoking times:	**Start:**			**Finish:**			
Cooling: Time:	Start						Finish
Temp:							
Corrective Action:							
CCP Met? Yes No	**Staff Initials:**						

WEIGHT AFTER DRYING:

Weight Loss Target: % of green weight

Date:	**Time:**	**Initials:**	**Weight:**
Date:	**Time:**	**Initials:**	**Weight:**
Corrective Action:			
CCP Met? Yes No	**Staff Initials:**		

VERIFICATION:

All CCPs Met?	Yes	No	
Corrective Actions:			
Verified by:		**Date:**	

Batch Log: Fermented Sausage Products

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Date:	**Recipe:**
Produced by:	**Quantity of meat used:**

CURING:

Type:	**Sodium Nitrite/Bactoferm**		
Weight:	**Scale accuracy check: True value:**	**Observed value:**	**OK?**
Cure Lot Number:			
CCP Met?	Yes	No	
Corrective Action:			
Staff Initials:			

pH DROP:

Initial pH/pH Drop		
CCP Met?	Yes	No
Corrective Action:		
	Staff initials:	

WEIGHT:

Initial Weight, lbs:					**% Weight loss target:**			
Drying Weight, lbs:								
Weigh Date:								
CCP Met?	Yes				No			
Corrective Action:								
				Staff initials:				

VERIFICATION:

All CCPs Met?	Yes	No	
Corrective Actions:			
Verified by:		**Date:**	

Batch Log: Fully Cooked, Dried Jerky

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Date:	**Recipe:**
Produced by:	**Green weight of meat used:**

SMOKE/COOK:

Final Internal Temp:		°F
CCP Met?	Yes	No
Corrective Action:		
	Staff Initials:	

COOLING:

Start Time:		**Temp:**	°F
	Staff Initials:		
First Check Time (< 2 hours):		**Temp:**	°F
	Staff Initials:		
Second Check Time (<4 hours or reaching 70):		**Temp:**	°F
Corrective Action:			
CCP Met? Yes No	**Staff Initials:**		

WEIGHT AFTER DRYING:

Date:	**Time:**	**Initials:**	**Batch Weight:**
Date:	**Time:**	**Initials:**	**Batch Weight:**
Corrective Action:			
CCP Met? Yes No	**Staff Initials:**		

VERIFICATION:

All CCPs Met?	Yes	No	
Corrective Actions:			
Verified by:		**Date:**	

Batch Log: Fully Cooked, Cured Sausage, Non-Shelf Stable

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Date:	
Recipe:	

CURING:

Type:	[Product Name, #1 or #2]	
Weight:		
Cure Lot Number:		
CCP Met?	Yes	No
Corrective Action:		
Staff Initials:		

SMOKE/COOK:

Final Internal Temp:		˚F
CCP Met?	Yes	No
Corrective Action:		
	Staff Initials:	

COOLING:

Start Time:		**Temp:**	˚F
		Staff Initials:	
First Check Time (< 2 hours):		**Temp:**	˚F
		Staff Initials:	
Second Check Time (<4 hours of reaching 70):		**Temp:**	˚F
CCP Met?	Yes	No	
Corrective Action:			
		Staff Initials:	

VERIFICATION:

All CCPs Met?	Yes	No	
Corrective Actions:			
Verified by:		**Date:**	

Batch Log: Preserving Fish by Hot Smoking

Store Name _____

Street Address _____

City _____State _____Zip Code _____

BATCH:

Date:	**Product:**
Recipe:	**Initial Weight:**

BRINING: CCP 1

Brining of Fish	**Weight of Salt _____ lb. Amount of Water _____ gal.** **Brine Pre-chilled?**	
	Date & Time in:	**Date & Time out**
Critical Limit Met?	**Yes**	**No**
Corrective Action:		
Staff Initials:		

SMOKE/DRY/COOK: CCP 2

Drying Step	**Time In:**	**Time Out:**
Cooking Step:	**°F.**	**Final Weight:**
Critical Limits Met?	**Yes**	**No**
Corrective Action:		
Staff Initials:		

COOLING: CCP 3

Cooling Parameters	**Start Time:**	**Temp:**	°F
First Check Time (< 2 hours):		**Temp:**	°F
Second Check Time (<4 hours of reaching 70):		**Temp:**	°F
Corrective Action:			
Staff Initials:			

Labeling: CCP 4

Label Content Review	**Required safe handling & storage instructions present**	**Correct use-by date is present**	
Corrective Actions:			
Staff Initials:		**Date:**	

VERIFICATION:

All CCPs Met?	**Yes**	**No**	
Corrective Actions:			
Verified by:		**Date:**	

APPENDIX 1: FOOD AND PROCESS HAZARDS

Biological Hazards

Biological **Hazards** can be bacteria, parasites, or viruses. Bacteria, parasites, or viruses that cause illness are called pathogens. In most cases, pathogens must grow or multiply in food to certain levels in order to cause foodborne illness. The following factors can affect the growth of pathogens:

Nutrients

Bacteria require food and water to carry on their life processes. Since what you are producing is a food product, nutrients are going to be available. Equipment that contains food residue can also be a nutrient source for bacteria.

Temperatures

Another essential factor that affects the growth of bacteria is temperature. Growth can occur over a wide range of temperatures from about 14°F. to 194°F., but individual bacteria have much narrower temperature ranges for growth.

Time

It's not just temperature that's the problem – the time at these temperatures can affect growth of bacteria. The goal is to minimize the time of exposure of foods to temperatures at which bacteria grow most quickly.

Moisture
The amount of available moisture in a food is measured as water activity. When substances like salt and sugar are added to a food, water is tied up and is less available to the bacteria.

Inhibitors

Foods can contain chemicals that are either natural or added that restrict or prevent growth of microorganisms. Salt is a good example of an added chemical that can inhibit growth of bacteria. Chemical preservatives like sodium nitrite, sodium benzoate, and calcium propionate can also inhibit the growth of microorganisms.

pH

pH is a measure of how acidic a food is. pH ranges from 0–14; 7 is neutral. Foods with a pH of 4.6 and below are considered acid foods, like most fruit juices. Foods with a pH above 4.6 are said to be low acid, like **meats** and vegetables. Most bacteria don't grow very well in acid foods, so you can use pH to **control** the growth of bacteria. Generally, food is considered to be in a safe pH range when the final pH is 4.6 or below.

Atmosphere

Some bacteria require a specific type of atmosphere for growth. Microorganisms are categorized as aerobes, anaerobes, facultative anaerobes, and microaerophilic. Aerobes require oxygen and include such bacteria as *Bacillus.* Anaerobes grow only in the absence of molecular oxygen. These organisms include *Clostridium.* Facultative anaerobes can grow whether the environment has

oxygen or not. *Microaerophilic* is a term applied to organisms which grow only in reduced oxygen environments. Knowledge of the atmosphere surrounding the food is an especially important consideration in determining which pathogens are likely to be a problem.

Most bacteria will not grow when the water activity is 0.85 or less. Many yeasts and molds can grow below this level, but this is a spoilage concern and generally not a food safety concern.

Chemical Hazards

A wide variety of chemicals are routinely used in the production and processing of foods. Some examples of common types of chemicals are listed in Table 3-2. While these types of chemicals may not be hazards if used properly, some can cause illness if not used properly. Therefore, the hazard analysis must consider whether any of these chemicals is used in a manner that creates a significant food safety problem.

Physical Hazards

Physical **hazards** are represented by foreign objects or extraneous matter that is not normally found in food. The presence of these items typically results in personal injuries such as a broken tooth, cut mouth, or a case of choking. Examples of physical **hazards** are found in Table 3-3. In some instances, physical contaminants may also include filth such as mold mats, insects, and rodent droppings. Although extraneous matter normally categorized as filth may not actually injure a consumer, some of these items can also contribute biological **hazards**. For example, rodents and their droppings are known to carry *Salmonella* species.

Food Code Tables of Hazards, Associated Foods, and Control Measures

Except as noted, the following tables from Annex 4 of the 2022 FDA Model Food Code provide detailed listings of biological, chemical, and physical hazards with preventive and control measures.

For detailed information on species-specific hazards associated with fish and fishery products, refer to the "Fish and Fishery Products Hazards and Controls Guidance," FDA, June 2022.

Annex 4, Table 1a – 1c. Selected Biological Hazards Found at Retail, Associated Foods, and Control Measures

BACTERIAL HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
Bacillus cereus (intoxication caused by heat-stable, preformed emetic toxin and infection by heat-labile, diarrheal toxin)	Meat, poultry, starchy foods (e.g., rice, potatoes), puddings, soups, cooked vegetables	Cooking, cooling, cold holding, hot holding
Campylobacter jejuni	Poultry, raw milk	Cooking, handwashing, prevention of cross contamination
Clostridium botulinum	Vacuum-packed foods, reduced oxygen packaged foods, under-processed canned foods, garlic-in-oil mixtures, time/temperature abused baked potatoes/sautéed onions	Thermal processing (time + pressure), cooling, cold holding, hot holding, acidification and drying, etc.
Clostridium perfringens	Cooked meat and poultry, cooked meat and poultry products including casseroles, gravies	Cooling, cold holding, reheating, hot holding

E. coli O157:H7 (other shiga toxin-producing *E. coli*)	Raw ground beef, raw seed sprouts, raw milk, unpasteurized juice, foods contaminated by infected food workers via fecal-oral route	Cooking, no bare-hand contact with RTE foods, employee health policy, handwashing, prevention of cross contamination, pasteurization, or treatment of juice
Listeria monocytogenes	Raw meat and poultry, fresh soft cheese, paté, smoked seafood, deli meats, deli salads	Cooking, date marking, cold holding, handwashing, prevention of cross contamination
Salmonella spp.	Meat and poultry, seafood, eggs, raw seed sprouts, raw vegetables, raw milk, unpasteurized juice	Cooking, use of pasteurized eggs, employee health policy, no bare-hand contact with RTE foods, handwashing, pasteurization or treatment of juice
Shigella spp.	Raw vegetables and herbs, other foods contaminated by infected workers via fecal-oral route	Cooking, no bare-hand contact with RTE foods, employee health policy, handwashing
Staphylococcus aureus (preformed heat stable toxin)	RTE TCS foods touched by bare hands after cooking and further time/temperature abused	Cooling, cold holding, hot holding, no bare-hand contact with RTE food, handwashing
Vibrio spp.	Seafood, shellfish	Cooking, approved source, prevention of cross contamination, cold holding

Source: FDA 2022 Model Food Code, Annex 4

RTE = ready-to-eat TCS = time/temperature control for safety food

Annex 4, Table 1b. Selected Parasitic Hazards Found at Retail, Associated Foods, and Control Measures HAZARD

PARASITIC HAZARDS	ASSOCIATED FOODS	CONTROL MEASURES
Anisakis simplex	Various fish (cod, haddock, fluke, pacific salmon, herring, flounder, monkfish)	Cooking, freezing
Taenia spp.	Beef and pork	Cooking
Trichinella spiralis	Pork, bear, and seal meat	Cooking

Annex 4, Table 1c. Selected Viral Hazards Found at Retail, Associated Foods, and Control Measures HAZARD

VIRAL HAZARDS	ASSOCIATED FOODS	CONTROL MEASURES
Hepatitis A and E	Shellfish, any food contaminated by infected worker via fecal-oral route	Approved source, no bare-hand contact with RTE food, minimizing bare-hand contact with foods not RTE, employee health policy, handwashing
Other Viruses (Rotavirus, Norovirus, Reovirus)	Any food contaminated by infected worker via fecal-oral route	No bare-hand contact with RTE food, minimizing bare-hand contact with foods not RTE, employee health policy, handwashing

Preventive Measures and Additional Hazards

Characteristics of Growth for Bacterial Pathogens Associated With Food Products With Examples of Preventive Measures

Pathogens	Temperature range for growth	Min. pH	Max. pH	Min. Aw	Max. % Water Phase Salt	Oxygen Requirement	Typical Preventive/Control Measures
Bacillus cereus	4° - 55°C.	4.3	9.3	0.92	10.0	Facultative anaerobe[1]	Proper handling/cooling temperatures; thermal processing of shelf stable canned food
Campylobacter jejuni	30° – 45°C.	4.9	9.5	0.987	1.7	Microaerophile[2]	Proper pasteurization/cooking, freezing, avoiding cross contamination; freezing; atmospheric packaging
Clostridium botulinum Type A, and proteolytic types B & F)	10° – 48°C.	> 4.6	9	0.935	10.0	Anaerobe[3]	Addition of nitrites and salt, refrigeration, acidification to below pH 4.6, reduction of moisture below 0.93
Clostridium botulinum Type E, and non-proteolytic types B & F	3.3° – 45°C.	>5.0	9	0.97	5	Anaerobe[3]	Addition of salt, refrigeration <3.3°C., reduction of moisture below 0.92
Clostridium perfringens	10° – 52°C.	5.0	9	0.93	7	Anaerobe[3]	Proper handling/cooling. Proper cooking times and temperatures; avoiding cross contamination by unsanitary equipment
Escherichia coli O157:H7	10° – 42°C.	4.0	10	0.95	6.5	Facultative anaerobe[1]	Proper cooking time/temperatures; prevent cross contamination; proper refrigeration
Listeria monocytogenes	2.5° – 44°C.	4.4	9.4	0.92	10	Facultative anaerobe[1]	Proper heat treatment, rigorous environmental sanitation program, separation of raw and ready-to-eat food and production areas
Salmonella	5° – 46°C .	3.7	9.5	0.94	8	Facultative anaerobe[1]	Proper heat treatment, separation of raw and cooked products, fermentation controls, reduced water activity
Shigella spp.	6.1° – 47.1°C.	4.8	9.3	0.96	5.2	Facultative anaerobe[1]	Proper heat treatment; proper holding temperatures; proper employee hygiene
Staphylococcus aureus toxin formation	10.0° – 48°C.	4.0	9.8	0.85	10	Facultative anaerobe[1]	Proper fermentation and pH control, employee hygiene, proper heat treatment and post-process product handling, reduced water activity

Vibrio spp.	20° - 45°C.	4.8	11.0	0.94	5-10%	Facultative anaerobe[1]	Proper heat treatment, prevention of cross contamination, proper refrigeration temperatures
Yersinia enterocolitica	-1.3° – 42°C.	4.2	10.0	0.945	7	Facultative anaerobe[1]	Proper refrigeration, heat treatments, control of salt and acidity, prevention of cross contamination

1 - Grows either with or without oxygen; 2 – Requires limited levels of oxygen; 3 – Requires the absence of oxygen (Sources: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry,[50] FDA, January 2018; and Bacteriological Analytical Manual[51], FDA, December 2019)

[50] https://www.fda.gov/files/food/published/Draft-Guidance-for-Industry--Hazard-Analysis-and-Risk-Based-Preventive-Controls-for-Human-Food---Bacterial-Pathogen-Growth-and-Inactivation-%28Appendix-3%29-Download.pdf

[51] https://www.fda.gov/food/laboratory-methods-food/bam-chapter-9-vibrio

*Preventive measures are defined as: "Physical, chemical, or other means that can be used to control an identified food safety hazard." The following tables provide examples of **preventive measures** for biological, chemical, and physical hazards.*

Table 3-2: Examples of Preventive Measures for Chemical Hazards

Hazard	Preventive Measure
Naturally Occurring Substances	Supplier warranty or guarantee; verification program to test each supplier's compliance with the warranty or guarantee.
Added Hazardous Chemicals	Detailed specifications for each raw material and ingredient; warranty or Letter of Guarantee from the supplier; visiting suppliers; requirement that supplier operates with a HACCP plan.
In-Process Chemicals	Identify and list all direct and indirect food additives and color additives; check that each chemical is approved; check that each chemical is properly used; record the use of any restricted ingredients.

Table 3-3: Examples of Preventive Measures for Physical Hazards

Hazard	Preventive Measure
Foreign objects in raw materials	Supplier's HACCP plan; use of specifications, Letters of Guaranty; vendor inspections and certification; in-line magnets; screens, traps, and filters; in-house inspections of raw materials.
Foreign objects in packaging materials, cleaning compounds, etc.	Supplier's HACCP plan; use of specifications, Letters of Guaranty; vendor inspections and certification, in-house inspections of raw materials.
Foreign objects introduced by processing operations or employee practices	Visual product examinations; proper maintenance of equipment; frequent equipment inspections, such as during or after cleaning and sanitizing.

Annex 4, Table 2a. Naturally Occurring Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Naturally Occurring Chemical Hazards	Associated Foods	Control Measures
Scombrotoxin	Primarily associated with tuna fish, mahi-mahi, blue fish, anchovies bonito, mackerel; also found in cheese	Check temperatures at receiving; store at proper cold holding temperatures; buyer specifications: obtain verification from supplier that product has not been temperature abused prior to arrival in facility.
Ciguatoxin	Reef fin fish from extreme SE U.S., Hawaii, and tropical areas; barracuda, jacks, king mackerel, large groupers, and snappers	Ensure fin fish have not been caught; purchase fish from approved sources. Fish should not be harvested from an area that is subject to an adverse advisory.
Tetrodotoxin	Puffer fish (Fugu; Blowfish)	Do not consume these fish.
Mycotoxins Aflatoxin Patulin	Corn and corn products, peanuts and peanut products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts. Other grains and nuts are susceptible but less prone to contamination. Also apple juice products.	Check condition at receiving; do not use moldy or decomposed food. Buyer Specification: obtain verification from supplier or avoid the use of rotten apples in juice manufacturing.

Toxic mushroom species	Numerous varieties of wild mushrooms	Do not eat unknown varieties or mushrooms from unapproved source.
Shellfish toxins Paralytic shellfish poisoning (PSP) Diarrhetic shellfish poisoning (DSP) Neurotoxin shellfish poisoning (NSP) Amnesic shellfish poisoning (ASP)	Molluscan shellfish from NE and NW coastal regions; mackerel, viscera of lobsters and Dungeness, tanner, and red rock crabs Molluscan shellfish in Japan, western Europe, Chile, NZ, eastern Canada Molluscan shellfish from Gulf of Mexico Molluscan shellfish from NE and NW coasts of NA; viscera of Dungeness, tanner, red rock crabs, and anchovies	Ensure molluscan shellfish are: - from an approved source; and - properly tagged and labeled.
Pyrrolizidine alkaloids	Plant food containing these alkaloids; most commonly found in members of the Borginaceae, Compositae, and Leguminosae families	Do not consume food or medicinals contaminated with these alkaloids.
Phtyohaemagglutinin	Raw red kidney beans (undercooked beans may be more toxic than raw beans)	Soak in water for at least 5 hours. Pour away the water. Boil briskly in fresh water, with occasional stirring, for at least 10 minutes.
Allergens	Foods containing or contacted by: milk. eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans	Use a rigorous sanitation regime to prevent cross-contact between allergenic and non-allergenic ingredients.

Editor's note: Effective January 1, 2023, the list of major food allergens in the United States also includes sesame.

Annex 4, Table 2b. Added Chemical Hazards at Retail, Along With Their Associated Foods and Control Measures

Added Chemical Hazards	Associated Foods	Control measures
Environmental contaminants: pesticides, fungicides, fertilizers, insecticides, antibiotics, growth hormones	Any food may become contaminated.	Follow label instructions for use of environmental chemicals. Soil or water analysis may be used to verify safety.
PCBs	Fish	Comply with fish advisories.
Prohibited substances (21 CFR 189)	Numerous substances are prohibited from use in human food; no substance may be used in human food unless it meets all applicable requirements of the FD&C Act.	Do not use chemical substances that are not approved for use in human food.

Toxic elements/compounds, mercury	Fish exposed to organic mercury: shark, tilefish, king mackerel, and swordfish. Grains treated	Pregnant women/women of childbearing age/nursing mothers, and young children should not eat shark, swordfish, king mackerel, or tilefish because they contain high levels of mercury. Do not use mercury containing fungicides on grains or animals.
Copper	High-acid foods and beverages	Do not store high-acid foods in copper utensils; use backflow prevention device on beverage vending machines.
Lead	High-acid food and beverages	Do not use vessels containing lead.
Preservatives and food additives: Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite)	Fresh fruits and vegetables, shrimp, lobster, wine	Sulfiting agents added to a product in a processing plant must be declared on labeling. Do not use on raw produce in food establishments.
Nitrites/nitrates Niacin	Cured meats, fish, any food exposed to accidental contamination, spinach, meat, and other foods to which sodium nicotinate is added	Do not use more than the prescribed amount of curing compound according to labeling instructions. Sodium nicotinate (niacin) is not currently approved for use in meat or poultry with or without nitrates or nitrates.
Flavor enhancers monosodium glutamate (MSG)	Asian or Latin American food	Avoid using excessive amounts.
Chemicals used in retail establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, and paints)	Any food could become contaminated with mercury-based fungicides	Address through SOPs for proper labeling, storage, handling, and use of chemicals; retain Material Safety Data Sheets for all chemicals.

Annex 4, Table 3. Main Materials of Concern as Physical Hazards and Common Sources

Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, lights, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth, cuts, infection; may require surgery to remove	Fields, buildings, machinery, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

APPENDIX 2: COMMON QUESTIONS AND ANSWERS

Questions and Answers: ROP Processes

Q: Does a plan have to cover specific recipes or can it be written in such a way to cover a category or categories of recipes?

A: The plan should be written to cover a process (a set of steps in a procedure that are at least essentially the same for as many products as follow that same basic process). You can include as many products as follow that basic process. If there are small differences between products at a single step, that step in the SOP (Part 4 of the **HACCP** template) can refer to the individual recipe cards or fabrication instructions for the details unique to each product. Those recipe cards or fabrication instructions can be external documents to the **HACCP plan**.

Q: We want to vacuum pack to preserve quality when freezing an item for future use. Spaghetti sauce is an example. If we cook, blast chill (using HACCP standards), vacuum pack, blast freeze and keep frozen until heated do we need a HACCP plan, can we do this with a plan? We will reheat to temperature in boiling water or commercial steamer. This is for internal use at the restaurant and not to sell retail in the bag.

A: As you have described this process, this could be done within a 48-hour **variance** with a written procedure only (**HACCP plan** not required). Freezing stops all bacterial activity. When frozen immediately after vacuum packaging, the 48-hour shelf life begins when the product is removed from the freezer.

Q: Kitchen is a separate facility from our retail location, so of course now travel is something I need to address. I think this means I would have to have the flow diagram as I already do, with an additional CCP for the travel procedure, as well as a second cold storage CCP once product arrives at the retail location, is that correct?

A: If the plan you are writing is for ROP storage of raw **meats**, you are not required to use a continuous temperature logger at any point. You would need to be sure your procedure for the main facility includes how you will pack and transport the ROP product for transfer to the satellite facility. Include how it will be kept at temperatures below 41°F. (hard-sided ice packs are a better choice than the soft-sided ones that puncture easily). At the satellite location you would need a receiving temperature log indicating what was received, temperature at receipt, and date/initials. Then a cooler temperature/date mark log for the product in storage, with the same procedures as at the primary kitchen. Receiving and cold storage would be CCPs for the satellite facility.

If this was a sous vide or ROP cook-chill process, you would need to have a means of tracking temperature continuously while the product is in transit from commissary to satellite locations. Since that transit time would be relatively brief, the regulatory authority may accept use of maximum temperature-registering “TTI” tapes or stickers calibrated to 40°F. as a maximum temperature, placed in each cooler. Those indicators provide a permanent record that should be included with the receiving log at the receiving facility. Another option would be low-cost reusable digital temperature loggers from which data can be uploaded to a computer after each use.

Remember that the satellite facility is operating as an extension of your **HACCP** process, so relevant temperature **monitoring**, training and other records will be required at the satellite facility.

Q: Local farms that are approved to slaughter on their properties: Is a farm that is inspected and approved by a state regulatory authority to slaughter, say ducks, considered to be a reputable (approved) source?

A: Yes, as long as each supplier is inspected by either USDA or a state regulatory authority, the supplier is an **approved** source.

Q: Large roasts or hams for sous vide – come-up times discussion. Related: How does the sous vide cooking batch size affect come-up time (CUT) requirements?

A: With large roasts and with large batches of standard portions of food, the come-up time (CUT) from below 41°F. to full internal cooking temperature is of great concern. If spores of certain harmful bacteria are exposed to excessively long CUT, the time in the temperature danger zone may be enough to allow the spores to activate, and for the new pathogen cells to produce toxin. Water in the sous vide bath must circulate freely between the bags of portioned product. The bath must be pre-heated to the desired cooking temperature to minimize CUT when cooking portioned product. Adding cold product to the preheated bath results in a temporary temperature drop; the larger the batch of product, the larger the drop in temperature if the bath volume is not also increased with batch size. For this reason, portions should be consistent in thickness and weight, and it is important to know how long the CUT will be for a specified number of portions of uniform size, and for a known bath volume with the sous vide circulator at the planned cooking temperature. For the safety of the process and to meet regulatory requirements, internal product temperatures should be **monitored**.

When using the sous vide technique to cook large roasts or hams, the concern for excessive CUT is greater. The center of the roast or ham will heat (and cool!) more slowly than the outside surfaces. USDA's FSIS Appendix A states that no more than 6 hours is to be allowed between refrigeration temperature and cooking temperature. (CUT is time spent in the temperature danger zone.) For practical reasons, CUT should be kept as much shorter than 6 hours as possible. To minimize CUT for large roasts, hams, and other large prime cuts, it may be necessary to use a larger bath with more water, and possibly additional circulators. Another option with the larger bath would be to preheat to a higher temperature than desired for cooking until the internal temperature of the product reaches at least 130°F. (the lowest allowed cooking temperature). Once the product has reached at least 130°F., adjust the temperature setting on the circulator or circulators to the desired cooking temperature. Remember that all cooking temperatures in the Food Code come with requirements for a specified length of time at the required temperature.

Q: How can you monitor come-up time (CUT) in fish for a sous vide process if the fish is frozen when you place it into the ROP bag?

A: Self-sealing foam tape, such as is sold in sous vide temperature **monitoring** kits, allows placement of a thermocouple needle probe through the wall of an ROP bag into the product inside the bag. As the temperature of the **fish** (or any other protein) rises toward 32°F., the flesh will soften to a point that allows the thermocouple probe to penetrate. After the package of **fish** has been in the pre-heated water bath for a few minutes, the **fish** will have softened to a point that will allow placement of the probe into the product. If you wait 10-15 minutes after placing the package into the water bath, test with the probe to see if you can insert the probe. If you do not succeed in inserting the probe properly, wait a few minutes and try again using a different spot in the self-sealing tape (or use another piece of the tape). Be sure the probe is inserted to the proper depth into the thickest part of the thickest piece of product.

Q: Is it acceptable to use generic product specifications (ingredients, packaging film) versus stating a particular supplier?

A: Yes! If you have identified a specific supplier along with the product specifications in your plan, and then at some time after the plan is **approved**, you change suppliers (for any reason), you would need to update your **HACCP plan**. If you simply state product specifications (such as: "food grade 3-mil, 1-gallon standard ROP bags"), you could use any **approved** supplier without needing to update your plan to reflect a supplier change.

Q: Can product be cooked to customer order (undercooked) in a sous vide process if a consumer advisory is posted? How does that look in a HACCP plan?

A: When cooking sous vide without a **variance**, the exact requirements of the Food Code must be followed. That includes cooking time and temperature requirements. You can choose to use either the primary internal temperature and time requirements found in Subparagraph 3-401.11(A), or the alternate lower internal temperatures with longer times, as specified in Subparagraph 3-401.11(B), with no **variance** required. If you want to allow cooking to order (undercooking), a **variance** will be required. In this case you must have the required consumer advisory and reminders posted, and the **HACCP plan** must include reference to the consumer advisory both in the process instructions and in the CCP summary table (Column 3, **Critical Limits**).

Q: Is it possible to integrate a continuous temperature monitoring system into a corporate system (educational or large institutional system)? What are the concerns?

A: Choosing an electronic temperature **monitoring** system to meet **HACCP** requirements that will also integrate with your organization's network is probably something your organization's IT support should assist with. They would be able to identify compatibility concerns. That could involve them having discussion with the manufacturers of systems you are evaluating to determine how compatible they are with the network.

Relating to the **HACCP** use of the electronic temperature **monitoring** system: This issue affects some corporate restaurant groups as well as culinary schools that are part of a larger institution. The concern is in the reason for the requirement: *food safety*. Who will be responsible for **monitoring** that system for operation and reviewing the data? Will you hold that responsibility, or will that be handled by corporate maintenance or IT (however named)? The problem, if not directly **monitored** by you, is how to meet and document compliance with the requirement to inspect the system twice daily for operation. Will you receive timely notification in the event of a failure of the **critical limit** of 41°F.? Can the system be programmed to notify multiple parties including you and IT or Maintenance in the event of a failure?

This question is really one that would require some research and the assistance of your organization's IT staff to arrive at the right solution for your application.

Q: Can par-cooked meats (non-continuous cooking) be stored using ROP? What are the requirements?

A: Par-cooked **meats** can be stored in ROP packaging like any raw **meats**; this includes **meats** that have been seared or briefly placed on a grill for grill marks, but not cooked to the required internal cooking temperature specified by the Food Code. Remember that par-cooked **meat** is not-ready-to-eat (**NRTE**) even if it looks fully cooked, so the packaged product must be labeled as **NRTE** food. The Food Code allows no more than one hour for the initial heating cycle, and the product must

then be cooled and refrigerated properly. The maximum storage time for par-cooked **meats**, like for raw **meats**, is 30 days under refrigeration (day of packaging is day 1).

Q: Can meats or produce (fruits or vegetables) be marinated in ROP?

A: Yes. Marinades are typically acidic. Raw foods have a high load of competing (friendly) bacteria. Those bacteria and the acidity of the marinade allow marination of raw **meats** or other raw foods under refrigeration. This can be done either under an **approved** 48-hour **variance** procedure, or under a **HACCP plan** along with other raw, non-marinated **meats**. Instructions in the preparation step of the Process SOP can refer to recipes or fabrication instructions for the marinated products. Those documents should contain the instructions specific to each product. The process SOP should include only the general instructions for all products.

Q: If I have my plan approved for storing raw meats, and later decide I want to use ROP to marinate meats or produce, do I need to update my HACCP plan?

A: You would have two options. You must do one or the other of these options:

- Update your existing **HACCP plan**. The plan must cover all products that will be packaged.
- Or, since marination time is typically measured in hours, you could have a separate **variance** procedure **approved** specifically for marinating products.

In either case, you should talk with your inspector for guidance.

Q: If I have raw meat such as a steak packaged in ROP with marinade, what is the shelf life? Can the product be cooked sous vide at 29 or 30 days? Does that cooked product still have a 7-day shelf life from the day it was cooked?

A: Based on 3-502.12(B) of the Food Code, **TCS** proteins stored in ROP under refrigeration at 41°F. or lower (but not frozen) with one additional hurdle (water activity <0.91, pH ≤4.6, commercially cured **meats** received in intact packages, or food with high level of competing bacteria) have a 30-day shelf life. Raw **meats** or vegetables have a high competing population of bacteria. Sous vide cooked products have a maximum 7-day shelf life, because the relatively high population of "friendly" bacteria associated with raw foods has been destroyed by cooking. The cooking temperatures used in sous vide are generally not high enough to destroy spores or viruses. The Food Code shelf-life limits are based on research that has determined the longest allowable safe storage time at 41°F. or lower. Now to answer these three questions:

1. Raw **meat** and **poultry** (but not **fish**) can be marinated in ROP under refrigeration with the same shelf life as if there were no marinade. The acidity of marinades tends to add an extra layer of protection (another hurdle).

2. The bagged and marinated product could be cooked sous vide after 29 or even 30 days, but at this point it should be served immediately with no further storage. Shelf-life values cannot safely be stacked in the storage-then-sous vide sequence beyond the 30 days allowed for raw protein storage.

3. If the raw product will be stored at 41°F. or lower in ROP with marinade for several days before sous vide cooking, subtracting the 7 days sous vide shelf life from the 30 days raw storage shelf life gives you the longest time the product can be stored raw in ROP under refrigeration (23

days). The product must be consumed or discarded within 30 days of placement in the ROP bag.

Q: Can ROP be used for fruits and juices?

A: Yes. If the fruits are acidic (most fruits) and are not cooked, they are not **time/temperature control for safety** food, so date marking will not apply. You would probably refrigerate these products anyway, so the products would have temperature **control** and pH as the hurdles keeping these products safe.

Q: Is it allowable to have alcohol in a recipe for an ROP process (such as bourbon BBQ ribs)? Would there be any benefit from the alcohol in controlling or eliminating harmful bacteria?

A: Alcohol is an **approved** ingredient in food. However, it would not be used as a major ingredient at a concentration (70 percent or higher by weight) that would provide effective **control** against pathogens.

Q: When writing the plan and establishing the personnel who will execute the plan, do you have to put in the employee's name or just a generic employee title of the person who will execute the plan?

A: It is recommended that position titles, not employee names, should be used. Changes to the **HACCP plan** generally must be **approved**. If you have named **HACCP team** members by name, every time someone leaves or a new employee is added, you would need to update the plan. Use job titles instead – executive chef, sous chef, etc. Be sure to include the role each person has in the **HACCP team**.

Q: How often do you need to calibrate the thermometers?

A: Bimetallic thermometers (dial type) can lose calibration easily, such as when they are dropped or subjected to high temperatures. Calibration should be checked and adjusted as necessary, daily at minimum, and if dropped. Digital thermometers are generally stable, and may be checked less frequently – but check the policy of your local regulatory authority. Ice point calibration check is the minimum appropriate method; if a thermometer is used only or primarily for cooking or hot temperatures, the water boiling point method should be used.

Q: When doing ROP and Freezing, what is the timeline on being able to keep an ROP product when freezing it?

A: Freezing stops all bacterial activity (growth/multiplication and toxin formation). If the product is frozen immediately after ROP packaging and any required cooling process, the shelf life "clock" starts when the product is taken out of the freezer as day 1 of the shelf life. There is no shelf-life limit for safety while the product is frozen (although quality may be affected by long-term storage).

Q: Do shellfish and other seafood fall under the same category as fish for ROP?

A: The Food Code definition of fish is as follows:

"Fish" means fresh or saltwater finfish, crustaceans, and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption.

Q: What is the freezing process for fish when using a HACCP plan with ROP? What freezing temperatures are needed to do ROP of Fish?

A: There are different aspects to this question that should be considered, based on the purpose of the freezing.

- Parasites are considered a potential **hazard** for most **fish**, except for a very few large species like some of the tuna. Freezing and cooking are two methods used to destroy parasites. If the **fish** is intended to be served raw (sushi, sashimi) or cooked to less than the required 145°F., freezing for parasite destruction is required (FDA Food Code ¶ 3-402.11) unless the **fish** was farm-raised and fed according to the FDA protocol described in that part of the regulation. If the **fish** is wild caught and fresh, or was not farm-raised in compliance with that FDA feeding protocol, or if the commercial **fish** processor could not supply a letter stating that one of those requirements had been met, your establishment would be required to freeze the **fish** according to one of those freezing options if the **fish** is to be served raw or undercooked. Your establishment would be required to maintain records documenting that freezing process for each affected lot of **fish**.

- If the **fish** is to be fully cooked, or if the supplier has provided documentation that the parasite destruction requirement has been met according to one of the allowed options, freezing could be to any temperature below 30°F.

- The recommended and probably most practical process would be to portion first, then freeze, then vacuum package within a short period of time (30 minutes?), then return the product to the freezer.

- After taking the ROP packaged **fish** out of the freezer, either remove the product from the bag immediately to thaw under refrigeration, or thaw quickly under cold running water, then remove the **fish** from the bag.

Q: If you have multiple protein items for a specific special process (all under same process), would you need a plan for each protein or can you list all proteins that will fall under one plan?

A: All proteins that follow the same sequence of steps can be included in a single **HACCP plan**. Minor process variations can also be accommodated in the same **HACCP plan**, if those variations do not cause unnecessary complexity. For example: In the preparation step before ROP packaging of raw proteins, you could refer to fabrication instructions in a separate document from the **HACCP plan** for each product. The same method can be used to provide instructions for **fish** in an ROP plan for storage of raw proteins: "Portion, freeze on sheet pan, then ROP the frozen fillets within 30 minutes total time; keep frozen, and remove from the bag for thawing."

Q: What is the shelf life for ROP raw meat? If receiving raw meat in a vacuum pack, you break the seal, process meat and then ROP in house, do you use the expiration date provided by the supplier or do you assign a new expiration date from the date it's processed in the retail food establishment? What is the shelf life for ROP of cooked meat?

A: The 2022 FDA Food Code allows up to 30 days shelf life for raw **meat** and **poultry**, or commercially cured **meats** repackaged at retail, when stored under refrigeration (not frozen). That span of 30 days includes the day the product is repackaged at retail. If the shelf-life date provided by the commercial producer is less than 30 days forward from the day the product is broken down and repackaged at retail, the commercial processor's expiration date must be used for safety.

For cooked **meats** (either cooked sous vide, or by a traditional cooking method) in ROP packaging, the FDA Food Code allows no more than a 7-day shelf life including the day the product was ROP packaged, when stored at 41°F. or lower.

Q: When identifying the person(s) who will monitor or execute the HACCP plan, can you state that the "HACCP Team" will monitor/execute the plan, or do you have to identify a specific person or facility title position as the person who will monitor/execute the plan?

A: "**HACCP Team**" would be acceptable, but you could also say "trained staff" or any other more specific job title. The concern would be that the responsibility is assigned to a specific trained person for maintenance of the **HACCP plan**.

Q: How specific do you have to be when identifying corrective action for a process or when a CCP failure exists?

A: **Corrective actions** must be specific and must be directed toward each **critical limit**. They must address what to do with affected food, and how to bring the process into verifiable compliance. Example 1: If food fails to meet a required cooking temperature while it is still in the process or cooking, "Continue cooking" tells what to do with the food as well as how to remedy the process if the cooking device is properly set and is functioning correctly. "Continue cooking and adjust cooking temperature" addresses both the food and the possibility that the cooking device may not be functioning correctly.

There may be specific actions required to determine the right **corrective action** out of two or more options:

Example 2: If the walk-in cooler is above 41°F., there are several possible reasons. If the door had just been open to allow for stocking of incoming shipments, the higher temperature may resolve on its own – so re-check temperature after half an hour or so to verify that temperature came back down. If that situation does not apply, check several product temperatures to determine if they are above or below 41°F. In that scenario, if the cooler temperature continues to rise, you may choose to move product to a different cooler if that is an option, or you may choose to ice the product down. In either case, you would also need to address the maintenance concern. You would need to determine if the cooler is overloaded, or if it requires a service call. (Are the refrigeration coils iced up?)

Example 3: If a batch of sous vide or ROP cook-chill product is not meeting the required cooling rate, there will be several options as well:

- Phase 1 of cooling, 135°F. to 70°F. within 2 hours (0.54°F. per minute). If this rate of cooling is not met, reheat to 165°F. and restart the cooling process using a more effective cooling method (ice paddles, ice as an ingredient, more ice added to bath, split batch into 2 ice baths, etc. – as appropriate. Then verify that the adjusted cooling process is meeting the required cooling rate.

- Phase 2 of cooling, 70°F. to 41°F. or lower within 4 hours after reaching 70°F. (0.12°F. per minute). If this cooling rate is not met and product is still above 41°F. after 6 hours of cooling, discard the product.

Q: In what section of the plan would you put the cooling procedures/monitoring calculations to determine corrective actions (sous vide and ROP cook-chill processes)?

A: In sous vide and ROP cook-chill **HACCP plans**, provide cooling instructions at the cooling step of the standard operating procedure (SOP). The **monitoring** instructions (cooling rate calculations) should be included in the **Monitoring** bullet after the **critical limit** bullet at that step. Changes to the cooling process should be covered in the **Corrective Actions** bullet at the SOP cooling step. The calculations described in the **monitoring** bullet should be used to verify that the **corrective action** was effective.

Q: Regarding vacuum sealing prepared foods: Do we cook the food and immediately portion and vacuum pack? Or, can we cook the food, cool it, portion, and then vacuum pack?

A: The 2022 FDA Food Code requires that **prepared** foods (**meats**, soups, stocks, sauces, vegetables, etc.) cooked in-house that are ROP packaged for storage must be bagged and sealed while still above 135°F. This is a safety measure to prevent bacterial recontamination as the ready-to-eat foods are being handled for packaging. Recontamination can include spoilage bacteria, but more importantly, it can also include pathogenic bacteria such as *Staph* or *Listeria*.

Q: Is there a timeline/requirement for how long you keep HACCP logs and process records?
A: Keep in mind that **HACCP** is a proactive safety plan to minimize **risk** of biological, chemical, and physical **hazards** that can cause significant injury to consumers. **HACCP** cannot guarantee a specified **hazard** will not occur; it is necessary to minimize the **risk** of occurrence of those **hazards**. If a **hazard** were to occur and result in illnesses or injury despite effective implementation of a good **HACCP plan**, those records are necessary to help identify the source or cause of the **hazard**, and to demonstrate that the establishment had implemented an **approved** plan. Record retention requirements vary among jurisdictions. A good practice for products with long shelf life (such as jerky, fermented dry sausages, or acidified foods) is to retain records at least 6 months beyond the expiration date of each product batch.

Q: If you cook, cool, and freeze, would the 7-day shelf-life count be from the date it is thawed from the frozen state?

A: When product is fully cooked, ROP packaged, cooled properly, then immediately frozen, the 7-day shelf life begins with the day the product is packaged – Day 1. Keep in mind the 7-day date mark is a consume- or discard-by date.

Q: Where would cheese fall in the ROP process when related to CCPs?

A: Under Subparagraph 3-502.12(E), hard and semi-soft cheeses (not soft cheeses) may be stored with a date mark of 30 days or less in ROP packaging under refrigeration. Soft cheeses are not allowed to be ROP packaged. The Food Code, Annex 3, does allow certain hard and semi-soft cheeses to be exempted from date marking; this would require a **variance** from the regulatory authority. The classification of cheeses as hard or semi-soft is based on percent solids or percent water. If you have a cheese product for which you are not certain of the classification, or for which you would like to request date mark exemption, contact your regulatory authority for guidance.

Production of cheeses would be a separate process requiring its own **HACCP plan**; although, if the finished products are to be ROP packaged, that step could be included in the **HACCP plan**.
Q: If the product is sometimes reheated for hot holding and sometimes used for immediate service, would both the cooking and reheating steps be CCPs?

A: Yes, both steps must be identified as CCPs. Cooking step is critical for products that will be served immediately, and reheating is critical (instead of cooking) for products that will be hot-held before service. Keep in mind there are two **critical limit** values both for cooking and reheating: time and temperature.

Q: If buying unfrozen ground beef from a supplier to be flavored and ROP packaged to be sold for home use, is there a holding time requirement? The patties will also be sold in-house.

A: If the ground beef is being sold in its raw state, with or without added seasonings, the shelf life (allowed date mark) is a maximum of 30 days under refrigeration.

Q: Could we have the same process for our veggie soup, meat soup, and frozen casseroles? Or should I just make a note indicating the process in parentheses?

A: If these products are all fully cooked and ready to serve in the restaurant, they may be included in the same ROP cook-chill **HACCP plan**. The initial preparation step in the standard operating procedure (SOP) section of the **HACCP plan** should refer to the individual preparation instructions for product-specific details such as recipe, method of cooking, etc. However, as far as the details of the **HACCP plan** are concerned, the preparation method before cooking does not matter – it is simply assembly of ingredients according to different recipes. The cooking step of the SOP must provide the **critical limits** for each category of product based on Food Code requirements.

Q: Can I make consumer meals (delivery or for home use, such as meatballs, ready-to-eat meals, or heat and eat) and sell to the consumer under the ROP process? Is that allowed? What process could be used to allow ready-made meals for delivery or for home consumption? Can you sell par-cooked under ROP to consumer for final cooking at home?

A: The best practice would be to package these products uncooked but otherwise fully prepared, with proper storage and cooking instructions provided on the product label (CCP). Par-cooked products are not cooked to the minimum required internal temperature, and the initial heating process at production must be no more than one hour. As such, par-cooked products are considered as if they are raw, so the allowed date mark would be 30 days including the day of packaging. If par-cooked **meats** have been seared or grilled, they may appear to be ready-to-eat while they actually are raw, so the product must be clearly labeled as "not **ready to eat** – must be cooked to …" (state the required temperature and provide cooking instructions).

Sale of fully cooked products in ROP packaging to consumers is not allowed under Subparagraph 3-502.12(D) of the Food Code. Depending on your local jurisdiction, a **variance** may be allowed under Subparagraph 3-502.11(D) with very specific, limiting conditions and additional requirements.

Q: Part 1 — Cured bacon – how does that work with slicing? Fresh belly, sliced into strips, ROP Raw Uncooked Meat, what is the process?

Q: Part 2 — Typically, cured bacon would be chilled prior to slicing. How does this apply to ROP? When packaging bacon for retail sales, how would that apply to the plan? If smoked, cured, sliced, and ROP packaged, is the process the same?

A: Part 1 – Pork belly that has not been cooked is treated as raw. Food Code section Subparagraph 3-502.12(B) allows 30 days refrigerated storage in ROP, including the day the product is packaged as day 1. The product could be packaged either sliced or unsliced. Once the package is opened, the product may not be repackaged in ROP.

A: Part 2 – ***Can the product be cooked according to the standard whole-muscle requirements, or the table in Subparagraph 3-401.11(B) for whole-muscle roasts?*** When the product has been fully cooked to a proper internal temperature, the packaging becomes an ROP cook-chill process, subject to Subparagraph 3-502.12(D) requirements. Keep in mind that the date mark of the cooked product will be 7 days, whether or not it is packaged in ROP. (This is not referring to the bacon after it has been fried for service). The recommended sequence of steps, including the Food Code requirements for the ROP cook-chill process, would be:

1. Package the product at or above 135°F. in portions you can use in 1 day.

2. Cool properly from 135°F. to 70°F. within 2 hours or less, then from 70°F. to 41°F. or lower within no more than 4 additional hours – total cooling time not to exceed 6 hours.

3. Store refrigerated at or below 41°F. for no more than 7 days including the day of cooking and packaging as day 1.

4. Open package and slice for use, store in proper cooler at or below 41°F., and use or discard before the allowed 7 days of the original date mark have expired. Once the ROP package is opened, the product may not be repackaged in ROP.

Q: Is 10K OTR film allowed for other ROP foods besides fish?

A: No. FDA only allows use of 10K OTR film for raw **fish**, with no additional ingredients. Use of this film requires a **variance**, and it falls under Subparagraph 3-502.11(D) of the Food Code. This film is also not **approved** for any application that involves application of heat, such as sous vide cooking or ROP cook-chill.

Questions and Answers: Meat Preservation and Curing; Smoking Fish for Preservation

Q: Why do some refrigeration requirements say <41°F. and some say <40°F.?

A: The USDA refrigeration requirement is less than or equal to 40°F.; the FDA (Food Code) requirement is less than or equal to 41°F. An exception is that FDA advises holding **fish** smoked for **preservation** at less than 38°F. (outside Food Code), to prevent growth and toxin formation by marine strains of *Clostridium botulinum*, the spores of which would not be destroyed or **controlled** adequately by the processing of the **fish**.

Q: If you are not using nitrite or nitrate, will that effect the longevity of the product being shelf stable?

A: We need to remember that especially in the **meat preservation** processes, we rely on multiple hurdles to maintain the safety of the product, and that same combination of factors also works to determine the ultimate shelf life of the product. Nitrite and nitrate are most effective on the *Clostridium* bacteria; salt content, reduced water activity, reduced pH, and the cooking and storage temperatures also help determine shelf life.

Q: If you are possibly altering the product (additional flavors), how would you build that into the original plan? Or would you make a new variation of the existing plan?

A: If your basic product, for example, is a summer sausage, you could make mild, medium, and "hot as blazes" recipes for the same basic product – just list the different ingredients in the recipe and in the ingredients list for the **HACCP plan**. If you make different varieties of bacon based on different types of wood used for smoking (such as apple wood or mesquite), your process is the same but the smoke ingredients are different – and yes, smoke is an ingredient, so the types of wood you use for smoking should be listed in your recipe and **HACCP plan** ingredients statement. Liquid smoke is also an ingredient.

Q: How would you do your own validation study if you are not following a published validated process?

A: Designing an acceptable **validation** study requiring scientific data will require the advice of a technical expert with experience in developing the required studies. The technical expert must have a clear understanding of your process, your objectives for the study, and the regulatory requirements that must be met. The state regulatory authority should be included in any such discussion. All such studies must be thorough enough to properly represent the process, considering the potential for day-to-day and batch-to-batch process variations. A properly designed study will likely be expensive, and may either validate, *or not validate*, your process, so it is best to follow published protocols that already are backed by significant research and supporting scientific data.

Q: Would we need to include language in the plan stating that if a product is outside the use-by date, we cannot use said product?

A: Use-by dates specified by regulation for foods produced at retail are "consume or discard by" dates for safety. This should be stated in the **HACCP plan** standard operating procedure (SOP) step where labeling occurs and where labels are **monitored** for expiration. It is also a good idea to provide an instruction on how shelf-life days are to be counted: the day on which the oldest **TCS** ready-to-eat ingredient becomes ready for consumption is the first day of the shelf life. If I prepare a chicken salad today (10/19/21) from chicken cooked this morning, there will be 6 additional days of shelf life (total 7 days, per Food Code ¶ 3-501.17). If the chicken was cooked on 10/17/21, and the salad was made on 10/19/21, the expiration date will be 10/23/21. These expiration dates are based on the research that shows that *Listeria*, which grows slowly under refrigeration, cannot grow to a harmful level within that 7-day period.

Q: Would the corrective action plan include mechanical failures as well?

A: **Corrective actions** must address the reasons for failure to meet a **critical limit**. As part of a **corrective action**, two major decisions must be addressed: 1.) What to do about food that may have been affected by the failure. Can the food be reconditioned by reprocessing, or must it be discarded? 2.) How to bring the process back into compliance, and how to ensure that the process remains in compliance with the required **critical limit**. Depending on the nature of the failure, there may be issues involving training, procedures, equipment … or others. When the **corrective action** must address an equipment issue, it may be necessary to consider concerns such as proper use (used as intended, not overloaded, etc.); periodic maintenance, and inspection to ensure the equipment is in good repair; or potential other concerns. Careful evaluation of each situation should identify the concerns that must be addressed.

Q: What are examples of approved packaging? (e.g., jerky)

A: Keep in mind that packaging materials, including sausage casings, twine used on curing **meats**, and packaging films are ingredients, so all must be from **approved** suppliers, and intended for food use.

Jerky is commonly packaged in bags with low oxygen permeability and with a sachet of chemical that either removes oxygen from the air in the bag. These sachets also must be **approved** for food use since they will be in contact with the food.

Q: Would freezing of the hot-smoked fish need to include freezing as part of the process?

A: If the **fish** will be cooked to a minimum of 145°F. as part of the process, that cook step is sufficient to destroy any parasites that may be present. If the **fish** will be cold smoked (not exceeding 90°F.), Food Code ¶ 3-402.11 provides two options: 1.) Use farmed **fish**, fed according to FDA parasite-free feeding protocol; OR 2.) ensure that the **fish** have been frozen according to one of three protocols for parasite destruction specified in that section of the regulation. Freezing may be provided by the supplier (Letter of Guaranty or supplier agreement required as documentation for your **HACCP** files), or you may provide as part of your process (freezing records required by ¶ 3-402.12). For a cold-smoking process, this will be a **critical control point** (CCP).

Q: Can we go by the USDA ratio of 4% by weight on whole muscle curing? (.0025% of the 4% to be nitrate salt)

A: The correct answer depends on the type of product you are producing (for example – bacon, or ham?) and on the method of curing (dry rub, immersion brining, or injection, or a combination). Consult the regulatory authority for guidance on the specific product you are producing and the method of production.

Q: I make jerky in a dehydrator using whole strips of meat. I use both a wet marinade and a dry rub both with Cure #1. I have seen videos saying that the meat needs to get to 160°F. quickly in the beginning – is this true? Then I see where once the jerky is dried, it needs to be heated up to a much higher temperature, over 200°F., in order to "cook off" bacteria. Is this true?

A: As whole muscle products, the temperature requirements required under the Food Code for retail would be the only temperature requirements for destruction of pathogens. So, beef and pork must be heated to 145°F. minimum internal temperature for at least 15 seconds, and **poultry** products must be heated to an instantaneous 165°F. internal temperature. Those temperatures and times obviously would not be sufficient to provide the required drying. Since this process falls outside Food Code, we look to USDA guidelines and other best scientifically sound practices for this process. The use of moist heat at 90% relative humidity during the cooking step provides a more effective kill step to destroy pathogens. Drying at too high a temperature can result in case hardening – the outside dries quickly, forming a hard shell that holds moisture in the inner part of the **meat**. Using heat at 200°F. would provide an effective kill, based on the minimum required cooking temperatures, but depending on drying time and the product, may result in a tougher or even more "crunchy" product. Moving directly from cooking to drying – especially if the product remains in the same equipment – introduces little or no **risk** for recontamination if that is a continuous process, so the 200°F. would be overkill in that respect.

Q: I plan on purchasing a commercial grade dehydrator. Is there a brand/model you recommend and how high of a temperature should it be able to reach?

A: The requirements for food processing equipment are found in Food Code ¶ 4-205.10. The NSF/ANSI or other certification of the equipment assures that the equipment is designed and demonstrated to have met the performance and sanitation concerns. Additional information in sections 4-1 and 4-2 of that chapter also provides equipment requirements, some of which may be relevant, and all of which have to do with design of the equipment for ease of sanitation. Regulatory authorities cannot provide equipment recommendations, other than that consumer-grade equipment generally would not be acceptable.

Q: What do we need from our supplier?

A: The FDA Food Code requires that all foods, ingredients, and packaging materials come from **approved** suppliers. For general purposes, manufacturer labels, invoices, and purchase agreements all provide enough information on recognizable, **approved** producers that an inspector could determine compliance on these items without special record-keeping requirements. However, specific documentation such as supplier agreements, Letters of Guaranty, letters of **HACCP** compliance, or compliance with the FSMA Produce Safety Rule or Good Agricultural Practices should be kept on file and referenced in the **hazard analysis** as documentation when:

- Local sourcing (such as to support local small producers) is a commitment of your retail food business, AND/OR

- **Control** of a **HACCP critical control point** relies on a supplier **control.** Examples are cold chain management to prevent histamine/scombroid toxin in tuna, freezing for destruction of parasites in **fish** that will be served raw, and assuring wild game to be custom processed is properly chilled before and during transport to control microbial growth. (In addition, game species intended for retail sale must come from an **approved** source.)

Q: What is the recommended humidity for the drying step for jerky during the dehydrating process?

A: In USDA's published guidance for production of jerky in small **food establishments**, they recommend maintaining relative humidity at 90% for at least 25% of the cooking step or a minimum of one hour, or injection of steam during the cooking step for at least one hour. The required cooking temperatures (145°F. for whole muscle beef, or 165°F. for **poultry**) must be met. More information is provided in the USDA guidance document.[52]

Q: Should I include in my HACCP plan information on equipment used in the process?

A: In describing the process in the preliminary steps of writing the **HACCP plan**, information is to be provided on the major equipment used in your process. Provide at least the manufacturer name and model number; a link to the specification sheet from the manufacturer is also helpful but not mandatory.

Q: Do HACCP plan changes need to be submitted for equipment changes?

A: The **HACCP plan** would only need to be re-**approved** if the process instructions change as a result of the change of equipment. If the new equipment requires different operating instructions, or if it

[52] fsis.usda.gov/sites/default/files/import/Compliance-Guideline-Jerky-2014.pdf#page=18

requires different cleaning and sanitizing instructions, the plan must be updated and re-**approved**. When updating a previously **approved** plan, it is helpful to highlight the changes so regulatory review can focus on your changes without having to re-review the entire plan. This would save reviewing time and speed up the approval process.

Q: Can we use #10 bags for cooked fish or what other ROP style bags can we use for fish? Can 10K OTR bags be used?

A: The Food Code currently only allows ROP storage of **fish** that is frozen before packaging in standard ROP bags, and for as long as the product remains in the ROP bag. When taken out of the freezer to thaw, the bag must be at least opened immediately, or the product must be completely removed from the bag to thaw. For cooked **fish**, freezing may not be practical or suitable due to quality (not safety) concerns – depending on your intended use of the product. For all food products, the bags used must be food-grade.

The 10K OTR bags allow a high rate of oxygen transmission into the bag through the plastic film. This is a mandatory **control** when the **fish** will be fresh, not frozen, to prevent growth and toxin formation by *Clostridium botulinum* (botulism toxin). These bags will not extend the shelf life of the cooked, ready-to-eat product. The 10K OTR bags are not **approved** for any application in which heat would be applied to the bag (such as sous vide cooking or bagging hot, ready-to-eat product for storage), and they are not **approved** for use with any products besides **fish** or when ingredients have been added to **fish**. These bags cannot be used for smoked **fish** because the added salt, as well as the smoke with its particulates and smoke chemicals, are added ingredients.

Q: Define a secure location for storing curing products.

A: Curing salt is a strictly regulated food additive because of the added nitrite (and nitrate, in the cure #2 or slow-cure products). Subparagraph 3-302.14(A)(2) of the Food Code) requires that food shall be protected from contamination resulting from addition of **unapproved** levels of food additives, as specified ¶3-202.12. Due to the potential health consequences from consuming unsafe levels of such compounds, only authorized, restricted access should be allowed to a secure storage location.

Q: Would cooling be included as a CCP and how would it work into a HACCP plan?

A: There are a number of ways a process could vary that would determine whether cooling according to requirements of ¶ 3-501.14 is actually required as a **critical control point** (CCP). That requirement applies only to cooked, **time/temperature control for safety** (**TCS**) foods.

- At the point where the product is fully cooked, if the product also has been dried to a water activity less than 0.85, it is a non-**TCS** food. If cooling is the next step, cooling would not be a CCP. Good examples would be processes such as smoked jerky, in which cooking proceeds directly to dehydration; or hot-smoking **fish**, in which brining is followed by smoking, drying, and cooking – in that order. If the water activity is less than 0.85 as the step before cooling is completed, the product is now non-**TCS** and the cooling requirement will no longer be a CCP.

- When a prerequisite program, such as the standard operating procedure (SOP) provides a level of safety at least equal to that provided by following the Food Code requirement for cooling, the SOP can be cited as a preventive **control** that eliminates the need for the CCP. As an example, if **fish** will not have water activity less than 0.85 after drying and cooking, but the SOP calls for cooling from the cooking temperature of 145°F. to below 38°F. (based

on FDA guidance for smoked **fish** production) within 30 minutes in a blast chiller, that SOP would be an acceptable **preventive measure** to replace the need for a cooling CCP.

This is a great question because it emphasizes the point that two processes that seem to be the same may actually have significant differences. The **HACCP plans** for the two processes may have different CCPs. The CCPs may be at different steps, or they could be in a different order.

Q: Is cold smoking considered a cooking step?

A: No. Usually done at 90°F., therefore not a cooking step.

Q: Is there an ability to utilize celery salt in substitution of nitrite or nitrate?

A: Celery salt is hard to regulate because it is difficult to substitute for nitrite or nitrate, and is therefore not regulated as a curing agent. The product must be identified as an ingredient in the **HACCP plan**. It was an age-old product used in curing, but inability to regulate is based on the variable amounts of nitrate within a given amount of celery salt.

Q: When testing is required to determine water activity levels, is the testing good only for validation of the initial recipe for approval, or does it have to be continually tested?

A: If your establishment is not using a recipe and process from a published, academic source, testing from a **processing authority** will be required at least initially, and may be required annually or more frequently. However, retail producers typically rely on water weight loss during the drying process to achieve the required dryness, rather than a direct measurement of water activity. For all **preservation** processes that use drying to achieve a minimum required water loss, **monitoring** of the weight loss is required for each process batch. The water activity analysis serves to validate that approach. Recipes must include specifications for percent lean of the **meat** used, and must be followed consistently to ensure repeatable results. If the recipe, or the process, is to be changed, a new **product assessment** must be obtained, and the changes must be submitted to the regulatory authority for approval *before product from the modified process may be sold.*

Q: Is there a facility recommended who can validate the recipe or test for water activity, pH, or water phase salt (WPS)?

A: Recognized Processing Authorities are recommended for product testing that will be submitted for regulatory approval. A list of Processing Authorities published by AFDO is found at Food Processing Authorities Directory (afdo.org/directories/fpa/).

Q: What is the function of sodium erythorbate? Does it reduce needed curing time in both safety and taste?

A: Sodium erythorbate is a curing accelerator – it encourages growth of the fermentation culture in production of dry and semi-dry sausages. Faster growth results in more acid production by the bacteria, and more acid production means faster pH reduction. Research has shown that the pH of fermented sausages must be reduced to below pH 5.3 within the allowed degree-hours at the specified fermentation temperature to prevent toxin formation by *Staph* bacteria that may be present.

Q: If an error is made in the process, could the product be corrected or saved to make safe again (i.e., too much cure for protein)? If cannot correct, what to do with the protein?

A: The answer depends on the potential **hazard** that could occur if a **critical limit** is not met, and on the point in the process where the problem occurs. Examples:

- If it was discovered that an incorrect amount of cure was added to a specified amount of **meat**, it may be feasible to make an adjustment to correct the cure-to-protein ratio as the product is being mixed. If not corrected at that point, it is too late to correct an excess amount of cure. However, if the amount of cure is too low, refrigeration should be required as a **corrective action** (to prevent growth of bacteria and toxin formation by *Clostridium botulinum* in place of the correct amount of nitrite).

- If your product is intended to be free of an allergen (soy, for example), and cross-contact has occurred with an ingredient or a surface that has traces of that allergen, the product is now potentially contaminated with that allergen. **Corrective actions** could include modifying the product label to include "may contain soy," or redirecting that product to another use in which the allergen may not be a concern. In this example, though, another **corrective action** might be to change the production schedule so that the allergen-free product is produced before, not after, the product that contains the allergen.

- If product is undercooked, continue cooking until the proper temperature has been reached and held for the required time.

- If product is cooling and does not drop from above 135°F. to 70°F. or below within two hours, reheat to 165°F. and restart the cooling process using a more effective means of active cooling. In the next phased of cooling, if the temperature does not drop from 70°F. to 41°F. or lower within 4 additional hours, the product must be discarded. When total cooling time has exceeded six hours, enough time has passed to allow possible toxin formation by *Bacillus cereus*, or spore activation by *Clostridium perfringens* (both are food pathogens).

Q: Why can measuring spoons NOT be used as a utensil for measuring ingredients?

A: Teaspoons, tablespoons, cups, etc., are units of volume, not weight. A level tablespoon of cure salt weighs differently than a level tablespoon of other ingredients. The regulations in 9 CFR Part 424 for curing require an accurate determination of the nitrite concentration. That concentration can only be calculated accurately when all ingredients are reported in weight units.

Q: What are the parts per million (PPM) for sanitizer solution for sanitizing equipment used for a Special Process?

A: It depends on the sanitizer being used. Specific parameters are found in Food Code ¶ 4-501.114. Sanitizer concentrations and use parameters stated in the Food Code for manual and mechanical washing will be the same for sanitizing equipment used in a **HACCP Plan** and Special Process.

Q: Can you cure a product while in an ROP process?

A: Yes. ROP can be used to more quickly infuse cure mixtures (dry rub or liquid brine) into **meat**. We have also seen hams and pork bellies (primarily bacon, pancetta, and pastrami) ROP packaged after the curing and smoking or cooking are completed, which would be an ROP cook-chill process. We have also seen hams cooked sous vide (in ROP packaging) after the curing step. All of these are

perfectly acceptable; the use of nitrite adds an extra hurdle (in addition to salt, refrigeration, and date marking) that helps prevent growth of *Clostridum botulinum* and *Listeria monocytogenes*.

Q: Prosciutto (example) – Curing with salt only, or packing the meat in salt – is that OK? If no nitrite added, will these products need a final cook step, and are they considered not a shelf stable (RTE) food?

A: Prosciutto and Virginia hams are two examples of dry-cured **meats** that may only be cured with salt – without sodium nitrite. In both cases, the end products are **shelf stable** based on the USDA standards of identity. This requires loss of enough moisture to reduce the water activity below 0.85. In the case of hams, USDA requires a minimum weight loss of 18%. Production of these dry-cured products does not include a heat treatment "lethality" step, although some dry-cured **meats** may be cold smoked (@90°F.) or may have liquid smoke added as an ingredient. These products should be cooked to at least 145°F. internal temperature for at least 15 seconds before serving.

Q: Could you use a wine to get to the required pH needed for curing?

A: Depending on the type of wine, the pH ranges from 3.0 to 4.0. This level of acidity is not strong enough to reduce surface pH of a ham or pork belly to 5.8 or lower in a dry cure, no-cook process. A stronger acid such as white vinegar or lactic acid solution as specified in FSIS Directive 7120.1 should be used in a dip for at least 30 seconds to achieve that pH reduction.

The only other type of curing process in which pH is a critical factor is in fermented, dry, or semi-dry sausages. In this process, bacterial fermentation cultures are used to achieve the required pH drop to 5.3 or lower within the allowed degree-hours. Some sausage recipes do contain wine as an ingredient, but more for flavor profile.

Q: Does smoking as part of the cooking process for flavor need a HACCP plan? When smoking a food product to preserve or extend shelf life, is a HACCP plan required?

A: If smoking only to impart flavor, it does not require a **HACCP plan**. If smoking to preserve food, you are using the smoking as a **control** to replace a Food Code requirement relating to how **time/temperature control for safety** foods are normally stored (refrigeration <41°F. for no more than 7 days). If your purpose is to either make the product **shelf stable**, extend shelf life beyond 7 days, or both, then the process is for **preservation** and a **HACCP plan** will be required.

Q: Can cured bacon be packaged using ROP?

A: If the bacon is uncured (brined or dry-rubbed without curing salt) and smoked, bacon would be ROP packaged like any other ROP cook-chill process. The brining or dry rub seasoning would be the initial preparation step, then smoking would be the initial cooking step if cooked to an internal temperature as required in ¶ 3-401.11. The final reheat step would be frying for service. Slicing could be after the initial smoking step or part of the preparation before frying for service.

If the bacon is to be cured, an additional CCP is required (cure-to-protein ratio), whether for flavor only or for **preservation**. This is part of the initial preparation process before smoking. If the only product of the ROP cook-chill process will be the bacon, that initial prep step should include the complete instructions for the curing process including preparation of the brine or dry rub mixture (recipe in all weight units), as well as how much of the dry rub or brine is used for a specified amount of pork belly. If there are other uncured products that will also use the ROP cook-chill process, those should follow the basic ROP cook-chill format with individual preparation instructions in their own recipes; it makes a cleaner **HACCP plan** in this situation to provide the bacon instructions and CCP

details in the bacon recipe rather than in the body of the **HACCP** procedures. The **hazard analysis** and CCP Summary tables must include the curing CCP and must make clear that that CCP is only for bacon.

Q: What fish may be cured using nitrites?

A: 21-CFR 172.175 and 21-CFR 172.177 only allow the use of nitrites in the following species: salmon, shad, sable **fish,** and chubs.

Q: If smoking fish for preservation, would it have to be frozen prior to ROP?

A: Hot smoking of **fish** must follow a validated process that includes several **critical control points**, including (in order) brining, cooking, drying, labeling for proper storage, and cold storage at or below 38^{o}F. The water phase salt concentration must meet a **critical limit** of greater than 3.5% and the water activity must meet a **critical limit** of 0.92 or lower to be packaged in standard ROP bags. Use of 10K OTR bags is not allowed. The ROP packaged product must be labeled with cold storage instructions (**critical limit** is 38^{o}F. or lower for label instructions and for cold storage temperature).

APPENDIX 3: THREE EXAMPLES OF HACCP PLANS

Model HACCP Plans for Whole-Muscle Curing Processes and Dry-Cured Shelf Stable Salami

Three model **HACCP plans** are presented on the following pages as examples of the thought processes, **hazard analyses,** and critical **controls** used in creating **HACCP plans** for the following processes:

- Dry Cured Hams, Pork Shoulders, and Pork Bellies
- Dry Cured Bacon
- Non-Heat-Treated, Shelf Stable (Fermented) Salami

These **HACCP plans** were created following the USDA-FSIS model used in different federally regulated meat processing facilities. The USDA model assumes the existence of separate, written prerequisite programs. Not all forms referenced in these examples have been provided; the formats vary; and varying amounts of reasoning supporting the hazard analysis decisions has been provided. In these respects, these models differ from the requirements of the FDA Food Code for retail.

Section 8-201.14 of the 2022 FDA Food Code requires specific prerequisite programs as components of **HACCP plans** written for special processes at retail. The model plans in this Appendix do provide excellent examples that can be of value in writing comparable **HACCP plans** for retail **food establishments** conducting these processes. It is essential to remember that HACCP plans for similar processes in different establishments may vary in their content and format. The FDA Food Code and the National Advisory Council on Microbiological Criteria for Foods provide basic requirements for all HACCP plans.

HACCP Plan for Dry Cured Hams, Pork Shoulders, Pork Bellies
(Non-Heat Treated, Shelf Stable)

HACCP PLAN FOR: _____

Signed and Approved:

_____ _____
Production Manager Date

Dry Cured Hams, Pork Shoulders, Pork Bellies (Non-Heat Treated, Shelf Stable)
Product Description

COMPANY NAME:

PRODUCT NAME:

- Dry Cured Pork (ham, shoulder, belly)

PRODUCT DESCRIPTION:

- Dried cured non-heat treated shelf-stable pork; final product is ready-to-eat (no further cooking required)

INTENDED USE OF PRODUCT?

- Restaurant general public consumption
- May also be sold for home use

TYPE OF PACKAGE?

- Poly-lined boxes for bulk storage
- Vacuum packaging for in-house storage and use or for consumer sales
- Poly-coated bags or paper wrapped in smaller portions for consumer sales

WHERE WILL IT BE SOLD?

- Restaurant – immediate service or sale to consumer for home use

LABELING INSTRUCTIONS:

- Ready to eat, shelf stable in unopened, original packaging
- Product identity, ingredients, name and address of restaurant

DISTRIBUTION METHOD?

- If shipped, in insulated container

Products/Ingredients Used to Produce Dry Cured Hams, Pork Shoulders, Pork Bellies (Non-Heat Treated, Shelf Stable)

MEAT/POULTRY AND BY-PRODUCTS	NONMEAT FOOD INGREDIENTS	BINDERS/EXTENDERS
Pork meat (whole muscle) Natural beef middles or bungs, hog middles or bungs)	Wine	
SPICES/FLAVORINGS	**RESTRICTED INGREDIENTS**	**PRESERVATIVES/ACIDIFIERS**
Salt Pepper (black, white cayenne) Garlic Paprika Fennel Sugar Cinnamon Mace Clove Juniper Berry	Sodium nitrite	
OTHER		
Plastic and paper packaging materials Box Label Artificial casings (collagen)		

Hazard Analysis Decision Making Document

Dry Cured Hams, Pork Shoulders, Pork Bellies (Non-Heat Treated - Shelf Stable)

The FDA definitions for "hazard" and "hazard analysis" were reviewed before the team started reviewing the hazard analysis and documenting the thought process for each response. Those definitions are included in the glossary section of this manual.

HAZARD ANALYSIS:

The following summarizes the discussions and thought process that impacted the decisions for each step of the flowchart for the three food safety hazard categories – biological, chemical, and physical. To the best of our knowledge the critical control points, critical limits, monitoring activities, verification and validation activities in this plan represent the most recent scientific advances and research available.

Receiving Meat:
Physical: We acknowledge that some meat may occasionally have buckshot, bullets, needles, etc. However, these cannot always be identified at the time of receiving and should be found as the product moves throughout the process. All of our products are ground to a final grind size that is smaller than what the FDA considers a choking hazard. Therefore, metal is not identified as a significant food safety hazard for this process step.

Chemical: Antibiotic Residue, Pesticides, and Growth Promotants – The USDA Residue Monitoring Program indicated that the great majority of pork is free of any residues. Based on this information,

the team does not think that these are significant food safety hazard that are reasonably likely to occur in these processes.

Biological: Pathogens (*Salmonella*, *E. coli* O157:H7, and *Trichinella*) – It is well documented that pork is not a common source for *E. coli* O157:H7. This facility only processes pork products, therefore it was determined that *E. coli* O157:H7 was not a hazard in this facility. The USDA Nationwide Pork Microbiological Baseline Data Collection Program: Market Hogs, April 1995 – March 1996. Even though these pathogens are a concern at receiving, there currently is nothing that can be done to prevent, eliminate, or reduce them at this step. Therefore, we acknowledge that steps later in the process must be taken to prevent, eliminate, or reduce to an acceptable level in a further processing step.

We know that we must take steps to control the potential growth of any pathogens. Therefore, subsequent steps (fermentation and drying) will be used to eliminate, reduce to an acceptable level, or control the potential growth of *Salmonella* and *Staphylococcus,* and *Trichinae* during processing.

Based on these facts, we feel that these hazards are not significant at this step.

Cold Storage and Cold Storage/Holding:
Physical, Chemical: None identified at this time. We could not think of any potential physical food safety hazards that could be introduced, controlled, or reduced during the cold storage of the raw meat products. Products that are covered or boxed will remain so during storage.

Biological: Pathogen growth is identified as a potential food safety hazard (*Salmonella*). In absence of controls, pathogen growth is a reasonably likely to occur food safety hazard.

We agree that proper cold storage temperature must be maintained to prevent the outgrowth of these pathogens. This is a shelf-stable product, and our process includes subsequent steps (fermentation and drying) that will prevent, eliminate, or reduce the pathogens to an acceptable level.

We monitor cold storage temperatures continuously throughout our production facility. All coolers and freezers are maintained at a temperature of 44.6°F. or below. As part of our GMPs, we monitor the cooler and freezer temperatures daily. If the temperature rises above 44.6°F., maintenance and management are notified immediately. In addition, the cooler and freezer thermometers are calibrated and checked periodically.

As the raw product (trim) moves through the process, the temperature is not critical in this type of product. The starter culture will be added at the mixing step, which is early in the raw meat processing steps. Once the lactic acid starter culture is added, warmer temperatures will only help ferment the product to a pH that increases safety. Fermentation will take place at very warm temperatures in a later processing step.

Therefore, we did not feel that the growth of these pathogens, due to temperature, presented a significant hazard in this facility.

Weighing:
Physical, Chemical, and Biological: None identified. The team could not identify any physical or biological hazards associated with this step. The product is shelf stable.

Receiving Non-Meat Ingredients:
Physical, Chemical, and Biological: None identified. The team could not identify any physical or biological hazards associated with this step. The product is shelf stable.

Storing of Non-Meat Ingredients:
Physical, Chemical, and Biological: None identified. The team could not identify any physical or biological hazards associated with this step. The product is shelf stable.

Addition of Non-Meat Ingredients:
Physical: None identified.

Chemical: None identified. This facility does not use ingredients containing any known allergens.

Biological: None identified. We felt that the raw meat was most likely the source of any biological contaminants, not the equipment. The written Sanitation Standard Operating Procedures address the proper procedures for cleaning and sanitizing equipment used during processing to remove any contaminants from prior use.

Grinding:
Physical: Metal. The plant does not have metal detection. We will rely on our production staff to keep a close watch for missing parts to the equipment. We grind all of our products to a size small enough to reduce any product to a size that would not be considered a choking hazard.

Chemical: Sanitizers. The written Sanitation Standard Operating Procedures address the proper procedures for cleaning and sanitizing equipment used during processing. Therefore, we determined that these hazards were not significant.

Biological: None identified. We felt that the raw meat was most likely the source of any biological contaminants, not the equipment. The written Sanitation Standard Operating Procedures address the proper procedures for cleaning and sanitizing equipment used during processing to remove any contaminants from prior use.

Mixing:
Physical: None identified.

Chemical: CCP C1

- Sanitizers. The written Sanitation Standard Operating Procedures address the proper procedures for cleaning and sanitizing equipment used during processing. There are no allergens used in the manufacture of this product. In addition, the plant has an allergen program that addresses potential cross contamination from other sources. Therefore, we determined that these hazards were not significant at this step.

- Nitrite. The use of curing agents containing nitrite is strictly regulated under 9 CFR 424.21. Overuse of nitrite constitutes a chemical hazard. Weighing of cure agent will be separate from all other ingredients, and the correct weight of cure will be measured once the weight of meat to be cured is determined based on the recipe.

Biological: None identified. We felt that the raw meat was most likely the source of any biological contaminants, not the equipment. The written Sanitation Standard Operating Procedures address the proper procedures for cleaning and sanitizing equipment used during processing to remove any contaminants from prior use.

Receiving Casings:

Physical, Chemical, and Biological: None identified. The team could not identify any physical or biological hazards associated with this step. The product is shelf stable.

Casing Preparation:
Physical, Chemical. and Biological: None identified. The team could not identify any physical or biological hazards associated with this step. The product is shelf stable.

Stuffing:
Physical: Metal. The plant does not have metal detection. We will rely on our production staff to keep a close watch for missing parts to the equipment. We grind all of our products to a size small enough to reduce any product to a size that would not be considered a choking hazard.

Chemical and Biological: None identified. We felt that the raw meat was most likely the source of any biological contaminants, not the equipment. The written Sanitation Standard Operating Procedures address the proper procedures for cleaning and sanitizing equipment used during processing to remove any contaminants from prior use.

Hanging:
Physical, Chemical, and Biological: None identified. The team could not identify any physical or biological hazards associated with this step. The product is shelf stable.

Fermentation: CCP B1
Physical, Chemical: None identified at this time. We could not think of any potential physical food safety hazards that could be introduced, controlled, or reduced during the cooking of products.

Biological: Pathogens *(Staphylococcus).* The team realized that these were significant hazards in these shelf-stable products. Therefore, the ground products are fermented to a pH of 5.3 within 1,200 degree-hours. According to the "Interim Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products" AMI Foundation, 1995 (see supporting documentation), this pH/time combination is sufficient to control *Staphylococcus* in ground products. We feel fermentation is needed in ground products due to the nature in which they are produced. Any time a meat product is ground the external surface (highest potential contamination) is incorporated into the middle of the product. This affords a higher **risk** level in ground products compared with whole muscle products.

In the case that a pH of 5.3 is not obtained, the product will continue to ferment until 5.3 is reached within the allowed time, and the end product will be sampled and tested for the pathogens identified. The further processing step of drying will address *Salmonella* and other pathogens.

Product pH and processing times are recorded once per product per batch. HACCP personnel visually observe the pH and time combination once per week.

Drying: CCP B2
Physical, Chemical: None identified at this time. We could not think of any potential physical food safety hazards that could be introduced, controlled, or reduced during the drying of shelf-stable meat products.

Biological: Pathogens. (*Salmonella* and *Trichina)* The team realized that these pathogens are significant hazards in these products. Drying products to a water activity (aW) of 0.92 or less will eliminate or reduce *Salmonella* to an undetectable level. According to the U.S. Food & Drug Administration Center

for Food Safety and Applied Nutrition, 2001, aW of 0.92 or less will control this pathogen. (See supporting documentation.)

Water activity is monitored on a homogenized sample by a designee once per product per batch based on product weight loss. Products will continue to dry until aW of 0.92 is reached. HACCP personnel will directly observe aW monitoring once per week.

For *Trichinae* control we are using Method No. 6 of CFR 9 318.10, "Prescribed treatment of pork and products containing pork to destroy *Trichinae."* Within that regulation we are calculating the number of days the product must dry at above 50°F. to destroy *Trichinae.* We reduced the number of days according to table 3A (stuffing diameter), table 3B (fermentation temperature), and table 4 (salt content). We have developed a drying schedule (see attachment) for our products that takes into account all of these factors and computes the proper number of days our products must stay in the drying room.

Packaging:
Physical: None identified.

Chemical: Sanitizers. The written Sanitation Standard Operating Procedures address the proper procedures for cleaning and sanitizing equipment used during processing. Therefore, we determined that these hazards were not significant.

Biological: Pathogens *(Listeria monocytogenes).* These are shelf-stable, ready-to-eat products and, in accordance with USDA 9 CFR part 430, all ready-to-eat products must consider *L. monocytogenes* as a reasonably likely hazard post-lethality. We currently comply with alternative 2 of USDA directive10,240.4. All of our products are dried to a water activity of below 0.92. This water activity prevents the growth of *L. monocytogenes* throughout the shelf life of the product. (See supporting documentation.) In addition, we currently have an environmental sampling prerequisite program that complies with this directive. Therefore, we did not consider *L. moncytogenes* a significant hazard in this process.

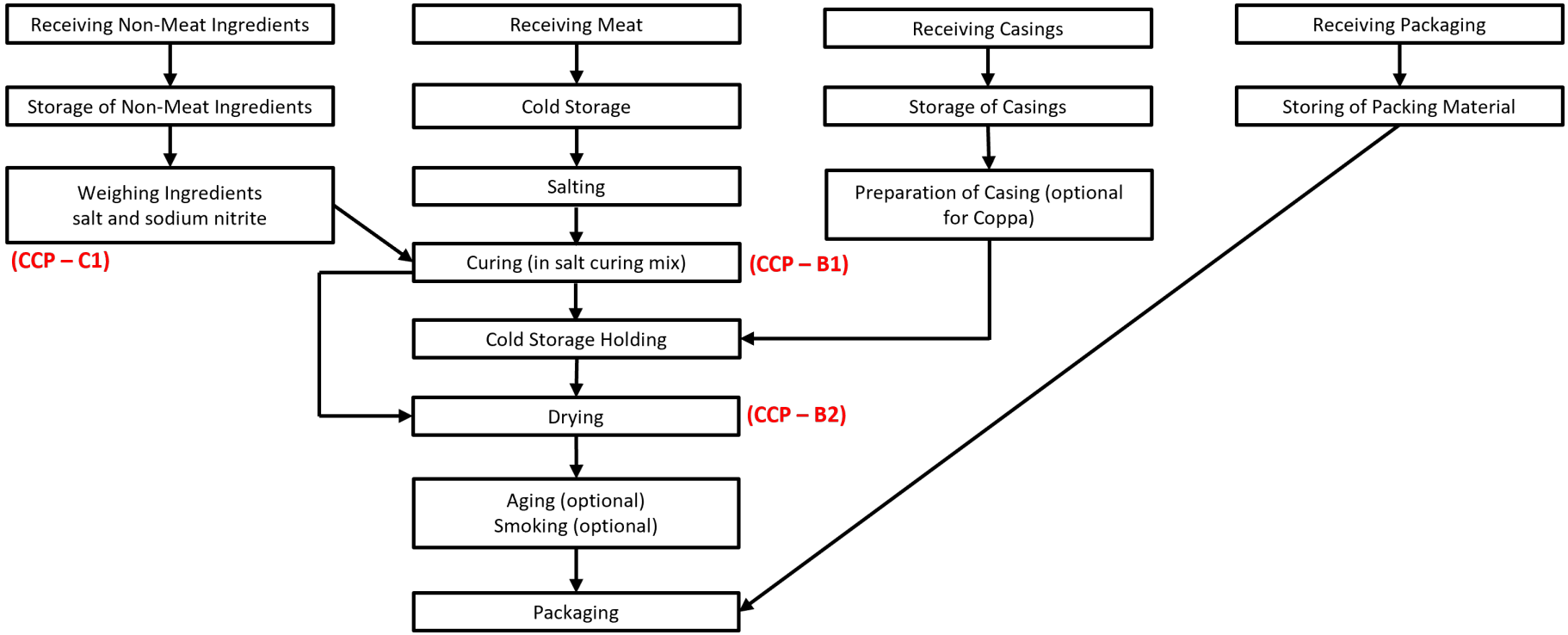
Receiving Packaging Materials:
Chemical: Chemical contaminants. Letters of Guaranty are on file from suppliers of packaging materials used in processed products.

Physical and Biological: None identified. The team could not identify any physical or biological hazards associated with this step.

Storing of Packaging Materials:
Chemical, Physical and Biological: None identified. The team could not identify any physical or biological hazards associated with this step.

Cold Storage/Tempering/Storing and Distribution
Physical, Chemical, and Biological: None identified at this time. At this point in the process the product is shelf-stable. We could not think of any potential physical, chemical, or biological food safety hazards that could be introduced, controlled, or reduced during these processing steps of a shelf-stable meat product.

Flowchart
Dry Cured Hams, Pork Shoulders, Pork Bellies (Non-Heat Treated, Shelf Stable)



Hazard Analysis Table: Dry Cured Dry Cured Hams, Pork Shoulders, Pork Bellies (Non-Heat Treated, Shelf Stable)

Ingredient/ Process Step	Potential hazard introduced, controlled, enhanced or reduced at this step	Is the potential food safety hazard significant?	What is the justification for your decision on significance (likelihood/severity)?	What control measures can be applied to prevent the significant hazard(s)?	Is this step a critical control point (CCP)?
Receiving Fresh Meat (1)	**Physical:** Metal	No	Unlikely to occur		No
	Chemical: Antibiotic residues	No	Unlikely to occur. USDA Residue Monitoring Program indicates that the great majority of livestock are free of residues when slaughtered in inspected facilities.		No
	Biological: Pathogens (i.e., *Staph, Salmonella,* and *Trichinae)*	Yes	Raw meat is a potential source of pathogens	Subsequent steps: Drying/aW	No
Cold Storage (2)	**Physical:** None identified				
	Chemical: None identified				
	Biological: Pathogen growth (i.e., *Staph, Salmonella*)	No	Improper cold storage temperatures could result in pathogen growth. Cold storage room temperatures are monitored as part of a GMP program.	Subsequent steps: Drying/aW	No
Salting (3)	**Physical:** None identified				
	Chemical: None identified				
	Biological: None identified				
Curing (4)	**Physical:** None identified				

	Chemical: Nitrite	Yes	Meat must remain in salt for required time and temperature … ppm of ingoing nitrite must comply with 9 CFR 424.21 restrictions		No
	Biological: Pathogens (i.e., *Salmonella*, *Trichinae)*	Yes	Proper curing and the subsequent steps of drying and aging will control these hazards		Yes CCP B1
Cold Storage Holding (5)	**Physical:** None identified				
	Chemical: None identified				
	Biological: None identified				
Drying/aW (6)	**Physical:** None identified				
	Chemical: None identified				
	Biological: Pathogens (i.e., *Salmonella*, *Trichinae)*	Yes	Potential pathogen survival if product is not dried to aW of 0.92 or below. Trichina larvae may survive if not salted and dried at proper times and temperatures.	Drying	Yes CCP 2
Aging/Smoke Optional (7)	**Physical:** None identified				
	Chemical: None identified				
	Biological: None identified				
Packing and Storage (8)	**Physical:** None identified				
	Chemical: None identified				

	Biological: Pathogen growth (i.e., *Staph, Salmonella*)	No	Water activity is below 0.92 and salt content is high enough to not require storage below 40°F. – product is shelf stable and ready-to-eat		No
Receiving Non-Meat Ingredients (1NM)	**Physical:** None identified				
	Chemical: None identified				
	Biological: None identified				
Storing of Non-Meat Ingredients (2NM)	**Physical:** None identified				
	Chemical: None identified				
	Biological: None identified				
Weighing (3NM)	**Physical:** None identified				
	Chemical: Nitrite	Yes	Using the proper amount of nitrite and salt in the dry cure mix		Yes CCP C1
	Biological: None identified				
Receiving Casings	**Physical:** None identified				
	Chemical: None identified				
	Biological: BSE (beef only)	Yes (beef only)	Letters of Guaranty from suppliers that casings are from young (<30 mo.) cows and or produced under a BSE program		No
	Physical:				

Storage of Casings	None identified				
	Chemical: None identified				
	Biological: None identified				
Receiving Packaging	**Physical:** None identified				
	Chemical: None identified				
	Biological: None identified				
Storage of Packaging Materials	**Physical:** None identified				
	Chemical: None identified				
	Biological:	No			No

HACCP Summary Table: Dry-Cured Hams, Pork Shoulders, Pork Bellies (Non-Heat Treated, Shelf Stable)

CCP	Hazard	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
CCP C1 Amount sodium nitrite in cure mix	Overuse of restricted ingredient	No more than 625 ppm sodium nitrite in cure mix Applies to whole muscle ham, shoulder, loin	Nitrite level	HACCP personnel will record ppm in cure.	Once per lot	HACCP personnel	1. Identify and eliminate cause of deviation. 2. Measures to prevent recurrence are established, such as retraining employees and/or adjusting equipment, as needed. 3. No product that is injurious to health or adulterated enters commerce. 4. Production Manager is responsible for implementing corrective actions.	Direct observation of weigh log monitoring for every lot of dry cured product by the HACCP personnel. Calibration of scale once daily when used.	Nitrite Log Scale Calibration Log
CCP B1 Drying/ Time and Temp-erature	Parasite: *Trichinae*	Product must dry at 75°F. for a minimum of 35 days or 80°F. for a minimum of 25 days USDA CFR 318.10	Time and Tempera ture of the drying room	Production Manager or designee will record drying room temperatur e and record number of days in drying room.	Drying Room Temperature = Daily Number of days = Once per batch before release	HACCP Manager or Designee	1. Identify and eliminate cause of deviation. 2. Continue to dry product until proper time /temp is met. This will bring CCP under control after corrective action is taken. 3. Measures to prevent recurrence are established, such as retraining employees and/or adjusting equipment, as needed. 4. No product that is injurious to health or adulterated enters commerce. 5. Production Manager is responsible for implementing corrective actions.	Visual direct observation of temperature recording once per day by the HACCP personnel. Visual direct observation of days recording once per batch. Calibration of thermometer once per week. HACCP personnel review records when needed.	Drying Log Drying Room Temp log Thermometer Calibration Log Deviation/ Corrective Action Log

CCP B2 Drying	Pathogen Control *Salmonella*	Product must reach a water activity of 0.92 or less.	Water Activity	Production Manager or designee will take water activity	Once every week	HACCP Manager or Designee	1. Identify and eliminate cause of deviation. 2. Continue to dry product until proper water activity is met. This will bring CCP under control after corrective action is taken. 3. Measures to prevent recurrence are established, such as retraining employees and/or adjusting equipment, as needed. 4. No product that is injurious to health or adulterated enters commerce. 5. Production Manager is responsible for implementing corrective actions.	Visual direct observation of aW monitoring once weekly by the HACCP personnel. Calibration of Aqua Lab once daily when used. HACCP reviews of drying when needed.	Drying Log Meter Calibration Log Deviation/ Corrective Action Log

Validation Reference:

Validation of Dry Cured Ham Process for Control of Pathogens, *Journal of Food Science*—Vol. 66, No. 9, 2001

https://www.researchgate.net/publication/228586018_Validation_of_Dry_Cured_Ham_Process_for_Control_of_Pathogens

Water Activity Calibration Log

Date	Time	Water Activity (METER)	Readings	Initials	Record Review	
					Date	Time

Calibrate using reference standards according to manufacturer's recommendations.
Any corrective action taken will be documented on HACCP Deviation Form.
Initials in the records review signify that the record was complete.

Scale Calibration Log

Date	Time	Scale	Readings	Initials	Record Review	
					Date	Time

Calibrate using reference standards according to manufacturer's recommendations.
Any corrective action taken will be documented on HACCP Deviation Form.
Initials in the records review signify that the record was complete.

Drying Room Temperature

Date	Time	Temp °F.	Initials	Direct Observations		HACCP Records	
				Initials	Date/Time	Initials	Date/Time

Any corrective action will be documented on the HACCP Corrective Action Form.
Temperature will be taken every morning when pre-op is performed.
Temperature will be verified once per day.
Temperature should be 50°F. or above.
Direct observation initials signify that monitory procedures were followed according to the HACCP plan.
Record review initials signify that the record is complete.

Dry Cure Drying Log

Product	Start Date/Time	Stop Date/Time	Total Hours	aW	Monitoring		Direct Observations		HACCP Records	
					Initials	Date/Time	Initials	Date/Time	Initials	Date/Time

Water activity should reach .92 or less.
Total days should match drying schedule for product diameter.
Any corrective action taken will be documented on HACCP Deviation form.
Direct observation initials signify that monitoring procedures were followed according to the HACCP plan.

Pre-Shipment Log

Product ID (Lot Number or Date)	Time/Date Records Reviewed	Findings Hold/Released	Employee Who Verified Records	HACCP Signature

If any corrective actions, log them on the HACCP Corrective Action form.

Corrective Action Log

CCP	Deviation/Problem	Product Type	Disposition of Product	Corrective Action Procedures	Responsible Person/Signature	Date

HACCP Change Log

Reason for Change to HACCP Log	Time/Date Change Made	Employee Who Approved Change	HACCP Signature

Example HACCP Plan for Dry Cured Bacon (Heat Treated, Non-Shelf-Stable)

HACCP Plan for Dry Cured Bacon (Heat Treated, Non-Shelf Stable)

HACCP PROGRAM FOR: _____

Signed and Approved:

_____ _____

Production Manager Date

Dry Cured Bacon (Heat Treated, Shelf Stable)
Product Description

COMPANY NAME:

PRODUCT NAME:

- Dry Cure Bacon

PRODUCT DESCRIPTION:

- Dry cured, heat treated, non-shelf-stable pork belly

INTENDED USE OF PRODUCT?

- Restaurant general public consumption
- May also be sold for home use
- Not ready-to-eat; must be fully cooked prior to consumption

TYPE OF PACKAGE?

- Poly-lined boxes for bulk storage
- Vacuum packaging for in-house storage and use or for consumer sales
- Poly-coated bags or paper wrapped in smaller portions for consumer sales

WHERE WILL IT BE SOLD?

- Restaurant – either for in-house service or sale to consumers for home use

LABELING INSTRUCTIONS:

- Keep refrigerated; shelf stable in unopened, original packaging
- Product identity, ingredients, name and address of restaurant

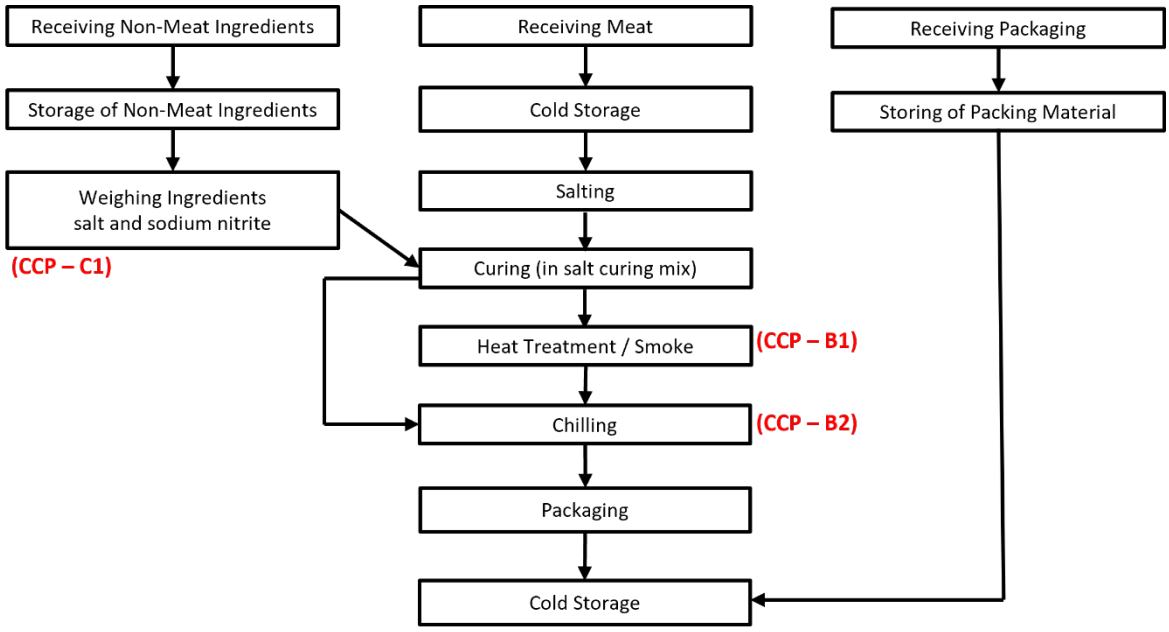
DISTRIBUTION METHOD?

- If shipped, in insulated container

Products/Ingredients Used to Produce Dry Cured Bacon

MEAT/POULTRY AND BY-PRODUCTS	NONMEAT FOOD INGREDIENTS	BINDERS/EXTENDERS
Pork belly (whole muscle)		
SPICES/FLAVORINGS	**RESTRICTED INGREDIENTS**	**PRESERVATIVES/ ACIDIFIERS**
Salt Pepper (black, white, cayenne) Sugar (white, brown)	Sodium nitrite	
OTHER		
Plastic and paper packaging materials Box Label		

Flowchart
Dry Cured Bacon (Heat Treated, Non-Shelf Stable)



Hazard Analysis Table: Dry Cure Bacon (Non-Heat Treated, Shelf Stable)

Ingredient/ Process Step	What are the potential hazard(s) introduced, controlled, enhanced, or reduced at this step?	Is the potential food safety hazard significant?	What is the justification for your decision on significance (likelihood/severity)?	What control measures can be applied to prevent the significant hazard(s)?	Is this step a critical control point (CCP)?
Receiving Non-Meat Ingredients (1NM)	**Physical:** None identified	No	Supplied Letter of Guaranty for quality and purity of ingredients		
	Chemical: None identified				
	Biological: None identified				
Storing of Non-Meat Ingredients (2NM)	**Chemical:** None identified	No	Use of GMP – Secure storage location Store in cool dry location		No
	Biological: None identified				
	Chemical: None identified				
Weighing Non-Meat ingredients (nitrite) (3NM)	**Physical:** None identified				
	Chemical: Nitrite	Yes	Using the proper amount of nitrite with the salt in the dry cure mix – overuse is potentially hazardous	Use of calibrated scale to measure restricted ingredients	Yes CCP 1C
	Biological: None identified				
Receiving Packaging	**Physical:** None identified				
	Chemical: None identified	No	Only food-grade packaging materials are used. Letters of Guaranty on file		No
	Biological: None identified				

Storage of Packaging Materials	**Physical:** None identified				
	Chemical: None identified				
	Biological: None identified				
Receiving Fresh Meat (1)	**Physical:** Metal	No	Unlikely to occur.		No
	Chemical: Antibiotic residues	No	Unlikely to occur. USDA Residue Monitoring Program indicates that the great majority of livestock are free of residues when slaughtered in inspected facilities.		No
	Biological: Pathogens (i.e., *Staph, Salmonella* and *Trichinae)*	Yes	Raw meat is a potential source of pathogens.	Subsequent steps - Heat treatment: *Trichinae* Pathogens	No
Cold Storage (2)	**Physical:** None identified				
	Chemical: None identified	No	Improper cold storage temperatures could result in pathogen growth. Cold storage room temperatures are monitored as part of a GMP program.		No
	Biological: Pathogen growth (i.e., *Staph, Salmonella*)	No			No
Salting (3)	**Physical:** None identified				
	Chemical: None identified	No	GMPs in place to outline proper use of dry cure mix on raw bellies		No
	Biological: None identified				
Curing (4)	**Physical:** None identified				

	Chemical: None identified	No	GMPs in place to define the time bellies need to dwell in cure		No
	Biological: None identified				
Heat Treatment (5)	**Physical:** None identified				
	Chemical: None identified				
	Biological: *Trichinae* (parasite)	Yes	Heat treatment will control *Trichinae*	Cook to required internal temperature	Yes CCP 1B
Chilling (6)	**Physical:** None identified				
	Chemical: None identified				
	Biological: *C. perfringens* growth	Yes	Improper cooling after heat treatment could allow for *C. perfringens* growth	Cool according to parameters per FDA Food Code ¶ 3-501.14	Yes CCP 2B
Packaging (7)	**Physical:** None identified				
	Chemical: None identified	No	GMP program in place to reduce risk of these hazards		No
	Biological: None identified				
Cold Storage (8)	**Physical:** None identified				
	Chemical: None identified	No	GMPs for finished product cold storage reduce the risk of these hazards; product is to be fully cooked prior to service.		No
	Biological: *C. perfringens* growth	Yes	Improper cold storage after heat treatment could allow for *C. perfringens* growth		

HACCP Summary Table: Dry Cured Bacon (Non-Heat Treated, Shelf Stable

CCP	Hazard	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
CCP 1C Amount sodium nitrite in cure mix	Overuse of restricted ingredient	No more than 200 ppm sodium nitrite in cure mix Applies to bellies dry cured for bacon	Nitrite level	HACCP personnel will record ppm in cure.	Once per lot	HACCP Personnel	1. Identify and eliminate cause of deviation. 2. Measures to prevent recurrence are established, such as retraining employees and/or adjusting equipment, as needed. 3. No product that is injurious to health or adulterated enters commerce. 4. Production Manager is responsible for implementing corrective actions.	Direct observation of weigh log monitoring for every lot of dry cured product by the HACCP personnel. Calibration of scale once daily when used.	Nitrite Log Scale Calibration Log
CCP 1B Heat Treatment	Parasite: *Trichinae*	Product must be heat treated to an internal tempera-true of 130°F. or greater for 30 minutes 9CFR 318.10	Tempera ture and dwell time of heat-treated belly	Production Manager or designee will record temperature and record dwell time	Each lot of dry cured bacon	HACCP Personnel	1. Identify and eliminate cause of deviation. 2. Continue to dry product until proper time/temp is met. This will bring CCP under control after corrective action is taken. 3. Measures to prevent recurrence are established, such as retraining employees and/or adjusting equipment, as needed. 4. No product that is injurious to health or adulterated enters commerce. 5. Production Manager is responsible for implementing corrective actions.	Visual direct observation of temperature recording once per day by the HACCP personnel. Visual direct observation of dwell time for each lot. Calibration of thermometer once per week. HACCP reviews heat treatment records for each lot when needed.	Temperature and Time Log Thermometer Calibration Log Deviation/ Corrective Action Log

CCP 2B Chilling	Pathogen Control *C. perfringens*	Product internal temperature must be reduced from 130°F. – 75°F. in less than two hours and from 75°F. - 41°F. In less than four hours FDA Food Code ¶ 3-501.14	Tempera ture	Production designee will take Temp.	Each lot of dry cured bacon	HACCP personnel	1. Identify and eliminate cause of deviation. 2. Continue to dry product until proper water activity is met. This will bring CCP under control after corrective action is taken. 3. Measures to prevent recurrence are established, such as retraining employees and/or adjusting equipment, as needed. 4. No product that is injurious to health or adulterated enters commerce. 5. Production Manager is responsible for implementing corrective actions.	Visual direct observation of Aw monitoring once weekly by the HACCP personnel. Calibration of thermometer once daily when used. HACCP reviews chilling records once daily when needed.	Chilling Log Thermometer Calibration Log Deviation/ Corrective Action Log

Example HACCP Plan for Salami (Non-Heat Treated, Shelf Stable)

HACCP Plan for Salami (Non-Heat Treated, Shelf Stable)

HACCP PLAN FOR: _____

Signed and Approved:

_____ _____

Production Manager Date

Salami (Non-Heat Treated, Shelf Stable)
Product Description

COMPANY NAME:

PRODUCT NAME:

- Fermented and dried salami (multiple varieties of various spice combinations and diameters)

PRODUCT DESCRIPTION:

- Fermented and dried non-heat treated shelf-stable salami; final product is ready-to-eat

INTENDED USE OF PRODUCT?

- Restaurant general public consumption
- May also be sold for home use

TYPE OF PACKAGE?

- Poly-lined boxes for bulk storage
- Vacuum packaging or chub packaging of individual salamis for in-house storage and use or for consumer sales
- Poly-coated bags or paper wrapped in smaller portions for consumer sales

WHERE WILL IT BE SOLD?

- Restaurant – either for in-house service or sale to consumers for home use

LABELING INSTRUCTIONS:

- Ready to eat, shelf stable in unopened, original packaging
- Product identity, ingredients, name and address of restaurant

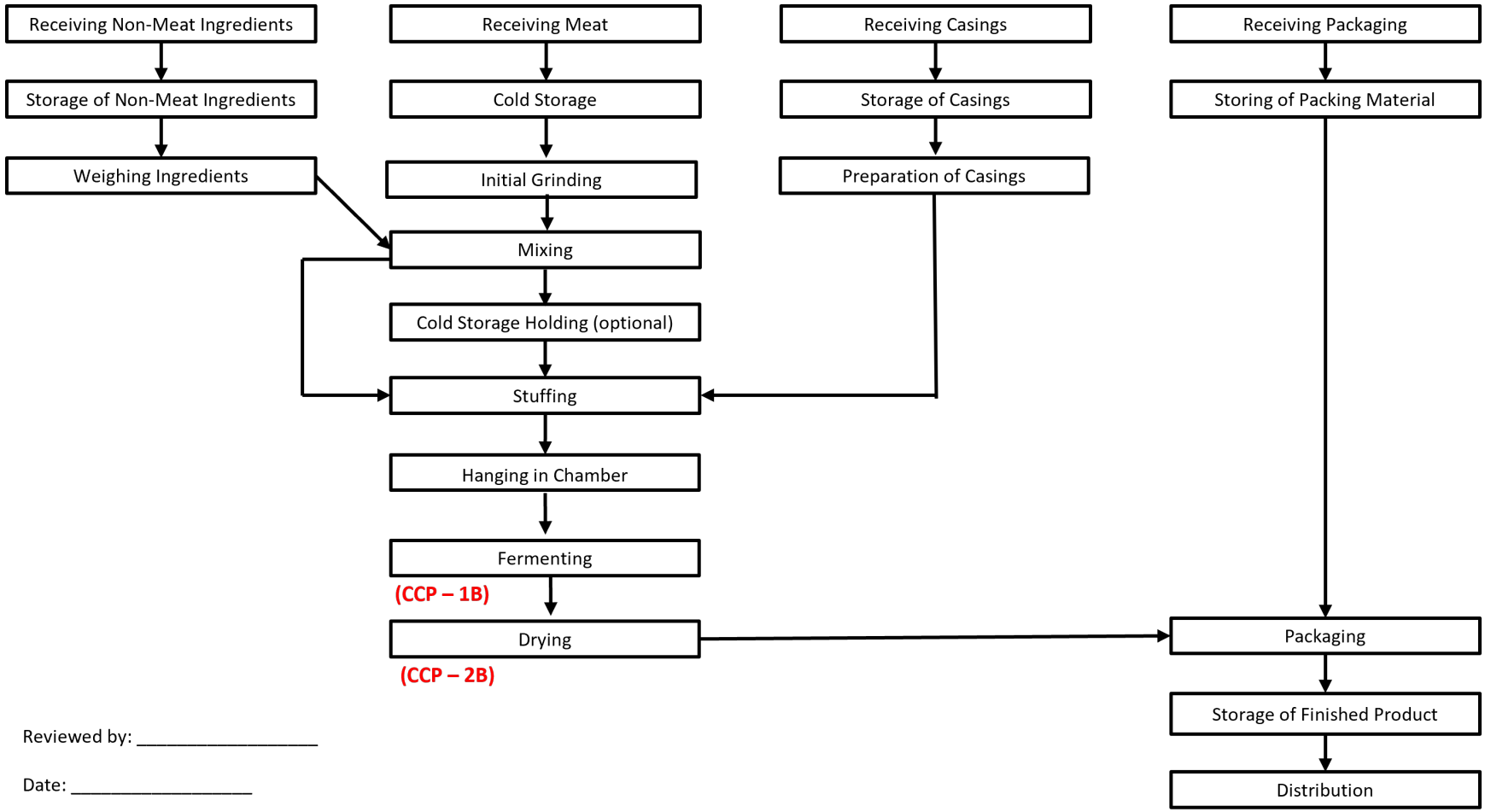
DISTRIBUTION METHOD?

- If shipped, in insulated container

Products/Ingredients Used to Produce Salami (Non-Heat Treated, Shelf Stable)

MEAT/POULTRY AND BY-PRODUCTS	NONMEAT FOOD INGREDIENTS	BINDERS/EXTENDERS
Pork meat Natural casings (beef, pork, and lamb)	Wine	Non-fat dry milk powder
SPICES/FLAVORINGS	**RESTRICTED INGREDIENTS**	**PRESERVATIVES/ ACIDIFIERS**
Salt Pepper (black, white cayenne) Garlic Paprika Fennel Sugar Cinnamon Mace Clove Juniper berry	Sodium nitrite Sodium nitrate	Lactic acid starter culture
OTHER		
Plastic and paper packaging materials Box Label Artificial casings (collagen)		

Flowchart
Fermented and Dried Salami (Non-Heat Treated, Shelf Stable)



Reviewed by: _____

Date: _____

Hazards Analysis Decision-Making Document

Non-Heat Treated - Shelf Stable Plan

The FDA definitions for *hazard* and *hazard analysis* were reviewed before the team started reviewing the hazard analysis and documenting the thought process for each response. Those definitions are included in the glossary section of this manual.

HAZARD ANALYSIS:

The following summarizes the discussions and thought process that impacted the decisions for each step of the flowchart for the three food safety hazard categories – biological, chemical, and physical. To the best of our knowledge the critical control points, critical limits, monitoring activities, verification, and validation activities in this plan represent the most recent scientific advances and research available.

Hazard Analysis Table: Salami (Non-Heat Treated, Shelf Stable)

Ingredient/ Process Step	Potential hazard introduced, controlled, enhanced, or reduced at this step	Is the potential food safety hazard significant?	What is the justification for your decision on significance (likelihood/severity)?	What control measures can be applied to prevent the significant hazard(s)?	Is this step a critical control point (CCP)?
Receiving Fresh Meat	**Physical:** Metal	No	Unlikely to occur.		No
	Chemical: Antibiotic residues	No	Unlikely to occur. USDA Residue Monitoring Program indicates that the great majority of livestock are free of residues when slaughtered in inspected facilities.		No
	Biological: Pathogens (i.e., *Staph, Salmonella,* and *Trichinae)*	Yes	Raw meat is a potential source of pathogens.	Subsequent steps: Fermentation and/or drying/aW	No
Cold Storage	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: Pathogen growth (i.e., *Staph, Salmonella*)	No	Improper cold storage temperatures could result in pathogen growth. Cold storage room temperatures are monitored as part of a GMP program.	Subsequent steps: Fermentation and/or drying/aW	No
Initial Grinding	**Physical:** Metal	No	Unlikely to occur		No
	Chemical: Sanitizer	No	SSOP addresses approved sanitizers used at acceptable levels		No
	Biological: None identified	No			No
Mixing	**Physical:** Metal fragments	No	Unlikely to occur		No
	Chemical: Allergens	No	Facility has an allergen program to address cross contamination from other raw materials used in the facility.		No

	Nitrite	Yes	Nitrite in excess concentration is a chemical hazard	Use calibrated scale to measure restricted ingredient	Yes CCP 1C
	Biological: None identified	No			No
Cold Storage Holding	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: Pathogen growth (i.e., *Staph, Salmonella*)	No	Improper cold storage temperatures could result in pathogen growth. Cold storage room temperatures are monitored as part of a GMP program.	Subsequent Steps: Fermentation and/or drying/aW	No
Stuffing	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: None identified	No			No
Hanging	**Physical:** Metal	No			No
	Chemical: None identified	No			No
	Biological: None identified	No			No
Fermenting	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: Pathogens (i.e., *Staphylococcus)*	Yes	Potential pathogen survival if product is not fermented to pH 5.3 or below within 1,200 degree-hours (see supporting documentation)	Fermentation	Yes CCP 1B
Drying/aW	**Physical:** None identified	No			No
	Chemical: None identified	No			No

	Biological: Pathogens (i.e., *Salmonella, Trichina*)	Yes	Potential pathogen survival if product is not dried to aW of 0.92 or below. *Trichina* larvae may survive if not salted, and dried at proper times and temperature.	Drying	Yes CCP 2B
Packaging	**Physical:** Glass from jars for Nduja	No	Glass control policy in place		No
	Chemical: Not identified at this time	No			No
	Biological: Pathogens (i.e., *Listeria monocytogenes*, *Trichinae*)	Yes	Prerequisite *Listeria* program that complies with Alternative 2 of 9 CFR part 430.		No
Storing Finished Product	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: None identified	No			No
Distribution	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: None identified	No			No
Receiving of Non-Meat Ingredients	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: None identified	No			No
Storing of Non-Meat Ingredients	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: None identified	No			No
Weighing	**Physical:** None identified	No			No

	Chemical: None identified	No			No
	Biological: None identified	No			No
Receiving Casings	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: BSE (Beef Only)	No	Letters of Guaranty from suppliers that casings are from young calves (<30mo.) and/or produced under a BSE program		No
Casing Storage and Preparation	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: None identified	No			No
Casing Preparation	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: None identified	No			No
Receive Packaging Materials	**Physical:** None identified	No			No
	Chemical: Chemical Contaminants	No	Only food-grade packaging materials are used. Letters of Guaranty on file.		No
	Biological: None identified	No			No
Storing of Packaging Material	**Physical:** None identified	No			No
	Chemical: None identified	No			No
	Biological: None identified	No			No

HACCP Summary Table: Salami (Non-Heat Treated, Shelf Stable)

CCP	Hazard	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
CCP 1C Amount sodium nitrite in cure mix	Overuse of restricted ingredient	No more than 156 ppm sodium nitrite applies to commin-uted sausages	Nitrite level	HACCP personnel will record ppm in cure.	Once per lot	HACCP personnel	1. Identify and eliminate cause of deviation. 2. Bring CCP under control after corrective action is taken 3. Measures to prevent recurrence are established, such as retraining employees and/or adjusting equipment, as needed. 4. No product that is injurious to health or adulterated enters commerce. 5. Production Manager is responsible for implementing corrective actions.	Direct observation of weight log monitoring for every lot of dry cured product by the HACCP personnel. Calibration of scale once daily when used.	Nitrite Log Scale Calibration Log Corrective Action Log
CCP 1B Fermentation	Toxin formation by *Staph. aureus*	pH 5.3 reached within 1,200 degree-hours	Product pH	Measure with calibrated pH meter	Once per batch	Production manager / designated, trained staff	1. Identify and eliminate cause of deviation. 2. Bring CCP under control after corrective action is taken 3. Measures to prevent recurrence are established, such as retraining employees and/or adjusting equipment, as needed. 4. No product that is injurious to health or adulterated enters commerce. 5. Production Manager is responsible for implementing corrective actions.	Direct observation of pH measurements for every lot of dry cured product by the HACCP personnel, and/or review of batch records. Calibration of pH meter once daily when used.	Batch Log pH Meter Calibration Log Corrective Action Log

CCP 2B Drying - aW	Potential growth of pathogens	aW 0.92 or lower	aW of finished product	Calibrated aW meter, 10% of production batch	Once per batch	Production manager / designated, trained staff	1. Identify and eliminate cause of deviation. 2. Bring CCP under control after corrective action is taken 3. Measures to prevent recurrence are established, such as retraining employees and/or adjusting equipment, as needed. 4. No product that is injurious to health or adulterated enters commerce. 5. Production Manager is responsible for implementing corrective actions.	Direct observation of aW monitoring for every lot of dry cured product by the HACCP personnel and/or review of batch records. Calibration of aW meter once daily by HACCP staff when used.	Batch Log aW Meter Calibration Log Corrective Action Log
CCP 2B Drying – Time/Temp	Potential survival of pathogens	Product must dry required no. of days at/above 50°F.	Every product must dry proper no. of days at or above 50°F. – see attached drying schedule	Production manager or trained designee will record temperature of drying room daily and record no. of drying days	Every batch – temperature continuous; days, once per batch	Production manager / designated trained staff	1. Identify and eliminate cause of deviation. 2. Bring CCP under control after corrective action is taken 3. Measures to prevent recurrence are established, such as retraining employees and/or adjusting equipment, as needed. 4. No product that is injurious to health or adulterated enters commerce. 5. Production Manager is responsible for implementing corrective actions.	Review of batch records by Production Manager prior to release of each batch for sale. Calibration of drying room thermometer once daily by HACCP staff.	Batch Log Thermometer Calibration Log Corrective Action Log

Unforeseen Hazards - Salami (Non-Heat Treated, Shelf Stable)

There are chances that unforeseen hazards may occur. Therefore, if an unforeseen hazard occurs, this establishment will:

- Segregate and hold the affected product, at least until the requirements of (2) and (3) are met.
- Perform a review to determine the acceptability of the affected product for distribution.
- Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce.
- Perform or obtain reassessment by an individual trained in accordance with USDA/FSIS Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule (9 CFR 417.7) to determine whether the newly indemnified deviation or other unforeseen hazard should be incorporated into the HACCP Plant.

Plant manager or designee is responsible for performing corrective actions to ensure appropriate corrective actions are taken.

Sanitation Standard Operating Procedures - Salami (Non-Heat Treated, Shelf Stable)

Supervisor: _____

Owner: _____

Signature: _____

Date: _____

The manager or designee is responsible for implementing and daily monitoring of the Sanitation SOP, and also recording findings and any corrective actions. All records pertaining to this SSOP will be maintained on file and made available for review.

Pre-Operational Sanitation – Facility, Equipment, Utensil Cleaning

General Equipment Cleaning. All equipment and utensils used for meat processing will be cleaned and sanitized prior to starting production.

Established cleaning procedures include:

- Equipment is disassembled, as necessary.
- Food debris is removed from equipment.
- Equipment parts are rinsed with water to remove remaining food debris.
- An approved cleaning solution is applied to equipment parts/surfaces and scrubbed as needed to remove soil.
- Equipment/parts are rinsed with potable water.
- Equipment/parts are inspected for cleanliness, and re-cleaned if necessary.
- Equipment/parts are sanitized with approved sanitizer, and rinsed with potable water.
- Equipment is reassembled, re-sanitized and re-rinsed (following manufacture recommendations; some sanitizers are required to be rinsed, prior to operation).

Implementation, Monitoring and Record Keeping. The manager or his designee performs daily organoleptic, sanitation inspection after pre-operational cleaning and sanitizing. The results of this inspection are recorded on Form # 1, Preoperational Sanitation Checklist. If inspection finds that equipment is acceptably clean, then the appropriate box is checked and initialed. If corrective actions are needed, such actions are documented on Form Attachment #3 (Deficiency Report).

Corrective Actions. When the manager or his designee determines that equipment or parts are not properly cleaned, the cleaning procedure and inspection are repeated. The manager or his designee monitors the cleaning process, and re-trains the employees doing the cleaning, if necessary. Corrective actions are recorded on Deficiency Report.

Cleaning of facilities, including floors, walls, and ceilings

Cleaning procedures:

- Debris is swept up and discarded.
- Facilities are rinsed with potable water.
- Facilities are cleaned with an approved cleaner.

Cleaning Frequency. Floors and walls are cleaned at the end of each processing day. Ceilings are cleaned as needed.

Implementation, Monitoring, and Record Keeping. The manager or their designee performs daily organoleptic, sanitation inspection after pre-operational cleaning of facilities (on days that products are being produced). The results of this inspection are recorded on Form Sanitation Pre-operational Checklist. If inspection finds that the facilities are acceptably clean, then the appropriate box is checked and initialed. If corrective actions are needed, such actions need to be completed and documented on Sanitation Deficiency Report, Attachment #3.

Corrective Actions. When the manager or manager's designee determines that the facilities are not properly cleaned, the cleaning procedure and inspection are repeated. The manager or their designee monitors the cleaning process, and re-trains the employees doing the cleaning, if necessary. Corrective actions are recorded on Form Deficiency Report.

Operational Sanitation-Equipment and Facility Cleaning

Meat processing is performed under sanitary conditions to prevent direct and cross contamination of meat products.

Established procedures for processing meat products include:

- Processing rooms and equipment will be kept clean and in good repair to prevent contamination of meat food products during production.

- All employees will clean and sanitize hands, gloves, knives, spatulas, cutting boards, etc., as necessary during processing to prevent contamination of meat products.

- All equipment and utensils are cleaned and sanitized throughout the day as needed to prevent contamination of products.

- Employee outer garments are maintained in a clean and sanitary manner and are changed at least daily, and more often if necessary.

Established procedures for product handling and storage include:

- Perishable products are stored under refrigeration. Storage and processing areas are maintained in sanitary conditions. Good manufacturing practices are incorporated to protect product from contamination during storage.

- Dry storage areas are cleaned as often as needed and rodent and pest control maintained. Items are stored off the floor and away from the walls allowing for proper inspection.

Implementation, Monitoring, and Record Keeping. The manager or manager's designee is responsible for ensuring that employee hygiene practices, sanitary product handling procedures, and cleaning procedures are maintained during a processing shift. The manager or their designee monitors these operational sanitation procedures once during each processing shift and these results are recorded on Form Attachment #2 (Operational Sanitation Checklist).

Corrective Actions. When the manager or designee identifies operational sanitation problems, the manager notifies employees to take appropriate action to correct the sanitation problems. If necessary, processing is stopped and/or employees are re-trained. Corrective actions are recorded on Form Attachment #3 (Sanitation Deficiency Report).

Procedures for Handling Contaminated Product

- Raw meat will be trimmed and washed to remove contaminates or condemned and denatured as appropriate.
- Cooked meat dropped on the floor with be condemned and denatured.
- Hands will be washed after handling floor debris.
- Hands, gloves, knives, and cutting boards contaminated during production will be washed and sanitized.

Employee Hygiene

- Employees will change outer garment and gloves between working with raw and cooked products.
- Outer garments and gloves will be removed and hung in designated areas before going on breaks or visiting the restroom.
- Hands will be washed prior to starting to work, and after returning from breaks or restroom visits.
- Head coverings are to be worn at all times during processing.
- Approved footwear must be worn.
- No smoking, eating, or drinking except in designated areas.
- No jewelry will be worn by food handlers including rings, watches, or earrings.

Finished Products

- All finished products will be handled and packed by employees with gloved hands.

Allergen Plan

Products containing allergen ingredients will be processed after all other products are done, or a clean-up will be done in between processing products that contain allergens and those that do not.

SALAMI DRYING SCHEDULE
METHOD NO 6 of 318.10

PRODUCT DIAMETER	Initial Days of Drying Table 3A	% Reduction For Temp* Table 3B	% Addition for Salt Content**	Total Days Drying Above 50°F.
1 1/2"	20	N/A	13%	20
2 3/4"	20	N/A	13%	23
4"	25	N/A	13%	29

*All salami products are fermented on a schedule that does not achieve temperatures and time to reduce the drying time. (See HACCP Summary Table, CCP 1B and Fermentation/Degree-Hour Log.
**All salami products are formulated with 2.9% salt including salt in the cure package. (Exact recipe is proprietary information.)
After calculating the number of days, the total was rounded up to the nearest full day.

Drying Log

Product	Start Date/Time	Stop Date/Time	Total Hours	aW	Monitoring		Direct Observations		HACCP Records	
					Initials	Date/Time	Initials	Date/Time	Initials	Date/Time

Water activity (aW) should reach .92 or less.
Total days should match drying schedule for product diameter.
Any corrective action taken will be documented on HACCP Deviation form.
Direct observation initials signify that monitoring procedures were followed according to the HACCP plan.

Drying Room Temperature Log

Date	Time	Temp °F.	Initials	Direct Observations		HACCP Records	
				Initials	Date/Time	Initials	Date/Time

Any corrective action will be documented on the HACCP Corrective Action Form.
Temperature will be taken every morning when pre-op is performed.
Temperature will be verified once per day.
Temperature should be 50°F. or above.
Direct observation initials signify that monitory procedures were followed according to the HACCP plan.
Record review initials signify that the record is complete.

Fermentation/Degree-Hour Log

Product	Start Date/Time	Stop Date/Time	Min. Temp	Max. Temp	Total Hours	pH	Monitoring		Direct Observations		HACCP Records	
							Initials	Date/Time	Initials	Date/Time	Initials	Date/Time

Total degree-hours are calculated by (max. temp – 60) x total hours from start of fermentation (stop time - start time).
pH should reach 5.3 within 1,200 degree-hours.
Any corrective action taken will be documented on HACCP Deviation form.
Direct observation initials signify that monitoring procedures were followed according to the HACCP plan.
Record review initials signify that the record is complete.

pH Calibration Log

Date	Time	pH METER	Readings		Initials	Record Review	
			pH 4.0	pH 7.0		Int.	Date/Time

Calibrate to pH 4.0 and pH 7.0 using reference standards.
Any corrective action taken will be documented on Corrective Action log.
Initials in the records review signify that the record was complete.

Water Activity Calibration Log

Date	Time	Water Activity	Readings		Initials	Record Review	
		Meter				Date	Time

Calibrate to reference standards by manufacturer's recommendation.
Any corrective action taken will be documented on HACCP Deviation form.
Initials in the records review signify that the record was complete.

Corrective Action Log

CCP	Deviation/Problem	Product Type	Disposition of Product	Corrective Action Procedures	Responsible Person/Signature	Date

Pre-Shipment Log

Product ID (Lot Number or Date)	Time/Date Records Reviewed	Findings Hold/Released	Employee Who Verified Records	HACCP Signature

Association of Food and Drug Officials

155 W Market Street
3rd Floor
York, PA 17401

Phone (717) 757-2888

www.afdo.org

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