# A RETAIL FOOD ESTABLISHMENT GUIDE FOR DEVELOPING A HACCP PLAN

# Meeting the Requirements of the FDA Food Code Variance in Relation to Specialized Meat and Poultry Processing Methods

# Table of Contents

# Section 1: Introduction to Food Safety Systems

## About HACCP

### What is HACCP?

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

The most basic concept underlying HACCP is that of prevention. The food processor/handler should have sufficient information concerning the food and the related procedures they are using, so they will be able to identify where a food safety problem may occur and how it will 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 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 are the HA (Hazard Analysis) part of HACCP. The proof of the control of the processes and conditions is the CCP (Critical Control Point) part. Flowing from this basic concept, 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 method in ensuring that safe food products are manufactured. The plan will be successful when other procedures are in place such as sanitation standard operating procedures (SSOP's) and by using good manufacturing practices (GMP's). Although the Food Code does not require them, these programs are fundamental in the development of a successful HACCP plan. SSOP's should include personal hygiene practices as well as daily sanitation of the food contact surfaces and equipment. Good sanitation practices are the foundation of manufacturing and preparing safe food.

HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution, and consumption of the finished product. For successful implementation of an HACCP plan, management must be strongly committed to the HACCP concept. A firm 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 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. One of the provisions of the Food Code is for retail food establishments that conduct certain food processes or operations to operate under a HACCP plan.

## Retail Processes or Operations that Require a HACCP Plan:

1. Smoking or curing food, except for smoking done for the purpose of imparting flavor only, and not as a part of the part of the cooking process.
2. Using food additives or adding components, including vinegar, as a method to preserve food (rather than to enhance its flavor) or change food into a non-potentially hazardous food.
3. Using a reduced oxygen method of packaging food.
4. Food Establishments that apply for a variance to:
    - Use more than one tagged shellstock container at a time.
    - Deviate from required cooking times and temperatures for raw animal foods.
    - Use molluscan shellfish life support system display tanks to store and display shellfish that are offered for sale.

## Additional Requirements

While the process of developing a HACCP plan is a rather universal one, there are some additional components that need to be included as part of the firm's HACCP plan. Section 4 provides details on the additional requirements such as standard operating procedures, duties of the person in charge. HACCP plans that cover reduced oxygen packaging operations must include several additional pieces of information.

# Definitions:

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

**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 which 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.*

**Food Code:** *Minnesota Rules 4626*

**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.*

**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 a food to be 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.*

**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.*

**Prerequisite Programs:** *Procedures, including Good Manufacturing Practices that address operational conditions providing the foundation for the HACCP system.*

**Preventative Measure:** *Physical, chemical, or other factors that can be used to control an identified health hazard.*

**Sensitive Ingredient:** *An ingredient known to have been associated with a hazard for which there is a reason for concern.*

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

**Step:** *A point, procedure, operation or stage in the food system from primarily production to final consumption.*

**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.*

**Verification:** *Those activities such as methods, procedures, or tests in addition to monitoring, that determines if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.*

# 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. The process works better if you take some preliminary steps. You may wish to use the example forms located in Section 5 or you may want to create your own forms.

1. ***Assemble the HACCP Team***
   The first thing that must be done is to bring together individuals in your facility that has a working knowledge of the various processing steps and operations in your facility. 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.

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 potentially hazardous foods that are covered. Foods and processes with similar 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, materials, 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.

4. ***Develop a Process Flow Diagram***
   At the fourth step, the HACCP team will draw a flow diagram that shows all the steps in the production process (everything from receiving through distribution.)

5. ***Verify the Process Flow Diagram***
   The final step is to take this flow diagram and verify its accuracy. The HACCP team can do this by having an impartial person do a "walk-through" of the entire production process, checking to see if there is anything missing from the diagram. This should be done by someone who knows, or is familiar with the production process.

# An Introduction to the 7 HACCP Steps

### 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. It's important to remember that you are dealing with *safety, not quality* issues.

The hazard analysis is actually 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 as to whether they are *"reasonably likely to occur."* If the HACCP team decides that a food safety hazard is likely to occur, then they need to find and list any preventive measures that could be used to control those food safety hazards. Preventive measures are defined as: *"Physical, chemical, or other means that can be used to control an identified food safety hazard."*

**INGREDIENT RELATED HAZARDS:** *As you evaluate the hazards in your process, don't forget about ingredient related hazards. Everything that goes into your product needs to be evaluated. Ingredient specifications, provided by your supplier, should give you details on the materials/ingredients being sold, including statements that the materials/ingredients are of food grade and are free of harmful components.*

**For example,** *the ingredient specification for dried legumes (beans) might state that there will be fewer that 5 small rocks or stones per ten pound bag and that no harmful pesticides were used* in the growing process.

### Principle 2: Identify Critical Control Points (CCP's)

A critical control point is defined as "A point, step or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

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

- Chilling or freezing
- Cooking
- Certain processing procedures; smoking, curing, acidification

Steps that are CCP's in one facility may or may not be CCP's in your facility. When making a HACCP plan, each facility must look at the unique conditions present in that facility.

### Principle 3: Establish Critical Limits for Each CCP

A critical limit is defined as "The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." Critical limits serve as boundaries of safety for 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 facility, know 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 CCP's are operating under control.

***Monitoring serves three main purposes:***

**First,** 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.)

**Second,** 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.)

**Third,** 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(s) that will be responsible for each monitoring procedure and frequency.

### Monitoring Requires Precision

Monitoring a CCP is a big responsibility. 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, and
- 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 CCP's monitoring should be dated and signed or initialed by the person doing the monitoring and the results recorded.

## Principle 5: Establish Corrective Actions

Corrective actions are defined as *"Procedures to be followed when a deviation occurs."* A deviation is defined as a *"failure to meet a critical limit."* Corrective actions are taken when monitoring shows you that a food safety hazard has gotten out of control at a CCP.

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 non-complying product;
2. Correcting the cause of the non-compliance to prevent a recurrence; and
3. 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).

As with the monitoring procedures, specific corrective action procedures must be developed for each CCP.

## Principle 6: Establish Recordkeeping Procedures

Record keeping procedures are important in making and keeping an HACCP system effective. Every time monitoring procedures are done, corrective actions are taken, or production equipment is serviced, a detailed record of that activity is made. This continual recording of this information allows you to keep track of everything that goes on in your facility.

You can think of HACCP records in two ways, development forms and day-to-day "working" logs. The development forms are all of the supporting documentation that go into building your first HACCP plan. The "working" logs are the sheets of paper where you collect the details of what happen on the production floor. You may wish to use the example forms located in Section 5, or you may wish to create your own forms.

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

- The HACCP plan itself and all supporting documentation.
- Records (including product codes) documenting the day-to-day functioning of the HACCP system such as daily monitoring logs, deviation/corrective action logs, and verification logs.

### Principle 7: Establish Verification Procedures

Every establishment should validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and should verify that the plan is being effectively implemented.

1. ***Initial validation.*** Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP'S, critical limits, monitoring and record keeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

2. ***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.

3. ***Reassessment of the HACCP plan.*** Every establishment should reassess the adequacy of the HACCP plan at least annually and whenever any changes occur 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. One 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.

4. ***Reassessment of the hazard analysis.*** Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur should reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. 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; packaging; finished product distribution systems or the intended use or consumers of the finished product.

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**Verification procedures help makes the HACCP plan work correctly.**

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# Section 2: The Preliminary Steps

## Introduction

Now that you have a general understanding of HACCP, let's get down to the specifics. Developing a HACCP plan starts with the collection of important information. This fact-finding process is called 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 purpose.
5. Verify the process flow diagram.

In order to show you how an HACCP plan is put together, we are going to show you examples of filled-out HACCP development forms. The thought of filling out all these forms can be a bit overwhelming at first; however, it is a straightforward process. We are going to be using an "Example Facility" to show you what each one of these forms might look like when completed.

# Step 1: Assemble the HACCP Team

**YOUR FIRST TASK** in developing a HACCP plan is to assemble your HACCP team. The HACCP team consists of individual(s) who will gather the necessary information for your HACCP plan.


***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 facility, 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, state extension offices, trade or professional associations, consultants, universities and libraries.

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

### Working with the "HACCP Team" Form

The Example Facility has six HACCP team members. One of whom is not only the general manager, but is also the owner. It is important to list all the team members and to state clearly what their HACCP team role is. (As you might think, filling out this form is relatively simple.) **Don't forget to sign and date the form.**

[**A note about the forms:** As with all HACCP forms and logs, the person who is responsible for an activity (whether it be drafting the forms, or doing the monitoring) should be the one who signs and dates the form or log.]

# Step 1
# HACCP Team Form

| Team Members | Role |
|---|---|
| Cindy Jones | General Manager |
| Mary Weston | Quality Control |
| Mark Baker | Wet Room Supervisor |
| Susan Smith | Packing Supervisor |
| Joe Jones | Extension Service |
| Pam Smith | Local Microbiologist |
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*Developed by:* Cindy Jones *Date* 12/10/98

# Step 2: Identify Products/Processes to be Covered

**NEXT,** make a complete listing of all the products and processes that must be covered under a HACCP plan. The foods should be categorized by the types of processes that must be covered. The Food Code requires HACCP plans for certain processes. In addition, the requirements for reduced oxygen packaged foods limit the types of foods that can be packaged in this manner.

### Product/Process Description Form

The following is an example of a format that could be used to list the products covered. This sample lists many types products and processes for this establishment - a typical store would not likely have all of these processes.

# Products/Processes Covered

Store Name *General J's Market*

Street Address *123 XYZ Street*

City *Anytown* State *MN* Zip Code *55555*

**Products/Processes Covered under the HACCP Plan**

**Smoking/Curing**
*All Beef Summer Sausage, Ring Bologna, Smoked Turkey Drumsticks, Wieners, Snack Sticks, Beef Jerky, Bacon*

**Reduced Oxygen Packaging**
*All smokehouse products listed above*
*Sliced ham, sliced smoked turkey, sliced salami, hard cultured cheese (sliced and block), raw meats (cut and ground meat and poultry)*

**Food Additives**
*Acidified rice*

**Variances**
*Molluscan shellstock sold from life support tanks*
*Sale of more than one tagged box of molluscan shellstock at any one time*
*Deviation of required cook times and temperatures for roast beef*

*Developed by:* *Cindy Jones* *Date* *12/10/98*

# Step 3: Develop a Complete List of Ingredients, Materials, Equipment and Recipes/Formulations

**THE THIRD STEP** is for the team to thoroughly review each product or process and write down all of the ingredients, materials and equipment used in the preparation or sale of a food and also to write down formulations or recipes that show methods and control measures that address the food safety concerns involved.

The ingredients list may be as simple as the recipe format listed below or may be more detailed as shown on the following page. As you can see on the following examples, ingredients and materials fall into several categories. If the category does not apply to your product/process, you don't have to write anything in that space.

*[If you use pre-packaged or pre-blended ingredients such as a seasoning mix, you can list it by blend (mix) name and just staple that products information to the back of your Ingredients Form.]*

Be sure a recipe is listed for every product you produce.

| Ring Bologna |
|---|
| FULL BATCH |
| 50 lbs pork trim |
| 50 lbs beef trim |
| 6 lbs (1 full package) of xyz brand bologna seasoning |
| 4 oz (1 full package) of Quick Cure with sodium nitrite |
| 10 lbs. of water |
| |
| Casings - natural beef casing |
| |
| *Also list procedures for producing the product.* |

**Smokehouse Operations Formulation/Recipe**

# Step 3
# Ingredients and Raw Materials Form

**Product/Process Name:** *Fully cooked, Ready-to-eat*

**Product/Examples:** *Beef Jerky*

| Meat/Poultry and Byproducts | Nonmeat Food Ingredients | Binders/Extenders |
|---|---|---|
| 50 lbs. Beef Rounds | | |
| **Spices/Flavorings** | **Restricted Ingredients** | **Preservatives/Additives** |
| ___ oz. Garlic<br>___ oz. Pepper (black)<br>___ oz. Soy Sauce | ___ oz. Sodium Nitrite | |
| **Liquid** | **Packaging Materials** | **Other** |
| ___ lb. Tap Water | Vacuum Plastic Pouch<br>Assorted Labels | |

*Developed by:* *Cindy Jones* *Date* *12/10/98*

An additional requirement is to include a listing of all equipment and materials *(such as packaging materials)* used for each product produced or each type of process. This information can be written in list form and be categorized for the different processes.

# Equipment List

**Store Name** *General J's Market*

**Street Address** *123 XYZ Street*

**City** *Anytown* **State** *MN* **Zip Code** *55555*

## Smokehouse Operations Equipment List

Walk-in Cooler: Brand _____ Size _____

Other products/Operations Supported _____

Grinder: Brand _____ Size _____

Mixer: Brand _____ Size _____

Stuffer: Brand _____ Size _____

Smokehouse: Brand _____ Size _____

Smoke generator/liquid smoke _____

Digital Thermometer _____

Assorted measuring container, hand utensils, lugs, totes, etc. _____

_____

## Reduced Oxygen Packaging Equipment List

Slicer: Brand _____ Model # _____

Vacuum Packaging Machine _____

Digital Thermometer _____

Assorted knives, tongs, trays, lugs, totes, hand utensils, etc. _____

Vacuum plastic pouch _____

Scale/labeling machine _____

# Step 4 & 5: Develop and Verify a Process Flow Diagram

**AT STEPS 4 AND 5** the team will create a document that will be used over and over again 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 doesn't need to be complex. Looking at your facility's floor plan can help you visualize the process from receiving to shipping. To find all the food safety hazards in your process you need to know exactly what steps that product/process goes through.

After the HACCP team has completed the flow diagram, it needs to be checked for accuracy. To do this, walk through the facility 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."

## Working with the "Process Flow Diagram Development and Verification" Form

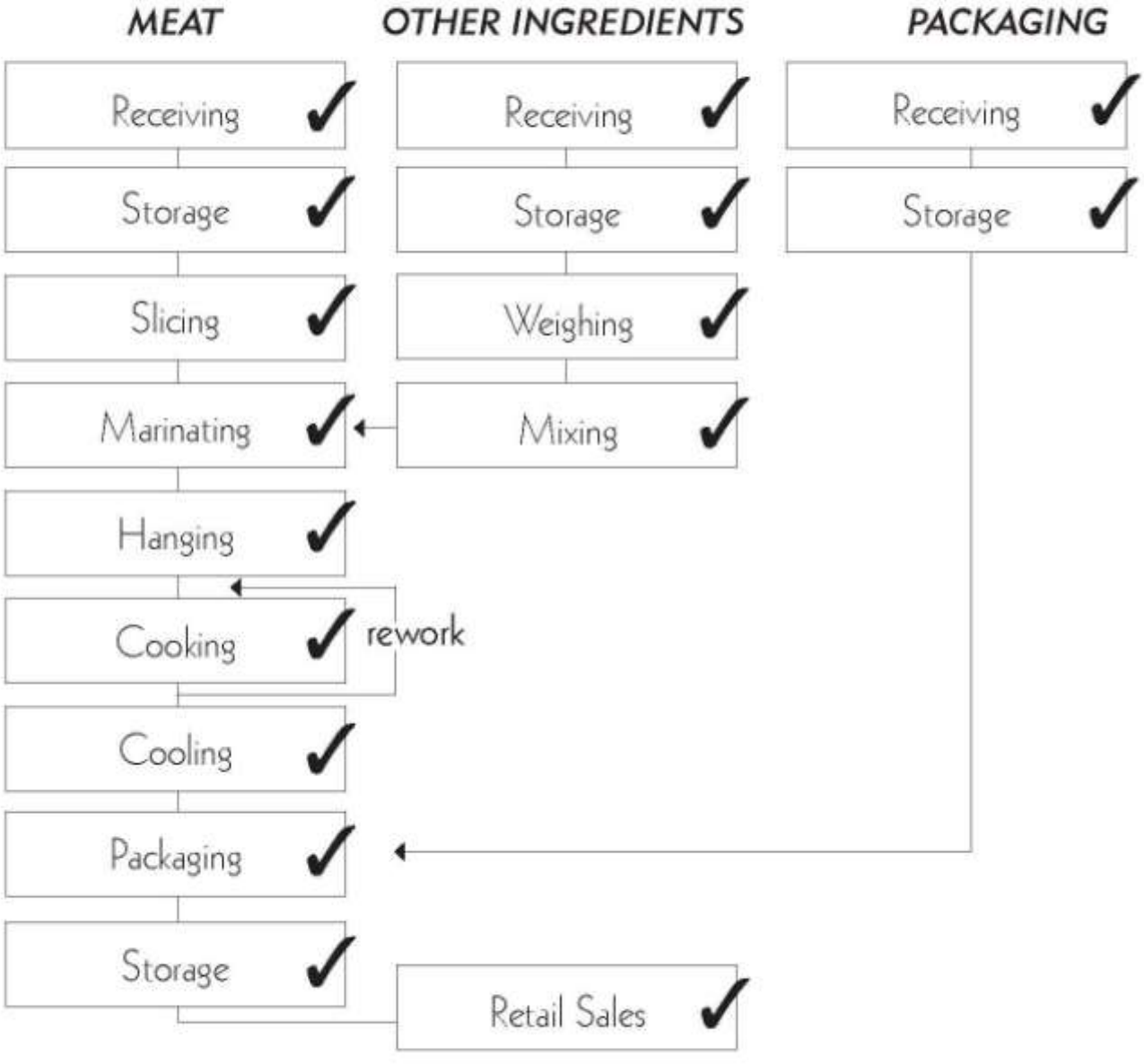
The Example Facility divided their flow diagram into three paths. Each of these paths represents one or more ingredients or raw materials. It made sense to combine certain categories. They grouped all meat items into "Meat", all-nonmeat food ingredients such as spices and preservatives into "Other Ingredients", which just left "Packaging Materials." These three categories represent the three main process routes that occur in their facility.

After the HACCP team completed their drawing, the flow diagram was **checked, signed and dated.** In the Example Facility as each step was verified they placed a check mark. The form must be **signed and dated** again after it is checked/reviewed.

# Steps 4 & 5
# Process Flow Diagram Development & Verification Form

**Product/Process Name** *Beef Jerky/Heat Treated, Shelf Stable*

**Flow Diagram:**




**Developed by:** *Cindy Jones* **Date** *12/10/98*

**Verified by:** *Mary Weston* **Date** *12/12/98*

# Conclusion:

The Example Facility has successfully completed the fact-finding part of the HACCP development process. Your work through the preliminary steps should have produced two tangible pieces of information:

1. A comprehensive list of ingredients and raw materials, and
2. A step-by-step production process breakdown, laid out simply in a flow diagram.

*With this information you are now ready to proceed to the next stage: Utilizing the 7 Principles of HACCP.*

# Section 3: Utilizing the 7 Principles of HACCP

## Understanding Hazards and Controls

This section is about using the seven principles of HACCP. Already you have gathered all of the specific information about our facilities products and processes. Now you'll put that information to use. When you have worked through the principles of HACCP, you'll have a complete HACCP plan.

Before we start with the first principal, we need to quickly review two important ideas; Food Safety Hazards and Preventative Measures. Hazards are defined as any biological, chemical or physical property that is reasonably likely to cause food to be unsafe for human consumption.

## Hazards are classified into these three categories: Biological, Chemical, and Physical.

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 the temperature that's the problem; it's the time at these temperatures that can affect growth of bacteria. The goal is to minimize the time of exposure of foods to temperatures where 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 water is tied up and is less available to the bacteria. The water activity of some foods is listed below:

***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 shows how acid a food is. pH ranges from 0 – 14 with 7 being 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.

| Food | Water Activity |
|---|---|
| Fresh meats, fish, fruits, and vegetables | 0.98 or above |
| Cured meat, processed cheese, bread | 0.93 – 0.98 |
| Dried meat, aged cheddar cheese | 0.85 – 0.93 |
| Cereal, flour, jam, nuts, salted fish | 0.60 – 0.85 |
| Chocolate, honey, noodles | 0.60 or below |

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.

**Table 3-1** lists some of the most important characteristics of growth for common foodborne pathogens. The appendix at the end of this manual lists more detailed information on specific food borne bacterial pathogens. Use this information in evaluating your foods or processes for potential bacterial hazards.

## 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 which 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.

**Table 3-1**

**BACTERIA - CHARACTERISTICS OF GROWTH**

| Pathogens | Temperature for Growth ($^oF$) | pH | Minimum Water Activity ($A_w$) |
|---|---|---|---|
| *Bacillus cereus* | 39 – 131 | 4.3 – 9.3 | 0.92 |
| *Campylabacter jejuni* | 86 – 113.7 | 4.9 – 9.5 | 0.99 |
| *Clostridium botulinum* | 38 – 118 | A: 4.5<br>E: 5.9 | A: 0.94<br>E: 0.97 |
| *Clostridium perfringens* | 50 – 125 | 5.0 – 9.0 | 0.93 |
| *Escherichia coli* | 45 – 121 | 4.0 – 9.0 | 0.95 |
| *Listeria monocytogenes* | 31 – 113 | 4.4 - 9.4 | 0.92 |
| *Salmonella* | 41 – 115 | 3.7 – 9.5 | 0.94 |
| *Shigella* | 43 – 117 | 4.8 – 9.3 | 0.96 |
| *Staphylococcus aureus* | 45 – 122 | 4.0 – 10 | 0.83 |
| *Vibrios* | 41 – 111 | 4.8 – 11 | 0.94 – 0.97 |
| *Yersinis enterocolitica* | 30 – 108 | 4.2 – 10 | 0.95 |

**Table 3-2**

| EXAMPLES OF CHEMICAL HAZARDS | |
|---|---|
| **Location** | **Hazard** |
| Raw Materials | Pesticides, antibiotics, hormones, toxins, fertilizers, fungicides, heavy metals, PCB's |
| | Color additives, inks, indirect additives, packaging materials |
| Processing | Direct food additives<br>-preservatives (high level of nitrates)<br>-flavor enhancers<br>-color additives |
| | Indirect food additives<br>-boiler water additives<br>-peeling aids<br>-defoaming agents |
| Building and Equipment Maintenance | Lubricants, paints, coatings |
| Sanitation | Pesticides, cleaners, sanitizers |
| Storage and Shipping | All types of chemicals |

**Table 3-3**

| EXAMPLES OF PHYSICAL HAZARDS | |
|---|---|
| **Cause** | **Source** |
| Glass | Bottles, jars, light fixtures, utensils, gauge covers, thermometers |
| Metal | Nuts, bolts, screws, steel wool, wire, meat hooks |
| Stones | Raw materials |
| Plastics | Packaging materials, raw materials |
| Bone | Raw materials, improper plant processing |
| Bullet/BB shot/Needles | Animals shot in field, hypodermic needles used for injections |
| Jewelry/Other | Rings, watches, pens, pencils, buttons, etc. |

*Preventative 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 3-4**

| EXAMPLES OF PREVENTATIVE MEASURES FOR BIOLOGICAL HAZARDS | |
|---|---|
| **Pathogen** | **Preventive Measure or Control** |
| Bacillus cereus | Proper handling and cooling temperatures of foods; thermal processing of shelf-stable canned food. |
| Campylobacter jejuni | Proper pasteurization or cooking; avoiding cross-contamination of utensils, equipment; freezing; atmospheric packaging. |
| Clostridium botulinum | Thermal processing of shelf-stable canned food; addition of nitrite and salt to cured processed meats; refrigeration of perishable vacuum packaged meats; acidification below pH 4.6; reduction of moisture below water activity of 0.93. |
| Clostridium perfringens | Proper handling and cooling temperatures of foods; proper cooking times and temperatures; adequate cooking and avoidance of cross-contamination by unsanitary equipment. |
| E-coli 0157:H7 | Proper heat treatment; prevention of cross contamination; proper refrigeration temperatures. |
| Listeria monocytogenes | Proper heat treatments; rigid environmental sanitation program; separation of raw and ready-to-eat production areas and product. |
| Salmonella spp. | Proper heat treatments; separation of raw and cooked product; proper employee hygiene; fermentation controls; decreased water activity; withdrawing feed from animals before slaughter; avoiding exterior of hide from contacting carcass during skinning; antimicrobial rinses scalding procedures; disinfecting knives. |
| Shigella | Proper heat treatment; proper holding temperatures; proper employee hygiene. |
| Staphylococcus aureus | Employee hygiene; proper fermentation and pH control; proper heat treatment and post-process product handling practices; reduced water activity. |
| Vibrios | Proper heat treatment; prevention of cross-contamination; proper refrigeration temperatures. |
| Yersinia enterocolitica | Proper refrigeration; heat treatments; control of salt and acidity; |

**Table 3-5**

| 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 or 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 3-6**

| EXAMPLES OF PREVENTIVE MEASURES FOR PHYSICAL HAZARDS | |
|---|---|
| **Hazard** | **Preventive Measure** |
| Foreign objects in raw materials | Supplier's HACCP plan; use of specifications, letters of guarantee; 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 guarantee; vendor inspections and certification, in-house inspections of raw materials. |
| Foreign objects introduced by processing operations or employee practices | In-line metal detectors; visual product examinations; proper maintenance of equipment; frequent equipment inspections. |

*You should now be able to identify many types of hazards. You should also know where to begin looking for their preventative measures.*

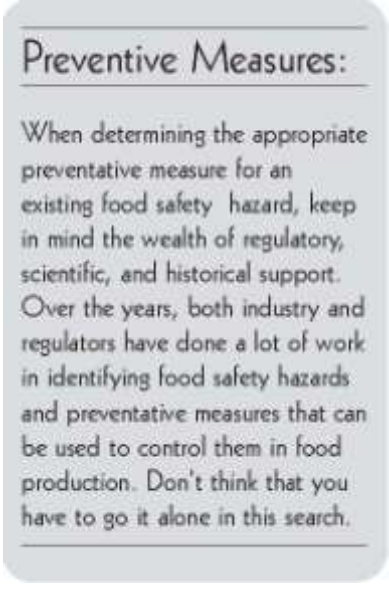
# Principle 1: Hazard Analysis

Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventative measures.

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.

Then, in the second "Evaluation" stage, each food safety hazards is evaluated based on how likely it is to occur. The term "reasonably likely to occur" is the ruler against which each hazard can be measured. Also during this evaluation stage the HACCP team investigates the appropriate preventative measures that will control the "likely to occur" food safety hazards.

*[Hazards can vary greatly from one store to another due to differences in sources of ingredients, product formulations, processing equipment, processing methods, duration of the processes, and storage methods. Make sure that your hazard analysis takes into account what's unique about your establishment.]*



## Hazard Identification and Evaluation

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

1. ***Here are some 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?
    - 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 of the food safety hazards that are reasonably likely to occur, 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 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?
   - Could this step create a situation where an ingredient, work in process, or finished product becomes contaminated with pathogens?
   - Could this step introduce a chemical or physical hazard into the product?

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

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

How can you be sure that you are producing safe food?

A properly functioning HACCP system assures 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 CCP's) is what makes the answer to that question a sure thing.

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 on pages 3-5 through 3-6 to use as a reference to find out some ways to keep those hazards under control.

It is sometimes the case that more than one preventive measure may be required to control a specific hazard, or that 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.

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

*Here's A Tip*

*When sitting down to figure out which steps in your process might or might not be CCP's, a common pitfall is to name too many.*

## Working with the "Hazard Analysis" Form

To explain how this form works, we are going to show you three production steps for which the Example Facility did a hazard analysis. The form is structured so that the three food safety hazard categories (chemical, biological, physical) are addressed in each of the four questions. 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 production step we're going to look at is receiving meat.

1. For the first question all you need to do is state what food safety hazards are present at that step. The Example Facility listed pesticides, hormones, and antibiotics as a chemical hazard. They listed pathogenic bacteria as a biological hazard because bacteria are found on all raw meat. They also listed plastic and bone fragments as physical hazards because the meat comes to them in plastic sheaths.

2. The second question asks you to decide whether or not the hazard is reasonably likely to occur at that step. The Example Facility answered "No" for the chemical, "Yes" for the biological, and "No" for the Physical.

3. The third question is where you explain why you answered "Yes" or "No", to the question of "reasonably likely to occur." For the chemical hazard, the Example Facility's justification is that these sources are normally within defined limits. For the biological hazard they assume that the bacteria is on the meat prior to arrival, so that it continues to be a potential hazard. They said "No" to both the plastic and bone fragments because in both cases there has never historically been a problem with these types of physical hazards in their facility.

   *[This "historical" basis for deciding whether a food safety hazard is "reasonably likely to occur" is perfectly legitimate. If your facility has a clean track record regarding a particular hazard, it's fine to include that information in your HACCP plan. All information must be documented.]*

4. The final question on the hazard analysis form is the place where you write the specific preventive measure(s) that will control the hazard you said was likely to occur. With each shipment of meat the Example Facility receives they feel that the "Letter of Guarantee" 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 hasn't stopped them from also having a second preventive measure. They also visually check the condition and temperature of the truck meat products, to make sure everything meets their standards.

# HACCP Principle 1
# Hazard Analysis Form

**Product/Process Name:** Beef Jerky/Heat Treated, Shelf Stable

**Process Step from Flow Diagram:** Receiving Meat

| C: CHEMICAL | B: BIOLOGICAL | P: PHYSICAL |
|---|---|---|
| *List the Hazards:* | | |
| Pesticides | Pathogens | Plastic |
| Hormones | | Bone Fragments |
| | | |
| *Is the hazard reasonably likely to occur?* | | |
| ☐ Yes ☒ No | ☒ Yes ☐ No | ☐ Yes ☒ No |
| *What is the basis for your decision?* | | |
| No evidence of any historical occurence at this facility. | Loss of control in time/temp can promote harmful bacteria growth. | No evidence of any historical occurence at this facility from this product/source. |

*What preventative measures can be applied at this step to prevent, eliminate or reduce the hazard to an acceptable level?*

Collect "Letter of Guarantee" from supplier that stipulates your requirements. If exceeds limits, product won't be accepted from supplier.

**Developed by:** Cindy Jones **Date** 12/13/98

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## The second production step we're going to look at is cooking.

1. **List the hazards.** The Example Facility 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 a biological hazard because bacteria is unavoidable on all raw meat.

   *[If you don't find a particular type of hazard at a step it's okay to write "Non Identified" as the Example Facility did.]*

2. **Is it "reasonably likely to occur"?** They answered "No" for the chemical hazard, and "Yes" for the biological hazard.

3. **What is the basis for your decision?** The Example Facility 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 (SSOP'S). They decided "Yes" for the biological hazard for the same reason as in the preceding process step.

   *[When working on your HACCP plan, you might want to revisit your SSOP's]*

4. **What are the preventive measures?** The Example Facility identified two preventive measures, cooking and water activity reduction for the biological hazard. They said this is because the cooking and the water activity reduction will help to reduce the hazard.

# HACCP Principle 1
# Hazard Analysis Form

**Product/Process Name:** Beef Jerky/Heat Treated, Shelf Stable

**Process Step from Flow Diagram:** Cooking

| C: CHEMICAL | B: BIOLOGICAL | P: PHYSICAL |
|---|---|---|
| *List the Hazards:* | | |
| Residues of sanitizing chemicals | Pathogen survival and growth in finished product. | (None Identified) |
| | | |
| | | |
| *Is the hazard reasonably likely to occur?* | | |
| ☐ Yes ☒ No | ☒ Yes ☐ No | ☐ Yes ☐ No (None Identified) |
| *What is the basis for your decision?* | | |
| Proper use will address this issue. | Loss of control in time/temp or moisture level can promote harmful bacteria growth. | (None Identified) |
| | | |
| | | |

*What preventative measures can be applied at this step to prevent, eliminate or reduce the hazard to an acceptable level?*

Smokehouse temperature is 190°F.

**Developed by:** Cindy Jones **Date** 12/13/98

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## The third production step we're going to look at is cooling.

1. **List the hazards.** The Example Facility listed the biological hazard of cross-contamination because any time when you have raw and finished product in the same facility the possibility for the raw product to cross-contaminate the finished product exists. The Example Facility also listed plastic as a physical hazard because this is the step where they "Pull" the jerky strips off the cooking trees into large plastic barrels.

2. **Is it "reasonably likely to occur"?** The Example Facility answered, "No" for the biological, and "No" for the physical.

3. **What is the basis for your decision?** The Example Facility said that the biological hazard was not likely to occur because the raw and cooked products are strictly kept apart as called for in their SSOP's. They said "No" to the physical hazard because the plastic barrels that are used are made of an extremely sturdy type of plastic and there's never historically been a problem with plastic shavings at this facility getting into the jerky.

4. **What are the preventive measures?** There aren't any preventive measures listed here because no food safety hazards were found to be reasonably likely to occur.

---

These forms are just one way of documenting the hazard analysis process. An alternative form can be found on page 5-14.

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# HACCP Principle 1
# Hazard Analysis Form

**Product/Process Name:** Beef Jerky/Heat Treated, Shelf Stable

**Process Step from Flow Diagram:** Cooling

| C: CHEMICAL | B: BIOLOGICAL | P: PHYSICAL |
|---|---|---|
| *List the Hazards:* | | |
| (None Identified) | Pathogen cross-contamination | Plastic |
| | | |
| | | |

*Is the hazard reasonably likely to occur?*

| C: CHEMICAL | B: BIOLOGICAL | P: PHYSICAL |
|---|---|---|
| ☐ Yes ☐ No | ☐ Yes ☒ No | ☐ Yes ☒ No |

*What is the basis for your decision?*

| C: CHEMICAL | B: BIOLOGICAL | P: PHYSICAL |
|---|---|---|
| (None Identified) | SSOP's for separation | No evidence of any historical occurence at this facility. |
| | | |
| | | |

*What preventative measures can be applied at this step to prevent, eliminate or reduce the hazard to an acceptable level?*

**Developed by:** Cindy Jones **Date** 12/13/98

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# 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."* Everything in your HACCP plan revolves around the proper identification of CCPs.

## 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.
- Prevention of cross-contamination between raw and cooked product.
- Certain processing procedures, such as filling and sealing cans, mixing and spicing, etc.
- "pH".
- Holding at proper refrigeration temperatures.

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. Usually no two stores have the same floor plan, equipment, or ingredients. The CCPs you identify will reflect the uniqueness of your processing facility.

One of the tools used to help determine critical control points is a "CCP Decision Tree." The use of a Decision Tree to identify significant hazards is not necessary for you to meet regulatory requirements. However, the thought process may be helpful for your team; you want to make sure that your HACCP system meets regulatory requirements.

## Working with the "CCP Decision Tree" Form

# Critical Control Point Decision Tree

*For the production of cooked products. Process Step* Receiving Meat

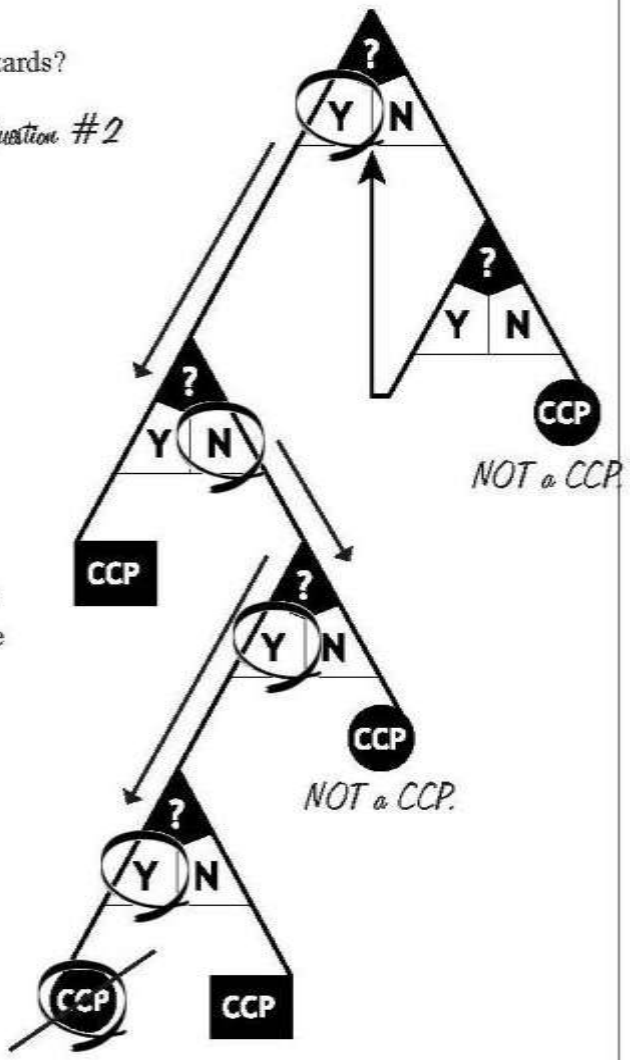
*Question 1A*
Do preventative measures exist for the identified hazards?
If no - go to Question 1B.
If yes - go to Question 2. Yes, go to Question #2

*Question 1B*
~~Is control at this step necessary for safety?~~
~~If no - not a CCP.~~
~~If yes - modify step, process or product and return to Question 1.~~

*Question 2*
Does this step eliminate or reduce the likely occurence of a hazard(s) to an acceptable level?
If no - go to Question 3.
If yes - CCP. No

*Question 3*
Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?
If no - not a CCP.
If yes - go to Question 4.

*Question 4* Yes
Will a subsequent step eliminate the identified hazards or reduce the likely occurence to an acceptable level?
If no - CCP.
If yes - not a CCP.




*Results:*
Yes - so it's NOT a CCP.

| BIOLOGICAL | CHEMICAL | PHYSICAL |
|---|---|---|
| ☐ CCP#_____ | ☐ CCP#_____ | ☐ CCP#_____ |
| ☒ Not a CCP | ☐ Not a CCP | ☐ Not a CCP |

**Developed by:** Cindy Jones **Date** 12/10/98
**Verified by:** Mary Weston **Date** 12/12/98

## *The second step they looked at was cooking.*

**Question 1a**

The Example Facility answered "Yes" here because they had identified the preventive measure of cooking (i.e. time and temperature) for this step.

**Question 1b**

As in the receiving example, move onto question 2.

**Question 2**

The Example Facility 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 wasn't any need to go on to questions 3 and 4.

[After finding all the CCP's in your process, the HACCP team needs to organize them. At the bottom of the CCP Decision Tree Form the Example Facility named the cooking CCP "CCP#01B". The "01" tells them what number the CCP is, and the "B" tells them it is a biological food safety hazard.]

# Critical Control Point Decision Tree

*For the production of cooked products. Process Step* Cooking

–

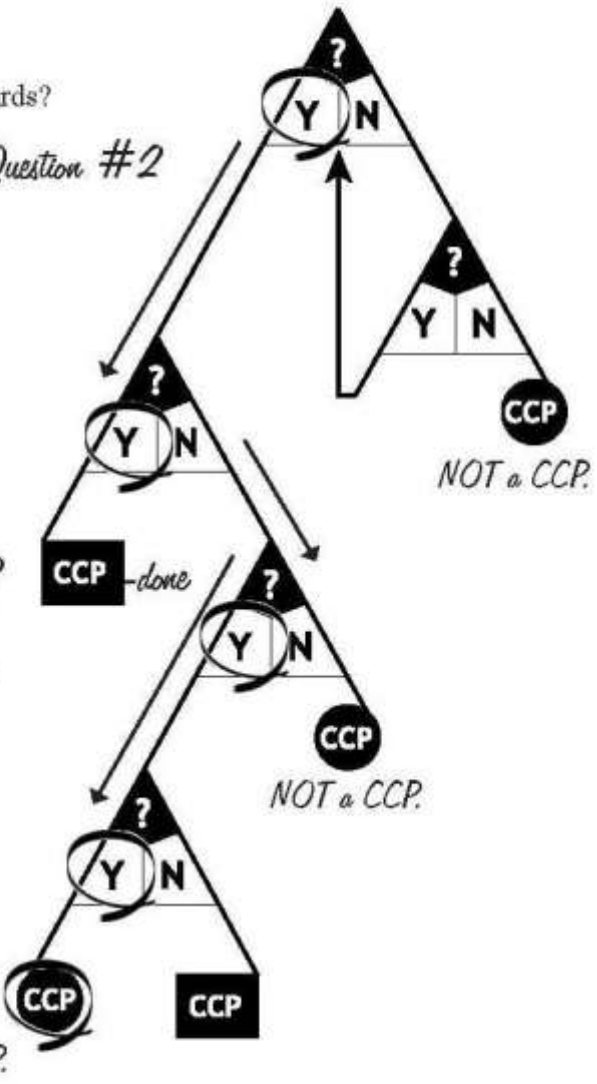
*Question 1A*
Do preventative measures exist for the identified hazards?
If no - go to Question 1B.
If yes - go to Question 2. *Yes, go to Question #2*

~~*Question 1B*~~
~~Is control at this step necessary for safety?~~
~~If no - not a CCP.~~
~~If yes - modify step, process or product and return to Question 1.~~

*Question 2*
Does this step eliminate or reduce the likely occurence of a hazard(s) to an acceptable level?
If no - go to Question 3.
If yes - CCP. *Yes, Identified as a CCP*

*Question 3*
Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?
If no - not a CCP.
If yes - go to Question 4.

*Question 4*
Will a subsequent step eliminate the identified hazards or reduce the likely occurence to an acceptable level?
If no - CCP.
If yes - not a CCP.




*Results:*

| BIOLOGICAL | CHEMICAL | PHYSICAL |
|---|---|---|
| ☒ CCP# #01B | ☐ CCP# | ☐ CCP# |
| ☐ Not a CCP | ☐ Not a CCP | ☐ Not a CCP |

**Developed by:** Cindy Jones **Date** 12/10/98

**Verified by:** Mary Weston **Date** 12/12/98

# Principle 3: Establish Critical Limits for Each Critical Control Point

A critical limit is defined as "The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." You can think of a critical limit as a boundary of safety for a CCP. The critical limit is the numerical value that must be reached to assure that hazards have been controlled. An example would be that "all sausage products must be cooked to 155°F for 15 seconds."

Each CCP will have at least one (possibly more) preventive measures 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.

2. ***Objectives are measurable or observable, such as time and temperature.***

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. ***Specifics.*** When drafting your critical limits be specific in your language. Use action words, and be specific when naming people and equipment. An example could be "bake, uncovered in preheated 350°F oven to an internal temperature of 165°F for 15 seconds."

The HACCP team will find that many critical limits for your identified CCP's 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, patty thickness, and conveyor speed. 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 establishment. The HACCP team may want to get help from outside HACCP experts when establishing critical limits. Remember that the critical limits must be able to maintain control over the food safety hazard. Once the team has identified all the limits, enter them onto the Critical Limits form.

Here are some controls commonly used as preventative measures.

• *Time and Temp - The temperature "danger zone" for biological hazards is between 40°F and 140°F. Bacteria grows fast! They have the ability 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 product 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 product's pH, such as adding an acidic substance like vinegar or soy sauce will decrease the growth rate of the bacteria.*

• *Water Activity - In addition to warm temperatures and a median pH, bacteria also need water to grow. Water activity ($A_w$) refers to the amount of water in a food product that is available, or free, for bacteria to use for growth and multiplication. Solutes (salts and vinegars), as well as dehydration, decrease the available water and can reduce bacterial growth.*

## Working with the "Critical Limits" Form

For each CCP the Example Facility has a separate page of critical limits.

1. ***Under the "Limit" heading.*** The Example Facility noted an internal temperature of 165°F for 15 seconds as the established critical limit. They then decided that the preventive measure of cooking at 190°F oven temperature for 3 hours would satisfy the critical limit.

2. ***Under the "Source" Heading.*** The Example Facility's first source is regulatory and scientific. They decided to take the established regulatory limits and use them, but then they also sent out samples of their finished product to be scientifically analyzed. The results of the lab tests confirmed that their critical limits were enough.

   [The source is the "evidence" that backs up your critical limits. The source provides that the critical limits you cite will effectively control the food safety hazards. Sources for critical limits can be scientific, regulatory or historical. The HACCP team has to find at least one source for each of your critical limits, but you can always put more if you want.]

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. These could be things such as letters from outside HACCP experts, or scientific reports, or lab test results. By holding onto these*

*supporting documents you also provide verification material when needed.*

# HACCP Principle 3
# Critical Limits Form

**Product/Process Name:** Beef Jerky/Heat Treated, Shelf Stable

**Process Step/CCP:** Cooking CCP#01B

**Critical Limits**
**Limit - (Time, Temp, pH, etc.)**

Internal temperature: 165 degrees Fahrenheit for 15 seconds.

Preventive Measure: Oven temperature: 190 degrees Fahrenheit for 3 hours.

**Source - (cite a regulation, scientific document, other resource)**

Meets regulatory requirements

Laboratory tests and results

**Developed by:** Cindy Jones **Date** 12/14/98

# 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 the 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 and discovers that the internal temperature has gone above the established critical limit of 40$^{o}$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, a facility 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 facility 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 along the production line occur. 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. This type of monitoring is preferred because it yields a permanent record. To make sure these activities stay accurate, you need to regularly check the monitoring equipment to make sure that it is calibrated correctly.

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. The Example Facility 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 limits, 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.

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 developed different logs to record the monitoring data at different CCP's. 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.

## Working with the "Monitoring Procedures" Form

The form that is shown as an example on the next page is to be used as a tool in the development of your HACCP plan. The information on this form is the "Who, What, When and How" of monitoring.

**For the Example Facility:**

- The Who is the cook on duty.
- The What is the temperature of the oven.
- The When is non-continuously - every 60 minutes, (+ 5 minutes), and
- The How is with the oven temperature gauge.

The Example Store felt this type of non-continuous monitoring would be effective because of the consistent heat environment of the oven. Their logic was that if the temperature taken at the beginning and end of the cooking cycle was the same, it could reasonably be assumed that it was okay for the whole cooking cycle.

## 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 period of time during which monitoring will occur. For example, write your time as "10a.m. +/-- 10 minutes"or "between the time period of 10 a.m. and 10:15 a.m."

# HACCP Principle 4
# Monitoring Procedures Form

**Product/Process Name:** Beef Jerky/Heat Treated, Shelf Stable

**Process Step/CCP:** Cooking CCP #01B

Monitoring Procedures - (Who, What, When, How)

The cook on duty records the oven temperature at intervals of 60 minutes, (±5 minutes) starting when a "lot" is placed in the oven and ending when the "lot" is removed from oven. Each oven is monitored individually using an oven temperature gauge.

**Developed by:** Cindy Jones **Date** 12/10/98

# Principle 5: Establish Corrective Actions

Corrective Action can be defined as "Procedures to be 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.

**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, and
5. 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 product that is injurious to health or is otherwise adulterated to enter commerce.
4. Reassess and, if necessary, modify your HACCP plan to properly address this type of deviation in the future.
5. 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 the line when a deviation occurs. They should have the authority to hold all "lots" 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.
- Additional cooking time.
- Quickly cooling product.

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

- That the deviation was identified.
- 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 Facility's corrective action form outlines exactly what they think should be done if a problem occurs with the CCP#01B.

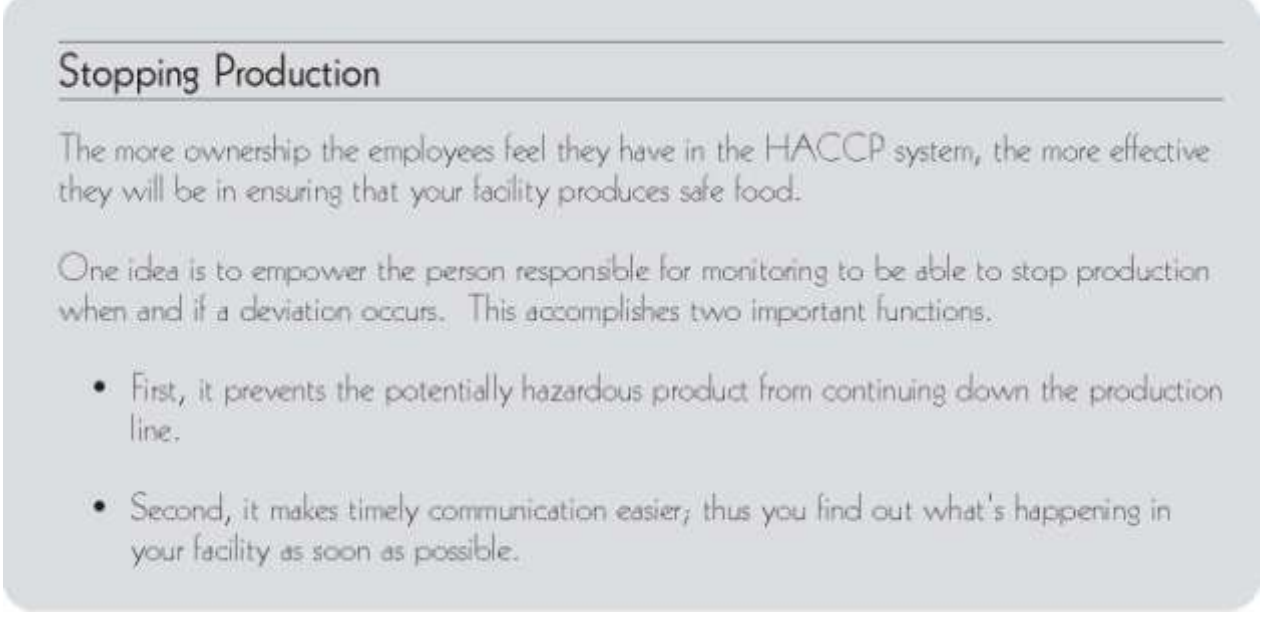
- **Under the "Problem" heading.**
  They state the critical limit that has been established for this CCP.

- **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 re-cooking the jerky.

- **Under "Corrective Action Procedures/Steps" heading.**
  As you can see, the Example Facility listed quite specific corrective actions for this CCP. Their directions are written concisely, and in the order they should be performed.

- **Under the "Who is Responsible" heading.**
  They are specific in naming a particular person.

- **Under the "Compliance Procedures" heading.**
  The Example Facility 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.)



Stopping Production

The more ownership the employees feel they have in the HACCP system, the more effective they will be in ensuring that your facility 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 down the production line.
- Second, it makes timely communication easier; thus you find out what's happening in your facility as soon as possible.

# HACCP Principle 5
# Corrective Action Procedures Form

**Product/Process Name:** Beef Jerky/Heat Treated, Shelf Stable

**Process Step/CCP:** Cooking CCP # 01B

Problem - (Critical limit exceeded)

Oven temp, below 190 degrees Fahrenheit

Disposition of product - (Hold, Rework, Condemn)

Hold, rework if possible.

Corrective action procedures/steps 1. Identify and segregate affected product, place on hold.

2. Rework if possible, otherwise condemn product: Reestablish correct cooking procedures (i.e. fix oven temp. settings, or move product to other oven for rework.)

3. Determine cause of deviation: broken oven thermostat.

4. Take steps to prevent recurrence: recalibrate/replace thermostat

5. Notify Quality Control Supervisor a.s.a.p.

Who is responsible for performing these corrective actions? John Smith - Cook on duty

Compliance procedures

Recalibrate/Replace oven thermostat.

Monitor CCP as usual during rework.

**Developed by:** Cindy Jones **Date** 12/14/98

# Principle 6: Establish Record Keeping Procedures

The records you keep for HACCP can make all the difference! Good HACCP records - meaning that 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 line.
- Records serve as written documentation of your facility's compliance with the HACCP regulations.

**Well maintained records protect both your customers and YOU.**

Your HACCP records should include your development forms and your daily logs for each CCP. You should also keep your hazard analysis development forms, your CCP determination sheets, a list of critical limits for each food safety hazard, clear corrective action instructions, and a copy of your compiled HACCP plan. When first establishing your recordkeeping 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, 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.

The Minnesota Food Code requires that you keep records on specified information; see page 4-3 for further detail. 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, and
- An orderly manner for entering the required data.

**Tips on Designing Records**

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

## Working with the "Recordkeeping Procedures" Form

- **Under the "Records" heading.**
  You can see that the Example Facility has filled out their Recordkeeping Form making sure to list both the development forms (the hazard analysis), and the logs.

*[One last note about the records you keep. 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, mark through the original 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 HAACP plan to show how you record this information.

# HACCP Principle 6
# Recordkeeping Procedures Form

**Product/Process Name:** Beef Jerky/Heat Treated, Shelf Stable

**Process Step/CCP:** Cooking CCP # 01B

*Records*

| Name and Location | | |
|---|---|---|
| Name: Hazard Analysis<br><br>Location: Office File Cabinet | Name: HACCP Plan Review Sheet - For each CCP<br><br>Location: Oven Room Wall | Name: Monitoring Log - For each CCP<br><br>Location: Oven Room Wall |
| Name: Deviation / Corrective Action Log<br><br>Location: Oven Room Wall | Name: Process - Monitoring Equipment Calibration Log - For each CCP<br><br>Location: Oven Room Wall | Name: Verification Procedures & Results Log - For each CCP<br><br>Location: Oven Room Wall |

**Developed by:** Cindy Jones **Date** 12/10/98

# Principle 7: Establish Verification Procedures

Your team needs to decide on what procedures the facility 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" the specific and technical process for determining that the CCP's and associated critical limits are adequate and sufficient to control likely 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 in the compilation of this information in regards to the sources and the amounts of such data.

[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 limits, you were collecting data that could also be used to validate your entire HACCP plan.

## Ongoing Verification

Verification is "the use of methods, procedures, or tests in addition to those used in monitoring, to determine whether the HACCP system is operating as intended." 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: (these aren't the only ones)

- Calibrate your monitoring equipment.
- Sample your product.
- Review your monitoring and corrective action logs.
- Personally inspect your facility'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 CCP's, critical limits, monitoring, and corrective actions. Also, the HACCP team needs to identify the schedules for conducting the verification checks.

## Reassessment of the HACCP Plan

It is a good idea to reassess the adequacy of your plan 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 changes that would require modification to your HACCP plan.

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.

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 recordkeeping procedures.

## Working with the "Verification Procedures" Form

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 done effectively.

*(Like the monitoring form in principle 4, the information on this form is the "Who, What, When and How" of verification.)*

**For the Example Facility:**

- The Who is the quality control supervisor.
- The What is each one of the three activities they need for their process,
- The When is specified after each activity, and
- The How would be determined as needed by the quality control supervisor.

## Finishing Your HACCP Plan

Each form that is used in the development of the HACCP plan and the HACCP plan itself needs to be reviewed in its entirety and signed and dated by the responsible official on the HACCP team. This person must make sure that the HACCP plan is complete. This assures the HACCP team that only the most complete and up-to-date plan is being used.

***The HACCP System***

The HACCP Plan is a written document that is based on the 7 principles of HACCP. A HACCP System is the results of the implementation of the HACCP plan. It includes the written HACCP plan itself but also any records produced, verification data and any prerequisite programs (either written plans or records for GMPs and SSOPs)

The HACCP system produces real results. HACCP is a way of getting and keeping control over your entire production process.

# HACCP Principle 7
# Verification Procedures Form

**Product/Process Name:** Beef Jerky/Heat Treated, Shelf Stable

**Process Step/CCP:** Cooking CCP # 01B

Verification Procedures - (Who, What, When, How)

- Thermometer calibration - Weekly
- Random observation of monitoring - Daily
- Review relevant records - Daily, prior to shipment
- Deviation response review - Ongoing
- Quality Control Supervisor

**Developed by:** Cindy Jones **Date** 12/10/98

# Section 4: Food Code Requirements

## Introduction

**HACCP** is a universal preventative 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, bakeries, etc. Processes that require operation under a HACCP plan were previously discussed in Section 1. Also included there was timing of HACCP plans. It is important to note that new or extensively remodeled establishments must submit the HACCP plan to the regulatory authority before the start of operation for approval in conjunction with the facility plan review.

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 some of the preliminary steps information become part of your official HACCP plan. Section 3 of this book focuses on developing the HACCP plan itself using the Seven Principles. The rule requires that most (although not all) of this information become part of your official HACCP plan. In addition, the Food code requires that the HACCP plan for your retail food establishment contain some additional components.

# Contents of a HACCP Plan

When a food establishment is required to have a HACCP plan, the plan and specifications shall include:

1. A categorization of the types of potentially hazardous foods that are specified in the menu.
   **This information was collected in Preliminary Steps – Number 2. See page 1-5 for more information. Be sure that this is included as one of the documents in your official HACCP plan.*

2. A flow diagram by specific food or category types identifying critical control points and providing information on the following:
   a. Ingredients, materials and equipment used in the preparation of a food.
   b. Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.

   **This information was collected in Preliminary Steps – Number 3 and 4. See page 1-5 for more information. Be sure that this is included as one of the documents in your official HACCP plan.*

3. A statement of Standard Operating Procedures for the plan identifying:
   a. Critical control points.
   b. Critical limits for each critical control point.
   c. The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge.
   d. 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. (verification)
   e. Action to be taken by the Person in Charge if the critical control points are not met. (corrective action)
   f. Records to be maintained by the Person in Charge to demonstrate that the HACCP plan is properly operated and managed.

   **Items 3a – f should all be included as part of your HACCP plan as developed in Section 3. The Person in Charge is ultimately responsible for ensuring that critical control points are monitored and corrective action is taken as necessary and that records are maintained to document this. The day-to-day activities could be assigned to an employee working in the HACCP operation.*

4. Additional scientific data or other information as required by the regulatory authority supporting the determination that food safety is not compromised by the proposal.

   **Types of information that might need to be included here are validation data, or data to support a variance.*

# Compliance with the HACCP Plan

In order to be in Compliance with the HACCP Plan a licensee shall:

A. Comply with a properly prepared HACCP plan, and

B. Maintain and provide to the regulatory authority, on request, the records specified in part 4626.1735 , item A, sub-items (3) and (4) that demonstrate that the following are routinely employed:

1. Procedures for monitoring critical control points.
2. Monitoring of critical control points.
3. Verification of the effectiveness of an operation or process.
4. Necessary corrective actions if there is a failure at a critical control point.

*When the rule requires that you prepare a HACCP plan for a certain operation, this HACCP plan does, in effect, become part of the rule for your establishment. You must comply with your properly prepared HACCP plan. By complying with the Standard Operating Procedures you have 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 that demonstrate 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.*

# Variances and the HACCP Plan

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. 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 includes:

1. A statement of the proposed VARIANCE of the Code requirement citing relevant Code section numbers;[Pf]
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; [Pf] and
3. A HACCP PLAN if required

If the REGULATORY AUTHORITY grants a VARIANCE or a HACCP PLAN is otherwise required the PERMIT HOLDER shall:

1. 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; [P] and
2. Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;

(A) Procedures for monitoring the CRITICAL CONTROL POINTS, [Pf]

(B) Monitoring of the CRITICAL CONTROL POINTS, [Pf]

(C) Verification of the effectiveness of the operation or process, [Pf] and

(D) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT. [Pf]

# Reduced Oxygen Packaging

**REDUCED OXYGEN PACKAGING (ROP)** is defined as any packaging procedure that results in a reduced oxygen level in a sealed packaged. You may be more familiar with the term 'vacuum packaging' which is one type of reduced oxygen packaging method. Another term used is "Modified Atmosphere Packaging", this is a process that uses a gas flushing and sealing process in a one-time modification of the atmospheric contents of the package.

If reduced oxygen packaging is one of the processes that are included in your HACCP plan, the Food Code requires that additional information be included. These items can be included in the formal HACCP plan or as separate documents.

## Reduced Oxygen Packaging Criteria

**The HACCP plan shall:**

1. Identify the food to be packaged.
   This information was collected in Preliminary Steps – Number 2. See page 1-5 for more information. 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 as long as the products meet the requirements as listed in number 2 below. Be sure that 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:
   a. has a water activity of 0.91 or less
   b. has a pH of 4.6 or less
   c. is a food with a high level of competing organisms, including raw meat, raw poultry, or a naturally cultured standardized cheese, OR
   d. is a meat or poultry product that is
      i. cured at a state inspected or USDA inspected meat facility and received in an intact package, or
      ii. cured using approved substances (nitrates/nitrites)

*The Food code limits the types of foods that can be packaged by a reduced oxygen method at the retail level. A store's HACCP plan must clearly state the foods that <u>can</u> be packaged using a reduced oxygen packaging method. Only specific products on this list can be reduced oxygen packaged. By limiting the types of food that can be Reduced Oxygen Packaged to those on the list, an additional barrier to the growth and toxin formation of Clostridium botulinum is provided and thereby helps to ensure a safe product.*

*In addition, except for fish that is frozen before, during, and after packaging, a food establishment shall not package fish using a reduced oxygen packaging method.*

**The following are examples of foods that <u>DO NOT</u> meet the above requirements and therefore <u>MAY NOT</u> be reduced oxygen packaged:**

1. Cooked turkey *(including whole or sliced turkey breast)*
2. Cooked roast beef
3. Sandwich spread *(including ham salad, chicken salad, etc.)*
4. Cooked fresh sausage *(not cured/smoked such as bratwurst)*
5. Raw or smoked fish
6. Processed salads *(such as potato salad, cole slaw).*

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:
   a. Keep Refrigerated or Frozen
   b. Discard the food if within 14 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. As stated, 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. For more information on mandatory labeling requirements, contact the Dairy and Food Inspection Division. Be sure that these labeling requirements are addressed in the HACCP plan as part of standard operating procedures.*

The following is an example of the label with the required information:

5. Limit the shelf life to no more than 14 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.

   *Pathogens, including 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:
   a. Comply with specific requirements relating to contamination from hands.

   b. Identify a designated area and the method by which:
      i. Physical barriers or methods of separation of raw foods and ready to eat foods minimize cross contamination; and
      ii. 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.*

   c. 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 for cleaning and sanitizing 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:
   a. Concepts required for a safe operation
   b. Equipment and facilities; and
   c. 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 might be – limiting foods to be packaged, temperature control, separation of raw and ready to eat, employee health and hygiene. A thorough understanding of how equipment operates, product flow as well as the standard operating procedures for the facility will also add to product safety. Ensure that these items are addressed.*

# Section 5: Sample Forms

# HACCP Team

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

| Team Members | Role |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

Developed by: _____ Date _____

# Product/Process Covered

Store Name _____

Street Address _____

City _____State _____Zip Code _____

**Product/Process Covered Under the HACCP Plan**

Smoking/Curing

_____

_____

_____

_____

_____

Reduced Oxygen Packaging

_____

_____

_____

_____

_____

Food Additives

_____

_____

_____

_____

_____

Variances

_____

_____

_____

_____

_____

Developed by: _____ Date_____

# Ingredients and Raw Materials

Store Name_____

Street Address _____

City_____State_____Zip Code _____

Product/Process Category _____

Product Examples _____

| Meat Poultry and Byproducts | Nonmeat Food Ingredients | Binders/Extenders |
|---|---|---|
| | | |
| Spice/Flavorings | Restricted Ingredients | Preservatives/Acidifiers |
| | | |
| Liquid | Packaging Materials | Other |
| | | |

Developed by: _____ Date_____

# Process Flow Diagram

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

**Flow Diagram**

Developed by: _____ Date_____

Verified by: _____ Date_____

# Equipment List

Store Name _____

Street Address _____

City _____State _____Zip Code_____

Process

Developed by: _____ Date_____

# Identifying Critical Control Points

Store Name_____

Street Address _____

City _____State _____Zip Code_____

Process/Step_____

**Critical Control Point Decision Tree**

***Question 1A***

Do preventative measures exist for the identified hazards?

If "no" - go to Question 1B.

If "yes" - go to Question 2.

***Question 1B***

Is control at this step necessary for safety?

If "no" - not a CCP

If "yes" - modify step, process or product and return to Question 1.

***Question 2***

Does this step eliminate or reduce the likely occurrence of a hazard(s) to an acceptable level?

If "no" - go to Question 3.

If "yes" - CCP.

***Question 3***

Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?

If "no" - not a CCP.

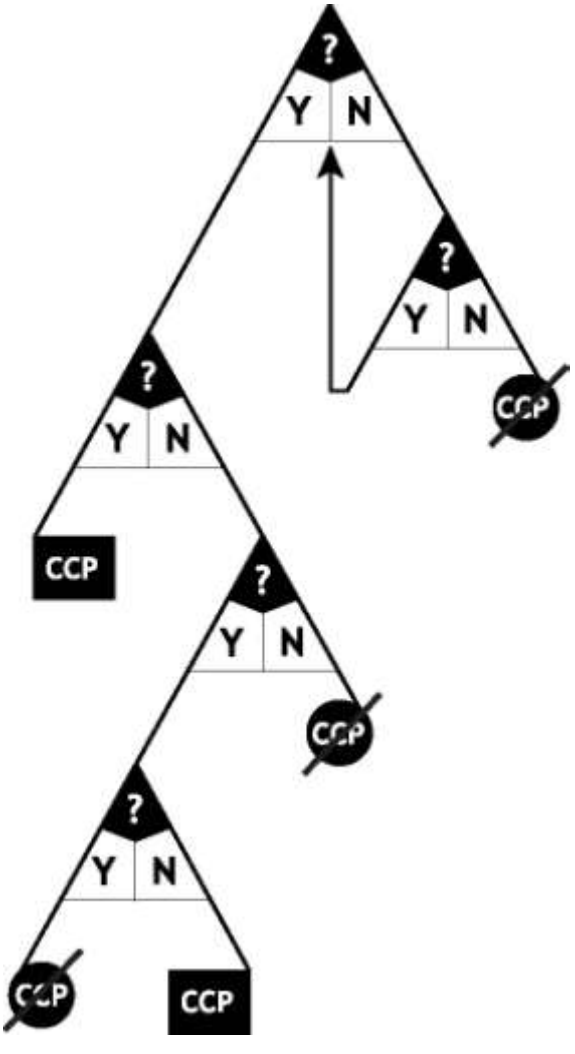
If "yes" - go to Question 4.

***Question 4***

Will a subsequent step eliminate the identified hazards or reduce the likely occurrence to an unacceptable level?

If "no" - CCP.

If "yes" - not a CCP.




| BIOLOGICAL | CHEMICAL | PHYSICAL |
|---|---|---|
| ☐ CCP#_____ | ☐ CCP#_____ | ☐ CCP#_____ |
| ☐ Not a CCP | ☐ Not a CCP | ☐ Not a CCP |

Developed by: _____ Date_____

# Critical Limits

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

Process Step/CCP _____

**CRITICAL LIMITS**

Limit *(time, temp, pH, etc.)* - _____

Source *(cite a regulation, scientific document, other resource)* - _____

Developed by: _____ Date_____

# Monitoring Procedures

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

Process Step/CCP _____

**MONITORING PROCEDURES**

(Who, What, When, How*)* - _____

Developed by: _____ Date_____

# Corrective Action Procedures

Store Name_____

Street Address_____

City _____State _____Zip Code_____

Product/Process Name_____

Process Step/CCP_____

Problem (critical limit exceeded*)* -_____

_____

_____

_____

Disposition of Product (hold, rework, condemn*)* -_____

_____

_____

_____

Corrective Action Procedure/Steps - _____

_____

_____

_____

Who is responsible for performing these corrective actions? - _____

_____

_____

_____

Compliance Procedures - _____

_____

_____

_____

Developed by: _____ Date_____

# Recordkeeping Procedures

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

**RECORDS**

| **Name and Location** |
| --- |
| |

Developed by: _____ Date_____

# Verification Procedures

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

Product/Process Name _____

**VERIFICATION PROCEDURES**

(Who, What, When, How*)* - _____

Developed by: _____ Date_____

# Hazard Analysis Form

Store Name _____

Street Address _____

City _____ State _____ Zip Code _____

**Product/Process Name:** _____

**Process Step from Flow Diagram:** _____

| *C: CHEMICAL* | *B: BIOLOGICAL* | *P: PHYSICAL* |
|---|---|---|
| *List the Hazards:* | | |
| | | |
| | | |
| | | |
| *Is the hazard reasonably likely to occur?* | | |
| ❑ Yes ❑ No | ❑ Yes ❑ No | ❑ Yes ❑ No |
| *What is the basis for your decision?* | | |
| | | |
| | | |
| | | |

*What preventative measures can be applied at this step to prevent, eliminate or reduce the hazard to an acceptable level?*

_____

_____

_____

***Developed by:*** _____ ***Date*** _____

# 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) Justify your decision for column 3 | (5) What preventative measure(s) can be applied to prevent the significant hazards? | (6) Is this step a critical control point? (YES/NO) |
|---|---|---|---|---|---|
| | BIOLOGICAL<br>CHEMICAL<br>PHYSICAL | | | | |
| | BIOLOGICAL<br>CHEMICAL<br>PHYSICAL | | | | |
| | BIOLOGICAL<br>CHEMICAL<br>PHYSICAL | | | | |
| | BIOLOGICAL<br>CHEMICAL<br>PHYSICAL | | | | |
| | BIOLOGICAL<br>CHEMICAL<br>PHYSICAL | | | | |
| | BIOLOGICAL<br>CHEMICAL<br>PHYSICAL | | | | |
| | BIOLOGICAL<br>CHEMICAL<br>PHYSICAL | | | | |

Developed by: _____ Date_____

# HACCP Plan

Store Name_____

Street Address_____

City _____State _____Zip Code _____

Product/Process _____Date _____

| (1) Critical Control Poin (CCP) | (2) Significant Hazards | (3) Critical Limits for each Preventative Measure | (4) | (5) | (6) | (7) | (8) Corrective Action(s) | (9) Records | (10) Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | Monitoring | | | | | | |
| | | | What | How | Freq-uency | Who | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

# HACCP Plan

Store Name_____ Store Address_____

Product/Process_____ Developed by_____ Date_____

| CCP | Hazard | Critical Limits | Monitoring | | | | Corrective Action(s) | Verification | Records |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| | | | | | | | | | |

# Appendix: Common Foodborne Bacterial Pathogens Sample HACCP Plans

# Common Foodborne Bacterial Pathogens

## *Bacillus cereus*

*Bacillus cereus* is an aerobic spore farmer. Two types of toxins can be produced, one results in diarrheal syndrome and the other in emetic syndrome.

**RESERVOIR:** WIDELY DISTRIBUTED IN THE ENVIRONMENT.

**IMPLICATED FOODS:** RICE, MEATS, DAIRY PRODUCTS, VEGETABLES, FISH, PASTA, SAUCES, PUDDINGS, SOUPS, PASTRIES AND SALADS.

*B. cereus* is widely distributed throughout the environment. It has been isolated from a variety of foods, meats, dairy products, vegetables, fish and rice. The bacteria can be found in starchy foods such as potato, pasta and cheese products, and food mixtures such as sauces, puddings, soups, casseroles, pastries and salads.

**GROWTH REQUIREMENTS**

TEMPERATURE (F) . . . . . 39 - 131
MINIMUM WATER ACTIVITY . . . . . 0.92
PH . . . . . 4.3 - 9.3
MAXIMUM SALT (%) . . . . . 18
ATMOSPHERE . . . . . AEROBE
SURVIVAL CONDITIONS . . . . . SALT-TOLERANT, SPORES ARE HEAT RESISTANT

This organism will grow at temperatures as low as 39°F, at a pH as low as 4.3, and at salt concentrations as high as 18%. Unlike other pathogens, it is an aerobe, and will grow only in the presence of oxygen. Both the spores and the emetic toxin are heat-resistant.

**CONTROLS:** REFRIGERATION CONTROL OF *BACILLUS CEREUS* CAN BE ACHIEVED THROUGH PROPER REFRIGERATION.

## *Campylobacter*

*Campylobacter jejuni* infection, called Campylobacteriosis, causes diarrhea, which may be watery or sticky and maintain blood. Estimated numbers of cases of campylobacteriosis exceed 24 million per year, is considered the leading cause of human diarrheal illness in the United States, and is reported to cause more disease than *Shigella* and *Salmonella* spp. combined.

**RESERVOIR:** CHICKENS, COWS, FLIES, CATS, PUPPIES

**IMPLICATED FOODS:** RAW OR UNDERCOOKED CHICKEN, MEAT, SEAFOOD, CLAMS, MILK, EGGS, NON-CHLORINATED WATER, RECONTAMINATED READY-TO-EAT FOODS.

Raw and undercooked chicken, raw and improperly pasteurized milk, raw clams, and non-chlorinated water have been implicated in campylobacteriosis. The organism has been isolated from crabmeat. It's carried by healthy chickens and cows, and can be isolated from flies, cats and puppies.

**GROWTH REQUIREMENTS**

TEMPERATURE (F) . . . . . 86 - 113
MINIMUMWATERACTIVITY . . . . . 0.99
PH . . . . . 4.39 - 9.5
MAXIMUMSALT (%) . . . . . 1.5
ATMOSPHERE . . . . . MICROAEROPHILIC SURVIVAL CONDITIONS . . . . SENSITIVE TO DRYING, HEATING, DISINFECTION, ACID, AIR

The thing that makes "Campy" unique is its very special oxygen requirements. It's micro-aerophilic, which means it requires reduced levels of oxygen to grow: about 3-15% oxygen (conditions similar to the intestinal tract). Another point worth noting is that it will not grow at temperatures below 86°F, or at salt levels above 1.5%.

The organism is considered fragile and sensitive to environmental stresses like drying, heating, disinfection, acid and air which is 21% oxygen. It requires a high water activity and fairly neutral pH for growth.

**CONTROLS:** SANITATION TO PREVENT RECONTAMINATION; COOKING; PASTEURIZATION; WATER TREATMENT.

The controls are very basic: proper cooking and pasteurization, proper hygienic practices by food handlers to prevent recontamination, and adequate water treatment.

## *Clostridium botulinum*

*Clostridium botulinum* is an anaerobic spore-former. Actually there are seven types of Clostridium botulinum - A, B, C, D, E, F and G - but the only ones we'll discuss here are type A, which represents a group of proteolytic bot, type E, which represents the nonproteolytic group. The reason for the distinction is in the proteolytic organisms' ability to break down protein.

This organism is one of the most lethal pathogens covered here. Symptoms include weakness and vertigo, followed by double vision and progressive difficulty in speaking, breathing and swallowing. There may also be abdominal distention and constipation. The toxin eventually causes paralysis, which progresses symmetrically downward, starting with the eyes and face, and proceeding to the throat, chest, and extremities. When the diaphragm and chest muscles become involved, respiration is inhibited, and death from asphyxia results. Treatment includes early administration of antitoxin and mechanical breathing assistance. Mortality is high - without the antitoxin, death is almost certain.

**RESERVOIR**: SOIL; FRESH WATER AND MARINE SEDIMENTS; FISH; MAMMALS

**IMPLICATED FOODS:** CANNED FOODS; ACIDIFIED FOODS; SMOKED AND UNEVISCERATED FISH; STUFFED EGGPLANT; GARLIC IN OIL; BAKED POTATOES; SAUTEED ONIONS; BLACK BEAN DIP; MEAT PRODUCTS; MARSCAPONE CHEESE.

*Bot* is widely distributed in nature and can be found in soils, sediments from streams, lakes and coastal waters, the intestinal tracts of fish and mammals, and the gills and viscera of crabs and other shellfish. Type E is most prevalent in fresh water and marine environments, while Type A is generally found terrestrially.

*Bot* has been a problem in a wide variety of food products: canned foods, acidified foods, smoked and uneviscerated fish, stuffed eggplant, garlic in oil, baked potatoes, sauteed onions, black bean dip, meat products, and marscapone cheese, to name just a few.

Two outbreaks in the 1960's involved vacuum-packaged fish (smoked ciscos and smoked chubs). The causative agent in each case was *C botulinum* type E. The products were packed without nitrates, with low levels of salt, and were temperature-abused during distribution, all of which contributed to the formation of the toxin. There were no obvious signs of spoilage because aerobic spoilage organisms were inhibited by the vacuum packaging, and because type E does not produce any offensive odors.

Three cases of botulism in NY were traced to chopped garlic bottled in oil, which had been held at room temperature for several months before it was opened. Presumably, the oil created an anaerobic environment.

| **GROWTH REQUIREMENTS** | **TYPE A** | **TYPE E** |
|---|---|---|
| TEMPERATURE (F) | 50 - 113 | 38 - 113 |
| MINIMUM WATER ACTIVITY | 0.94 | 0.97 |
| PH | 4.6 - 9.0 | 5.0 - 9.0 |
| MAXIMUMSALT (%) | 10 | 5 |
| ATMOSPHERE | ANAEROBE | |
| SURVIVAL CONDITIONS | HEAT RESISTANT | |

Type A and type E vary in their growth requirements. Minimum growth temperature for type A is 50°F, while type E will tolerate conditions down to 38°F. Type A's minimum water activity is 0.94, and type E's is 0.97 - a small difference on paper, but important in controlling an organism. The acid-tolerance of type A is reached at a pH of 4.6, while type E can grow at a pH of 5. A type A is more salt-tolerant; it can handle up to 10%, when 5% is sufficient to stop the growth of type E.

Although the vegetative cells are susceptible to heat, the spores are heat resistant and able to survive many adverse environmental conditions. Type A and type E differ in the heat-resistance of their spores; compared to E, type A's resistance is relatively high. By contrast, the neurotoxin produced by *C.bot* is not resistant to heat, and can be inactivated by heating for 10 minutes at 176°F.

**CONTROLS:** DESTRUCTION: THERMAL PROCESSING

**PREVENTION OF TOXIN FORMATION:** ACIDIFICATION, SALT, WATER ACTIVITY CONTROL, NITRITES, REFRIGERATION

There are two primary strategies to control *C. bot*. The first is destruction of the spores by heat (thermal processing). The second is to alter the food to inhibit toxin production - something which can be achieved by acidification, controlling water activity, the use of salt and preservatives, and refrigeration. Water activity, salt and pH can each be individually considered a full barrier to growth, but very often these single barriers - a pH of 4.6 or 10% salt - are not used because they result in a product which is unacceptable to consumers. For this reason multiple barriers are used.

One example of a product using multiple barriers is pasteurized crabmeat stored under refrigeration; here, type E is destroyed by the pasteurization process, while type A is controlled by the refrigerated storage. (Remember that type E is more sensitive to heat, while type A's minimum growth temperature is 50°F.)

Another example of multiple barriers is hot-smoked, vacuum packaged fish. Vacuum packaging provides the anaerobic environment necessary for the growth of *C. bot*, even as it inhibits the normal aerobic spoilage flora which would otherwise offer competition and give telltale signs of spoilage. So heat is used to weaken the spores of type E, which are then further controlled by the use of salt, sometimes in combination with nitrites. Finally spores of type A are controlled by refrigeration.

Vacuum-packaging of foods which are minimally processed, like sous vide products, allows the survival of *C. bot* spores while completely wiping out competing microflora. If no control barriers are present, the *C. bot* may grow and produce toxin, particularly if there is temperature abuse.

Given the frequency of temperature abuse documented at the retail and consumer levels, this process is safe only if temperatures are carefully controlled to below 38°F throughout distribution. Vacuum-packaging is also used to extend the shelf-life of the product. Since this provides additional time for toxin development, such food must be considered a high risk.

## *Clostridium perfringens*

*Clostridium perfringens* is an anaerobic spore former and one of the most common agents of foodborne gastroenteritis. Perfringens poisoning, the disease caused by the organism, is characterized by intense abdominal cramps and diarrhea.

**RESERVOIR:** HUMANS, DOMESTIC AND WILD ANIMALS, SOIL, SEDIMENT

**IMPLICATED FOODS:** MEAT, POULTRY, GRAVY, CASSEROLES

*C. perfringens* is widely distributed in the environment and is frequently in the intestines of humans and many domestic and wild animals. Spores of the organism persist in soil and sediments.

*C. perfringens* has been found in beef, pork, lamb, chicken, turkey, stews, casseroles, and gravy.

**GROWTH REQUIREMENTS**

| | |
|---|---|
| TEMPERATURE (F) | 50 - 125 |
| MINIMUMWATERACTIVITY | 0.93 |
| PH | 5.0 - 9.0 |
| MAXIMUM SALT (%) | 7 |
| ATMOSPHERE | ANAEROBIC |
| SURVIVAL CONDITIONS | HEAT-RESISTANT |

*Clostridium perfringens* is a mesophilic organism. Since it is also a spore-former, it is quite resistant to heat, and temperatures for growth range from 50°F to 125°F. pH, water activity and salt ranges for growth are fairly typical.

**CONTROLS:** PROPER COOLING, HOLDING, AND REHEATING: EDUCATION OF FOOD HANDLERS.

Far from killing the spores, cooking encourages them to germinate when the product reaches a suitable temperature. Rapid, uniform cooling after cooking is needed. In virtually all outbreaks, the principal cause of perfringens poisoning is failure to properly refrigerate previously cooked foods, especially when prepared in large portions. Proper hot holding (above 140°F) and adequate reheating of cooked, chilled foods (to a minimum internal temperature of 165°F) are also necessary controls. The education of food handlers remains the critical aspect of control.

## *Escherichia coli*

There are four classes of pathogenic *E. coli*; enteropathogenic (EPEC), enterotoxigenic (ETEC), enteroinvasive (EIEC), and enterohemmoragic (EHEC). All four types have been associated with food and water borne diseases.

**EPEC** - Gastroenteritis/infantile diarrhea - Outbreaks have been primarily associated with infants in day-care and nursery settings.

**ETCA** - Traveler's diarrhea - Contamination of water supplies or food does occasionally lead to outbreaks. Outbreaks have been associated with water and can be contaminated by raw sewage and on imported cheese.

**EIEC** - Bacillary dysentery - Contaminated water supplies can directly or indirectly (by contaminating food supplies) be the cause of outbreaks; infected food handlers can also be a source.

**EHEC** - Hemorrhagic colitis - All people are believed to be susceptible to hemorrhagic colitis. The strain E. coli 0157:H7 has become infamous following several outbreaks and probably countless more unreported illnesses. Foods commonly associated with illnesses are undercooked ground beef, unpasteurized apple cider, raw milk, fermented sausage, water and raw vegetables.

**GROWTH REQUIREMENTS**
TEMPERATURE (F) . . . . . 45 - 121
MINIMUM WATER ACTIVITY . . . . . 0.95
PH . . . . . 4.0 - 9.0
MAXIMUMSALT (%) . . . . . 6.5
ATMOSPHERE . . . . . FACULATIVE ANAEROBICE
SURVIVAL CONDITIONS . . . . . WITHSTANDS FREEZING AND ACID ENVIRONMENTS

*E. coli* are mesophilic organisms; they grow best at moderate temperatures, at moderate pH, and in conditions of high water activity. It has, however, been shown that some E. coli strains are very tolerant of acidic environments and freezing.

**CONTROLS:** PROPER COOKING; PROPER HOLDING TEMPERATURES; PERSONAL HYGIENE; EDUCATION; PREVENTING FECAL CONTAMINATION OF ANIMAL CARCASSES.

Food may be contaminated by infected food handlers who practice poor personal hygiene or by contact with water contaminated by human sewage. Control measures to prevent food poisoning therefore include educating food workers in safe food handling techniques and proper personal hygiene, properly heated foods, and holding foods under appropriate temperature controls. Additionally, untreated human sewage should not be used to fertilize vegetables and crops used for human consumption, nor should unchlorinated water be used for cleaning food or food contact surfaces.

Prevention of fecal contamination during the slaughter and processing of foods of animal origin is paramount to control foodborne infection of EHEC. Foods of animal origin should be heated sufficiently to kill the organism. Consumers should avoid eating raw or partially cooked meats and poultry, and drinking unpasteurized milk or fruit juices.

## *Listeria*

*Listeriosis*, the disease caused by this organism, can produce mild flu-like symptoms in healthy individuals. In susceptible individuals, including pregnant women, newborns, and the immunocompromised, the organism may enter the blood stream, resulting in septicemia. Ultimately listeriosis can result in meningitis, encephalitis, spontaneous abortion and still birth.

**RESERVOIR:** SOIL, SILAGE, OTHER ENVIRONMENTAL SOURCES.

**IMPLICATED FOODS:** DAIRY PRODUCTS, VEGETABLES, MEAT,

POULTRY, FISH, COOKED READY-TO-EAT PRODUCTS.

*L. monocytogenes* can be isolated from soil, silage and other environmental sources. It can also be found in man-made environments such as food processing establishments. Generally speaking, however, the drier the environment, the less likely it is to harbor this organism.

*L. mono* has been associated with raw or inadequately pasteurized milk, cheeses (especially soft-ripened types), ice cream, raw vegetables, fermented sausages, raw and cooked poultry, raw meats, and raw and smoked fish.

*L. mono* is a psychotropic faculative anaerobe. It can survive some degree of thermal processing, but can also be destroyed by cooking to an internal temperature of 158°F for 2 minutes. It can also grow at refrigerated temperatures below 31°F. Reportedly, it has a doubling time of 1.5 days at 40°F. There is nothing unusual about this organisms pH and water activity range for growth. *L. mono* is salt-tolerant; it can grow in up to 10% salt, and has been known to survive in 30% salt. It is also nitrite-tolerant.

**GROWTH REQUIREMENTS**

| | |
|---|---|
| TEMPERATURE (F) | 31 - 113 |
| MINIMUM WATER ACTIVITY | 0.92 |
| PH | 4.4 - 9.4 |
| MAXIMUM SALT (%) | 10 |
| ATMOSPHERE | FACULATIVE ANEROBE |
| SURVIVAL CONDITIONS | SALT AND NITRITE TOLERANT |

**CONTROLS:** COOKING, PASTEURIZATION, PREVENTION OF RECONTAMINATION

Prevention of recontamination after cooking is a necessary control; even if the product has received thermal processing adequate to inactivate L. monocytogenes, the widespread nature of the organism provides the opportunity for recontamination. Furthermore, if the heat treatment has destroyed the competing microflora, L. mono might find itself in a suitable environment without competition.

## *Salmonella*

There are four syndromes of human salmonellosis: Salmonella gastroenteritis, Typhoid fever; non-typhoidal Salmonella septicemia and asymptomatic carrier. Salmonella gastroenteritis may be caused by any of the Salmonella species other than Salmonella typhi, and is usually a mild, prolonged diarrhea.

True typhoid fever is caused by infection with Salmonella typhi. While fatality rates may exceed 10% in untreated patients, they are less than 1% in patients who receive proper medical treatment. Survivors may become chronic asymptomatic carriers of Salmonella bacteria. Such asymptomatic carriers show no symptoms of the illness, and yet are capable of passing the organisms to others (the classic example is Typhoid Mary).

Non-typhoidal Salmonella septicemia may result from infection with any of the Salmonella species and can affect virtually all organ systems, sometimes leading to death. Survivors may become chronic asymptomatic carriers of Salmonella bacteria.

**RESERVOIR:** DOMESTICATED ANIMALS AND FECES, WATER, SOIL, INSECTS

**IMPLICATED FOODS:** RAW MEAT, POULTRY, SEAFOOD, EGGS, DAIRY PRODUCT, YEAST, SAUCES, SALAD DRESSINGS, CAKE MIXES, CREAM FILLED DESSERTS, CONFECTIONERY, ETC.

Salmonella often live in animals - especially poultry and swine - as well as in a number of environmental sources. The organisms have been found in water, soil and insects, on factory and kitchen surfaces, and in animal feces. They can also survive in a variety of foods, including raw meats and poultry, dairy products and eggs, fish, shrimp and frog legs, yeast, coconut, sauces and salad dressing, cake mixes, cream-filled desserts and toppings, dried gelatin, peanut butter, orange juice, cocoa and chocolate.

**GROWTH REQUIREMENTS**

| | |
|---|---|
| TEMPERATURE (F) | 41 - 115 |
| MINIMUMWATERACTIVITY | 0.94 |
| PH | 3.7 - 9.5 |
| MAXIMUM SALT (%) | 8 |

ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . . . SENSITIVE TO MODERATE HEAT

Salmonella spp. are also mesophilic organisms which grow best at moderate temperatures and pH, and under conditions of low salt and of high water activity. They are killed rapidly by moderate heat treatment, yet mild heat treatment may give them the ability to develop heat resistance up to 185°F. Similarly, the organisms can adapt to an acidic environment.

**CONTROLS:** SANITATION TO PREVENT RECONTAMINATION, COOKING, PASTEURIZATION, PROPER HOLDING TEMPERATURES.

Ordinary household cooking, personal hygiene to prevent recontamination of cooked food, and control of time and temperature are generally adequate to prevent salmonellosis.

## *Shigela*

There are actually four species of Shigella. Because there is little difference in their behavior, however, they will be discussed collectively.

Illness is Shigellosis, typical symptoms include fever, cramps, inflammation and ulceration of intestine, and diarrhea. This disease is easily transmitted from person to person.

**RESERVOIR:** HUMAN, ANIMAL

**IMPLICATED FOODS:** SALADS, RAW VEGETABLES, POULTRY, MEAT, FISH, FRUIT, DAIRY PRODUCTS, BAKERY PRODUCTS.

The only significant reservoir for Shigella is humans. Foods associated with shigellosis include salads (potato, tuna, shrimp, macaroni and chicken), raw vegetables, milk and dairy products, poultry, fruits, bakery products, hamburger and fin fish.

**GROWTH REQUIREMENTS**

TEMPERATURE (F) . . . . . 43 - 117
MINIMUM WATER ACTIVITY . . . . . 0.96
PH . . . . . 4.8 - 9.3
MAXIMUM SALT (%) . . . . . 5
ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . . . SURVIVES ACIDIC CONDITIONS

The growth conditions for *Shigella*, which are mesophilic organisms, are similar to those of *Salmonella*. *Shigella* can survive under various environmental conditions, including low acid.

**CONTROLS:** COOKING, PROPER HOLDING TEMPERATURES, SANITATION TO PREVENT RECONTAMINATION, ADEQUATE WATER TREATMENT.

*Shigella* can spread rapidly under the crowded and unsanitary conditions often found in such places as summer camps, refugee camps and camps for migrant workers, and at mass gatherings such as music festivals.

The primary reasons for the spread of Shigella in foods are poor personal hygiene on the part of food handlers, and the use of improper holding temperatures for contaminated foods; conversely, the best preventive measures would be good personal hygiene and health education. Chlorination of water and sanitary disposal of sewage would prevent waterborne outbreaks of shigellosis.

## *Staphylococcus aureus*

*Staphylococcus aureus* produces a highly heat-stable toxin. Staphylococcal food poisoning is one of the most economically important foodborne diseases in the U.S., costing approximately $1.5 billion each year in medical expenses and loss of productivity. The most common symptoms are nausea, vomiting, abdominal cramps, diarrhea and prostration.

**RESERVOIR:** HUMANS, ANIMALS, AIR, DUST, SEWAGE, WATER

**IMPLICATED FOODS:** POULTRY, MEAT, SALADS, BAKERY PRODUCTS, SANDWICHES, DAIRY PRODUCTS.

*Staph* can be found in air, dust, sewage and water, although humans and animals are the primary reservoirs. *Staph* is present in and on the nasal passages, throats, hair and skin of at least one out of two healthy individuals. Food handlers are the main source of contamination, but food equipment and the environment itself can also be sources of the organism.

Foods associated with *Staph* include poultry, meat, salads, bakery products, sandwiches and dairy products.

Due to poor hygiene and temperature abuse, a number of outbreaks have been associated with cream-filled pastries and salads such as egg, chicken, tuna, potato, and macaroni.

**GROWTH REQUIREMENTS**
TEMPERATURE (F) GROWTH. . . . . 45 - 122
TOXIN PRODUCTION . . . . . 50 - 118
MINIMUM WATER ACTIVITY GROWTH . . . . . 0.83
TOXIN PRODUCTION . . . . . 0.85
PH . . . . . 4.0 - 10.0
MAXIMUM SALT (%) GROWTH . . . . . 25
TOXIN PRODUCTION . . . . . 10
ATMOSPHERE . . . . . FACULATIVE ANAEROBIC
SURVIVAL CONDITIONS . . . . TOLERANT OF HIGH SALT AND LOW MOISTURE

*S. aureus* grows and produces toxin at the lowest water activity (0.85) of any food pathogen. And, like type *A bot* and *Listeria*, *Staph* is quite salt-tolerant and will produce toxin at 10%.

**CONTROLS:** HEATING, PROPER EMPLOYEE HYGIENE, PREVENTION OF TEMPERATURE ABUSE

Foods which require considerable handling during preparation and which are kept at slightly elevated temperatures after preparation are frequently involved in staphylococcal food poisoning. And, while *S. aureus* does not compete well with the bacteria normally found in raw foods, it will grow both in cooked products and in salted products where the salt inhibits spoilage bacteria. Since Staph is a faculative anaerobe, reduced oxygen packaging can also give it a competitive advantage. The best way to control Staph is to ensure proper employee hygiene and to minimize exposure to uncontrolled temperatures. Remember that while the organism can be killed by heat, the toxin cannot be destroyed even by heating.

## *Vibrios*

There are quite a few species of Vibrios, but only four will be covered.

***Vibrio parahaemolyticus*** - The bacteria is naturally occurring in estuaries and other coastal waters. Illness is most commonly associated with fish and shellfish which are raw, undercooked or recontaminated after cooking.

***Vibrio cholerae 01*** - Epidemic cholera - Poor sanitation and contaminated water supplies will spread the disease; feces contaminated foods including seafood have also been associated with outbreaks.

***Vibrio cholerae non-01*** -The reservoir for this organism is estuarine water - illness is associated with raw oysters, but the bacteria has also been found in crabs.

***Vibrio vulnificus*** - This organism also occurs naturally in estuarine waters. So far only oysters from the Gulf of Mexico have been implicated in illness, but the organism itself has been found in both the Atlantic and Pacific Oceans.

**GROWTH REQUIREMENTS**
TEMPERATURE (F) . . . . . 41 – 111
MINIMUM WATER ACTIVITY . . . . . 0.94 - 0.97
PH . . . . . 4.8 - 11.0
MAXIMUMSALT (%) . . . . . 5 – 10
ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . SALT TOLERANT; HEAT SENSITIVE

Vibrios are mesophilic and require relatively warm temperatures, high water activity and come neutral pH for growth, they also require some salt for growth, and are quite salt-tolerant. They are, however, easily eliminated by a mild heat treatment.

**CONTROLS:** COOKING, PREVENTION OF RECONTAMINATION, TIME/TEMPERATURE ABUSE, CONTROL PRODUCT SOURCE.

All the Vibrios can be controlled through cooking and the prevention of cross-contamination afterward. Proper refrigeration prevents proliferation, which is particularly important because of the short generation times for these species. To guard against cholerae, processors should know the source of the product and be cautious about importing from countries experiencing an epidemic.

## *Yersinia*

*Yersinia* ssp: *Y. entercolitica*; Y. *pseudotuberculosis*; *Y. pestis* Of the 11 recognized species of *Yersinia*, three are known to be potentially pathogenic to humans:

enterocolitica, pseudotuberculosis and pestis. Only enterocolitica and pseudotuberculosis are recognized as foodborne pathogens. *Y. pestis*, the organism responsible for the black plague, is not transmitted by food.

Yersiniosos is often characterized by such symptoms as gastroenteritis with diarrhea and/or vomiting, but fever and abdominal pain are the hallmark symptoms. Yersinia infections mimic appendicitis, which has led to unnecessary operations.

**RESERVOIR:** LAKES, STREAMS, VEGETATION, SOIL, BIRDS, ANIMALS AND THEIR FECES

**IMPLICATED FOODS:** RAW VEGETABLES, MILK, ICE CREAM, CAKE, PORK, SOY, SALAD, SEAFOOD, CLAMS, SHRIMP

Yersinia can be found in raw vegetables, milk, ice cream, cakes, pork, soy products, salads, oysters, clams and shrimp. They are found in the environment, in such places as lakes, streams, soil and vegetation. They've been isolated from the feces of dogs, cats, goats, cattle, chincillas, mink, and primates; in the estuarine environment, many birds - among them, waterfowl and seagulls - may be carriers. The foodborne nature of Yersiniosis is well established, and numerous outbreaks have occurred worldwide.

**GROWTH REQUIREMENTS**

TEMPERATURE (F) . . . . . 30 - 108
MINIMUMWATERACTIVITY . . . . . 0.95
PH . . . . . 4.2 - 10.0
MAXIMUM SALT (%) . . . . . 7
ATMOSPHERE . . . . . FACULATIVE ANAEROBE
SURVIVAL CONDITIONS . . . . . WITHSTANDS FREEZING AND THAWING; SENSITIVE TO HEATING AND SANITIZERS

**CONTROLS:** SANITATION TO PREVENT RECONTAMINATION; COOKING; PASTEURIZATION; WATER TREATMENT; PROPER HOLDING TEMPERATURES

Key factors for controlling Yersinia include proper cooking or pasteurization, proper food handling to prevent recontamination, adequate water treatment, and care taken to ensure that products are not time or temperature abused. Proper use of sanitizers is also an effective control. Essentially, to control Yersinia, it is necessary to keep things clean and moving.

# Sample Plans

The following represents a sample Food Safety Plan for a fictitious company. Recognizing that the HACCP plan is only part of the food safety plan, additional supporting information is included on GMP's and SOP'S.

**The plan is composed of the following sections:**

- ***Plan for Smokehouse operations including:***
  - Equipment list
  - Formulation/Recipe
  - Flow Diagram
  - Standard Operating Procedures including Critical Control Points, Critical Limits, Monitoring, and Corrective Actions

- ***Plan for Reduced Oxygen Packaging Operations including:***
  - Equipment List
  - Flow Diagram
  - Standard Operating Procedures including Critical Control Points, Critical Limits, Monitoring, and Corrective Actions

**Plan for ...**.

***Also included is General information that might apply for all HACCP plans which includes:***

- Training Program
- Standard Operating Procedures for Person in Charge
- Labeling
- Cleaning and Sanitizing Procedures
- Good Manufacturing Practices - Employee Practices

SAMPLE

# Retail Food Establishment
# Food Safety Plan

Including:

## HACCP PLAN

For: Smokehouse Operations

Reduced Oxygen Packaging

## GMP's/SOP's

Employee Practices

Cleaning and Sanitizing Procedures

Verifications Procedures by *Person in Charge*

Labeling Requirements

Training Program

## J's Market
## 505 Saratoga St.
## Anytown, MN

**JANUARY 13, 2000**

## Smokehouse Operations Equipment List

Walk-in Cooler – brand _____ size _____

Other products/operations supported _____
Grinder
Mixer
Stuffer

Smokehouse - brand _____
Smoke generator/liquid smoke

Digital Thermometer
Assorted measuring containers, hand utensils, lugs, totes, etc.

---

## Smokehouse Operations Formulation/Recipe

RING BOLOGNA

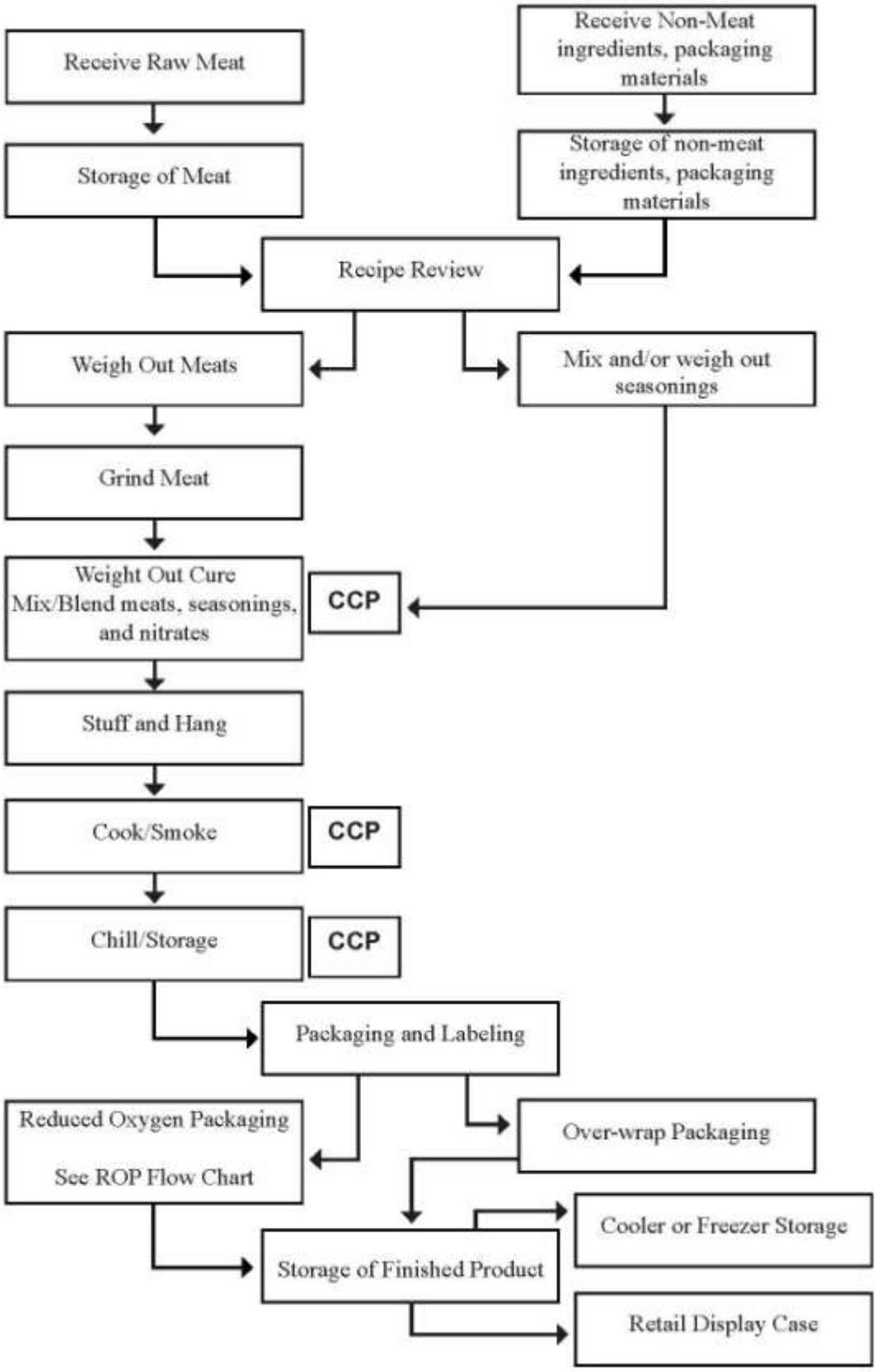
Full batch
- 50 pounds pork trim
- 50 pounds beef trim 6.5 (1 full packet) pounds of XYZ brand Bologna Seasoning
- 4 oz (1 full packet) of Quick Cure 10 pounds water

- Casings - Natural beef casing

***Also include procedures for producing the product that show who food safety concerns are controlled.***

## Recipes to be included for every product

## Smokehouse Operations Flow Diagram


Receive Raw Meat
Receive Non-Meat ingredients, packaging materials
Storage of Meat
Storage of non-meat ingredients, packaging materials
Recipe Review
Weigh Out Meats
Mix and/or weigh out seasonings
Grind Meat
Weight Out Cure Mix/Blend meats, seasonings, and nitrates
CCP
Stuff and Hang
Cook/Smoke
CCP
Chill/Storage
CCP
Packaging and Labeling
Reduced Oxygen Packaging
See ROP Flow Chart
Over-wrap Packaging
Cooler or Freezer Storage
Storage of Finished Product
Retail Display Case

# Smokehouse Operations Standard Operating Procedures

## CURED-SMOKED/COOKED SAUSAGE

1. Receiving/Storage of meat products, seasonings, fillers, cure agents, packaging materials, sawdust. Check the temperature of meat products on receipt. These products must be received at 41°F or less- products at higher temperatures should be rejected. Perishable products must be stored in refrigeration at 41°F or less or frozen at 0°F or less - Ensure that all products are stored under sanitary conditions to prevent contamination.

2. Ensure that facilities are clean and sanitary and in good condition and that equipment is clean and sanitary and is working properly and safely. Ensure that sawdust is in the smoke generator and install a temperature recording chart on the smokehouse.

3. Ensure that food handlers are in compliance with Employee Practices requirements in the Good Manufacturing Practices.

4. Review the recipe to confirm that all required ingredients, are on hand and assemble spices, fillers, cure agents, casings, packaging materials, etc in the work area.

5. Establish the size of the batch to be made. Almost all pre-mix units come packaged for 100 pounds of meat.

*Example:*

| | | | |
|---|---|---|---|
| 100.00 | Lbs. | Meat | |
| 6.50 | Lbs. | Seasoning and filler (one bag) | |
| .25 | Lb. | Cure (separate packet) | RESTRICTED INGREDIENT |
| 10.00 | Lbs. | Water | |
| 116.75 | Lbs. | Gross weight | |

If less than a full batch is to be made, calculations must be made to reduce all ingredients by the same amount.

Examples of reduced batches are:

***1/2 batch***

| | | | |
|---|---|---|---|
| 50.00 | Lbs. | Meat | |
| 3.25 | Lbs. | Seasoning and filler | |
| .125 | Lb. | Cure | RESTRICTED INGREDIENT |
| 5.00 | Lbs. | Water | |
| 58.375 | Lbs. | Gross weight | |

***1/4 batch***

| | | | |
|---|---|---|---|
| 25.00 | Lbs. | Meat | |
| 1.625 | Lbs. | Seasoning and filler | |
| .0625 | Lb. | Cure | RESTRICTED INGREDIENT |
| 2.5 | Lbs. | Water | |

29.1875 Lbs. Gross weight

Weigh out meat, seasonings and fillers, and water. Do not necessarily assume that containers/pails/lugs/scoops of ingredients always weigh the same. Record entries for these ingredients on the batch record.

6. Grind the meat.

7. ***Critical Control Point* -** Weigh out cure and premix with at least 1 pint of water to provide better distribution with the other ingredients. Pre-mix seasonings with part of the remaining water. In the automatic mixer, mix meat with seasoning/water blend, fillers, remaining water, and cure /water blend.

   ***Critical Limit* -** For full batches (100 pounds), net weight of cure is .25 lbs; for 1/2 batch/50 pounds net weight of cure is .125 pounds; for 1/4 batch (25 pounds) net weight of cure is .0625 pounds. Because of the small amounts of cure required batches, weighing of cure ingredients must be done on a certified digital scale. Thoroughly mix ingredients, especially the cure mixture to ensure even distribution throughout the batch.

   ***Monitoring*** - Observe the mixing process to ensure complete distribution. Complete entries on the batch record. Attach seasoning and cure bag to batch record.

   ***Corrective Action*** - If errors are noticed before any further steps are completed, take the following steps:
   - If insufficient cure has been added, additional amounts up to the amount required in the recipe can be added and the batch re-mixed
   - If too much cure was added, additional meat and seasonings can be added to extend the batch and remixed. If errors are noted after the cook step, nothing can be done to save the batch and the entire batch must be discarded.

8. Stuff the mixed product into the appropriate size and type of casing for the product being made. Use only clean, fresh casings that have been stored properly to prevent contamination. Hang to product onto rods and into smokehouse. Insert temperature probe into product into sausage.

9. ***Critical Control Point* -** Smoke and Cook. Set smokehouse computer to the appropriate cycle for the product being produced. The smokehouse will automatically shut down when the programmed temperature is reached.

   ***Critical Limit*** - Minimum internal temperature of product are: Beef and Pork - 155°F for 15 seconds Poultry - 165°F for 15 seconds.

   ***Monitoring*** - Inspect temperature chart to ensure that the highest attained temperature has been met. Record the highest attained temperature on the Batch Record.

   ***Corrective Action*** - If minimum temperature has not been met, reset the smokehouse and re-cook until the minimum time and temperature have been met.

10. ***Critical Control Point* -** Cooling. The product must be rapidly cooled. This may be part of the smokehouse cycle if the unit has an internal shower. Showering with water will assist in bringing the temperature down. Next, the product must be removed from the smokehouse and placed in the cooler (which is at 41°F or less). This should happen immediately after the smokehouse cycle is completed as it is important that the cooling process begins right away.

When cooked product is placed into the cooler, ensure that it is placed so that it is protected from cross contamination by raw meat.

***Critical Limit*** - Products must be cooled from 140°F to 70°F within 2 hours and from 70° to 41°F within another 4 hours.

***Monitoring*** - Check internal temperature at 1 hour and 45 minutes, at 2 hours, and again at 6 hours. Record internal temperature on batch record.

***Corrective Action*** - If the temperature taken at 1 hour 45 minutes is at 75° For greater, notify the Person in Charge and take immediate action to reduce the temperature. This can be accomplished by showering with cold water or if a greater temperature reduction is necessary, product could go into a water bath. If product does not meet the critical limits at 2 and 6 hours, it must be discarded.

1. **Packaging/Labeling** - if product is packaged by a Reduced Oxygen packaging method, refer to Standard Operating Procedures for ROP. If product is packaged by over-wrapping, ensure that packaging materials (trays, wrap) are in a sanitary condition and do not subject the food to cross contamination. Food employees must limit direct hand contact with exposed ready to eat food. Products be labeled with mandatory labeling requirements.
2. **Storage/Display** - Place packaged food into refrigerated storage, either retail display cases or cooler storage at 41°F or less.

# Smokehouse Operations

J's Market
505 Saratoga St. W
Anytown MN 55555

## Batch Record

Required to be completed for each product made as official record of monitoring critical control points.

PRODUCT _____ PRODUCTION DATE _____ CODE/LOT ID _____

*FORMULATION:*

Beef: _____ LBS Water: _____ LBS
Pork: _____ LBS Other: _____
Turkey: _____ LBS _____
Veal: _____ LBS _____

Seasonings: *Contents and Weight* _____

_____

_____

*CURING AGENT: Critical Control Point*

Type _____ Weight _____ Signature _____
How incorporated (mix, injected, soak, etc.) _____
Cure Lot Number _____
Other Processing _____

_____

_____

*SMOKE/COOK: Critical Control Point*

Temperature Checks: _____
FINAL INTERNAL TEMPERATURE* _____ *°F *Minimum cook temperature of 155°F (165°F for poultry)*
Signature _____

*COOLING: Critical Control Point*

Temperature Checks _____
Temp at 2 Hours* _____ **Must be 70°F or less*
Signature _____
Temp at 6 Hours* _____ *Must be 41°F or less
Signature _____

All CCP's Met? ❑ Yes ❑ No

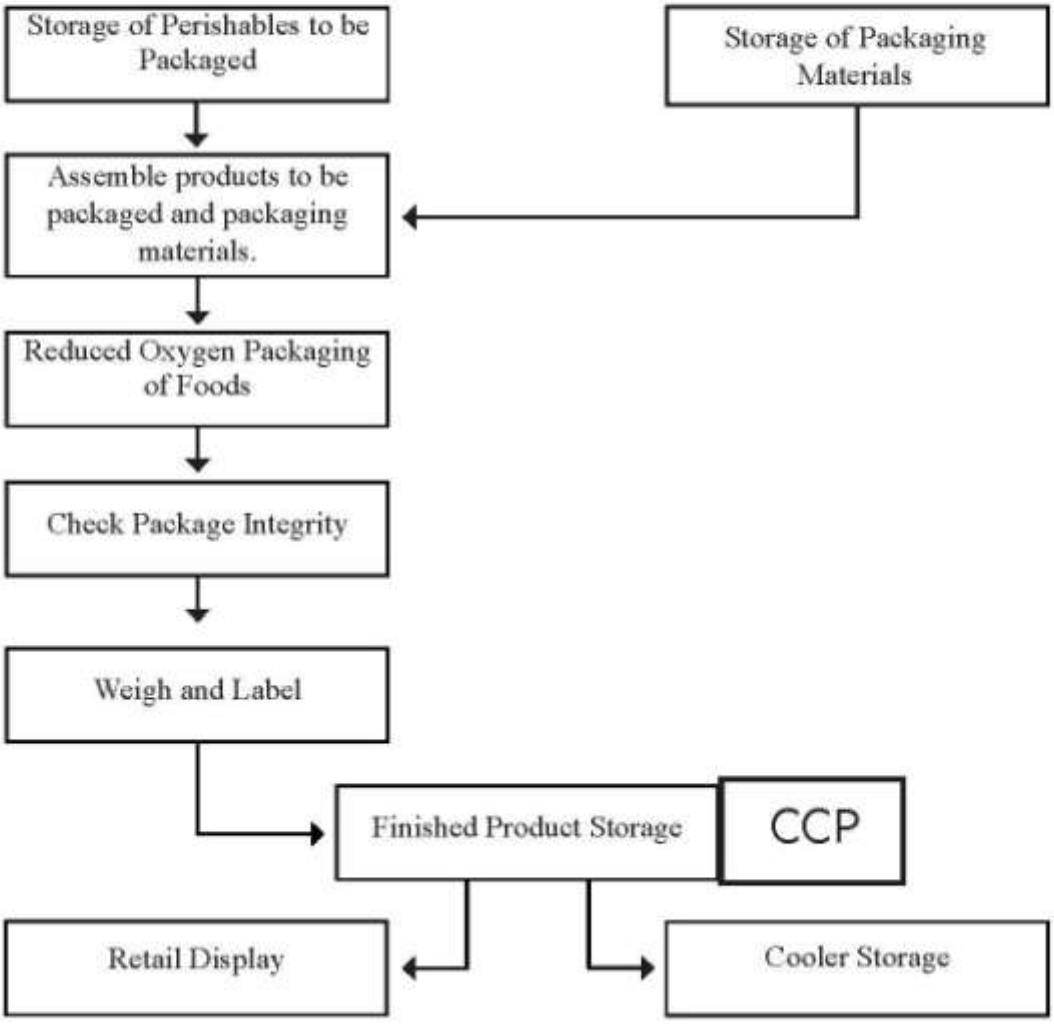
Signature _____

## Reduced Oxygen Packaging

### Equipment List

- Slicer - brand _____
- Vacuum Packaging Machine - _____
- Digital Thermometer
- Assorted knives, tongs, trays, lugs/totes, hand utensils

### Flow Diagram



# Reduced Oxygen Packaging Standard Operating Procedures

*Only food handlers that are trained in the use of the reduced oxygen packaging equipment and process of reduced oxygen packaging and have a thorough understanding of the HACCP plan shall operate or conduct ROP operations.*

1. Ensure that facilities in the area where ROP operations are to be conducted are clean and sanitary and are in good physical condition. ROP operations must only be conducted in the designated area in the meat department. No packaging of ready to eat foods can be conducted while raw foods are present or are being processed in the same room. Only properly cleaned and sanitized equipment is to be used in the operation.

2. Ensure that all equipment is operating properly and safely. Ensure that equipment involved in the ROP process has been properly cleaned and sanitized according to regulation and store policy. This equipment includes (but not limited to): tables, cutting boards, slicer, knives, tongs, trays,

3. Ensure that food handlers are in compliance with Employee Practices requirements in the Good Manufacturing Practices. This includes employee hygiene, handwashing, clean clothing, etc.

4. Assemble packaging materials, labels, etc. necessary to the operation.

5. Assemble products that are to be packaged.
   - Products to be ROP shall remain at room temperature no longer than 30 minutes during the packaging process, therefore, only remove sufficient quantities so that this is managed.
   - Products that can be ROP are limited to list provided.

6. Place foods in the packaging materials. Food Employees must limit direct hand contact with exposed, ready-to-eat food when deli tissues, spatulas, tongs, dispensing equipment, or other utensils can be used.

7. Place bags in vacuum machine ensuring that adequate space is provided around each package. Ensure that machine settings are appropriate for product being packaged. It is important that a full vacuum is provided or if using gas displacement, that the equipment is working properly. Start the machine and wait for the lid to open indicating that the process is complete

8. Remove packages from the machine. Visually check the seal to ensure that it is tight and that there are no food materials in the seal. Make a note of any indicators of a faulty seal such as wrinkles or an incomplete seal. Packages with a faulty seal should be re-packaged. Trim excess packaging as required.

9. Weigh and label each package. Ensure that all required information is provided on the label. Ensure that the shelf life is no longer than 14 days.

10. ***Critical Control Point *** Place packaged food into refrigerated storage, either retail display cases or cooler storage.

    ***Critical Limit -***Temperature in storage must be 41°F or less. Products will be considered to be temperature abused if they are exposed to temperatures above 41°F for more than 4 hours.

    ***Monitoring*** - The designated employees of the meat department will check and record the actual temperature in both the walk-in cooler and retail case that contains in-store packaged products at intervals not to exceed 4 hours. If temperatures are out of range, notify the Person in Charge and move products to other approved

storage location that does meet temperature requirements. Record temperature on cold storage log.

***Corrective Action*** -Discard temperature abused products. Make necessary adjustments or repairs to cooler or case prior to restocking. Document any corrective actions on the log.

11. Visually check ROP products on a daily basis in the retail case or as products in reserve storage are brought out to the retail case and check the package integrity (faulty seals, 'puffy' packages, holes, tears, or packages that may have otherwise lost their 'vacuum') and contents of the package (slime, mold, discoloration). Packages that do not meet the requirements should be destroyed. Also check for products that have passed their 'use by' date.

## Cold Storage Log

Store Name _____

Store Address _____

Month/Year _____ Cooler/Location _____

| DATE | TIME | TEMP. | S | TIME | TIME | S | DATE | TIME | TEMP. | S TEMP. TEMP. | S |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | 17 | | | | |
| 2 | | | | | | | 18 | | | | |
| 3 | | | | | | | 19 | | | | |
| 4 | | | | | | | 20 | | | | |
| 5 | | | | | | | 21 | | | | |
| 6 | | | | | | | 22 | | | | |
| 7 | | | | | | | 23 | | | | |
| 8 | | | | | | | 24 | | | | |
| 9 | | | | | | | 25 | | | | |
| 10 | | | | | | | 26 | | | | |
| 11 | | | | | | | 27 | | | | |
| 12 | | | | | | | 28 | | | | |
| 13 | | | | | | | 29 | | | | |
| 14 | | | | | | | 30 | | | | |
| 15 | | | | | | | 31 | | | | |
| 16 | | | | | | | | | | | |

**S= signature of person taking/recording temperature**

If air temp is more than 45°, check product temperature;
If product temp is more than 41° but less than ___°, move product to another cooler, cool to 41 ° within 4 hours and make necessary repairs to case;
If product temperature is higher than ___°, discard product and make necessary repairs to the case
Any record noted above 41°F, must have explanation/corrective action noted below:

*For example:*
*5/4 – temp at 45° – case on defrost – product temp - 39° - OK or*
*5/5 – temp at 50° – product temp 50° – 100 pounds of sausage product destroyed*

Records Reviewed by: _____ Date: _____
Comments:

# Labeling

**Mandatory Labeling Information**

1. Name of Product
2. Name, address including zip code of store
3. Net weight statement
4. Complete and detailed ingredients statement
5. On fresh/raw meat products, the Safe Handling Statement must be included
6. Nutrition facts may be required, contact the Minnesota Department of Agriculture

**In addition, Reduced Oxygen packaged food labels must also include:**

1. The Statement: **Keep Refrigerated or Frozen**
2. Instructions to discard the food if within 14 days of its packaging if it is not consumed
3. The shelf life must not be longer than 14 days from packaging to consumption or the original manufacturers "sell by"' or "use by" date, whichever occurs first.

**Shelf life for various products will be as follows:**

| | |
|---|---|
| All in-store smokehouse products | XX days |
| Sliced cold cuts (ham, smoked turkey, salami, etc.) | XX days |
| Cheese (block or sliced) | XX days |
| Raw meats or poultry | XX days |

**Sample Label**

# Training Program - For Food Handlers Conducting Reduced Oxygen Packaging

**Understanding the potential hazards associated with reduced oxygen packaging**

While the process of packaging foods using a reduced oxygen method extends the shelf life, it also can pose a serious public health threat.

Generally, bacteria survive under conditions where there is oxygen is present - aerobic conditions - or where oxygen is not present anaerobic conditions. Some bacteria have the ability to adapt to either condition. Under traditional packaging conditions (aerobic conditions), spoilage bacteria would normally thrive and the product would spoil before the more hazardous types of bacteria might become a problem. During the process of 'vacuum packaging' or 'reduced oxygen packaging', the air inside the package (which is approximately 21 % oxygen) is eliminated, creating anaerobic conditions and thereby changing the types of bacteria that can survive in the package. Spoilage organisms are eliminated, but several types of pathogenic bacteria survive and actually thrive under these conditions. The pathogen of greatest concern is Clostridium botulinum. While botulism bacteria will normally be killed in a cooking step, spores of the bacteria may survive and could grow and produce toxin if the conditions are right. These conditions are similar to those that occur in a vacuum/reduced oxygen package. Other pathogens of concern may be Listeria monocytogenes, Yersinia enterocolitica, Campylobacter jejuni, and Clostridium perfringens.

## Concepts Required for a Safe Operation

A thorough understanding of the of the HACCP plan, the use of the reduced oxygen packaging equipment, and the standard operating procedures are critical to a safe operation. Areas to focus on include: products that can be packaged, temperature control, prevention of cross contamination, and health and personal hygiene of food handlers.

***Products that can be packaged by ROP***

State regulations limit the types of foods that can be packaged. This store's HACCP plan defines the foods that can be packaged using reduced oxygen packaging. **Only specific products on this list can be reduced oxygen packaged**. Any addition to the above list must first have the approval of the PERSON IN CHARGE. Changes must be noted in the HACCP PLAN. Foods to be reduced oxygen packaged at the retail level must be limited to one that does not support the growth of Clostridium botulinum because of one of the following requirements:

1. has a water activity of 0.91 or less
2. has a pH of 4.6 or less
3. is a food with a high level of competing organisms, including raw meat, raw poultry, or a naturally cultured standardized cheese
4. is a meat or poultry product that was cured at a USDA meat plant and received in an intact package or cured using approved substances (nitrates/nitrites).

By limiting the types of food that can be ROP to those on the list, an additional barrier to the growth of Clostridium botulinum is provided and thereby helps to ensure a safe product.

In addition, except for fish that is frozen before, during, and after packaging, a food establishment shall not package fish using a reduced oxygen packaging method.

Following are examples of foods that do not meet the above requirements and therefore may NOT be reduced oxygen packaged: Cooked turkey (including whole or sliced turkey breast), cooked roast beef, sandwich spread (including ham salad, chicken salad, etc.), cooked fresh sausage (not cured/smoked such as bratwurst), fresh salads.

***Temperature Control***

Temperature control is a very important factor in keeping all potentially hazardous foods safe. But the extended shelf life and decreased oxygen concentration allows certain pathogens to multiply in reduced oxygen conditions. To reduce the potential for growth of these pathogens, products (packaged and unpackaged) must be stored at cooler temperatures of 41$^{o}$ F or less. Employees must monitor the cooler temperatures at least every 4 hours to ensure that foods are not allowed to be out of the temperature requirements for extended periods of time.

***Preventing Cross Contamination***

Raw foods should be handled separately from cooked and ready to eat foods to avoid cross contamination. Utensils, equipment and work surfaces used for raw foods should be thoroughly cleaned and sanitized prior to using for cooked or ready-to-eat foods. In addition, ensure that ready-to-eat foods are stored so that blood or juices from raw products cannot drip or otherwise come into contact with them. Food handlers can also be a source of cross contamination through improper handwashing, or soiled clothing or aprons.

***Employee Health and Hygiene***

The health and personal hygiene of food handlers can also play a critical role in producing a safe ROP food. It is vital that employees working in this operation follow the Employee Practices guidelines in the Good Manufacturing Practices. (See Page xx). Particular attention should be paid to #1 - Handwashing procedures, #6 Clean Outer

Garments, and #1 0 - Food handling.

## Cleaning and Sanitizing Procedures - Equipment 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. Detergent cleaners suspend and help remove various food soils. Chemical sanitizers (chlorine, iodine, acid, or quaternary ammonia types) reduce the numbers of pathogens and other microorganism to insignificant levels.

**The clean up process must be completed in accordance with the following procedures.**

- **Pre-cleaning** - Equipment and utensils shall be pre-flushed, pre-soaked, or scraped as necessary to eliminate excessive food debris.

- **Washing** - Equipment and utensils shall be effectively washed to remove or completely loosen soils using manual or mechanical means. Only approved chemicals are to be used in this process. Approved chemicals for WASHING are: _____

- **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. Exposure time is important to ensure effectiveness of the chemical. Approved chemicals and exposure times for SANITIZING are:
  _____
  _____

Ensure that an appropriate chemical test kit is available and routinely used to ensure that accurate concentrations of the sanitizing solutions are being used.

## Frequency of Cleaning

**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 potentially hazardous foods, throughout the day at least once every four hours
6. Utensils and equipment that are used to prepare food in a refrigerated room that maintains the utensils, equipment, and food under preparation at 41°F or less and are cleaned at least once every 24 hours
7. Before using or storing a food thermometer.
8. For 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.
9. For ice bins, at a frequency necessary to preclude accumulation of soil or mold.
10. Food contact surfaces of cooking equipment shall be cleaned at least once every 24 hours.

Non-food-contact surfaces of equipment shall be cleaned at a frequency necessary to prevent accumulation of soil residues.

# Good Manufacturing Practices - Employee Practices

1. Hands are to be thoroughly washed in a designated hand sink with soap and water, paying particular attention to the areas underneath the fingernails and between the fingers by scrubbing thoroughly with a using a fingernail brush. Dry with single use towels. Handwashing is to be done at the following times:

    - 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 as necessary to remove soil and prevent cross contamination
    - when switching between raw and ready-to-eat foods
    - 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.

3. Eating and drinking is 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 in a food prep area as long as it is handled to prevent contamination.

4. Effective hair restraints must be worn in processing areas.

5. Smoking and other uses of tobacco are prohibited.

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. Frocks 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 and locker rooms.

8. Foot wear is to be kept clean.

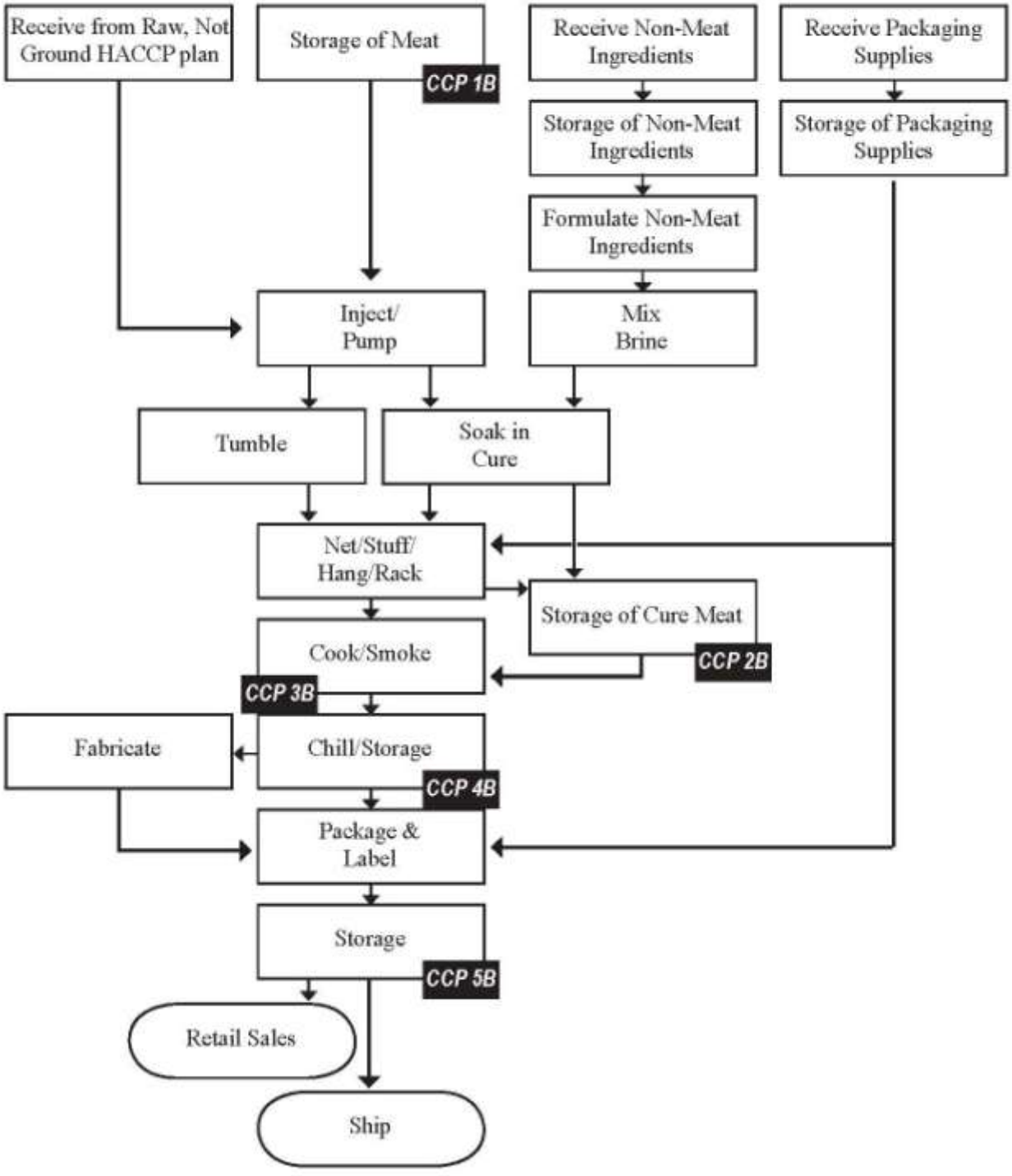
9. No jewelry (except a wedding band or other plain ring) is allowed during handling of food.

10. Food Employees shall report to the Person in Charge when they have a symptom caused by illness, infection, or other source that is:
    - associated with diarrhea, vomiting or other acute gastrointestinal illness
    - jaundice
    - a boil, infected wound or other lesion containing pus that is open or draining unless if on the hands or wrists, unless a finger cot or other impermeable cover protects the lesion and a single use glove is worn if on exposed portions of the arms, the lesion is protected by an impermeable cover.

***The Person in Charge shall impose the proper restrictions and exclusions according to rule.***

## Flow Diagram for HACCP Category: Fully Cooked, Not Shelf Stable Whole Muscle Products

Example Product(s): Hickory Smoked Bacon, Hickory Smoked Boneless Ham



m a i
- e t n

## Flow Diagram for Smoked Sausage

| | POTENTIAL HAZARDS | CCP/CP | CRITICAL LIMITS | POTENTIAL HAZARDS | CORRECTIVE ACTIONS |
|---|---|---|---|---|---|
| **RECEIVING** | Rapid bacterial growth, spoilage, cross- contamination, foreign objects. | CP | Frozen items must be kept frozen. Chilled items must be kept at 40°F or below. No cross-contamination, foreign objects or spoilage. | Visual inspection. Use a digital thermometer. | Reject thawed frozen items. Reject chilled items above 40°F. Reject product with foreign objects. |
| **STORAGE** | Rapid bacterial growth, spoilage, cross- contamination, foreign objects. | CP | Temperature at 40°F or below. Any product stored above 70°F or a four-hour period must be discarded. | Record temperature every four hours. After normal working hours, the cooler will be on automatic alarm system. | Adjust cooler temperature. Discard any product that exceeds 70°F for more than four hours. |
| **GRINDING** | Rapid bacterial growth and cross- contamination. | CP | Utensils and equipment must be clean. Employees must meet personal sanitary standards. | Visual inspection. | Stop production and modify procedure. |
| **MIXING** | Insufficient mixing or amounts may result in poor distribution of cure. | CCP | Cure must be properly distributed, following uniform formulation mix. | Observe batch make slip, date and weight of product. Attach seasoning and cure bag. | Modify and re-blend, following uniform formulation mix. |
| **STUFFING AND HANDLING** | Cross- contamination between personnel and equipment. | CP | Utensils and equipment must be clean. Employees must meet personal sanitary standards. | Visual inspection. | Stop production and rework product. |
| **COOKING AND SMOKING** | Pathogens and bacterial spores may survive if product is not properly cooked. | CCP | Internal temperatures must be: Beef and Pork: 155°F Poultry: 165°F | Inspect temperature chart. Verify that the minimum time and temperature have been met. | Re-cook product until the minimum time and temperature have been met. |
| **CHILLING** | Surviving bacterial spores may germinate to vegetative cells if chilling is to slow. | CCP | Products must be cooled to 70°F within two hours, and to 40°F and below within another 4 hours. | Record internal temperature on batch make slip at two hours and six hours. | Discard any product not cooled to 40°F or below within six hours. |
| **PACKAGING AND LABELING** | Products may be incorrectly labeled. Outdated product may not be safe. Economic fraud. Cross-contamination. | CP | Overwrap product to prevent bacteria growth. Policies for rotation, disposal, and proper labeling must be followed. Follow good manufacturing practices. | Record the lot code and refrigeration statement. Follow proper procedures for coding and dating. Follow good manufacturing practices. | Reject or discard improper packaging. Discard outdated products. |
| **DISPLAY** | Improper temperature may result in rapid and progressive growth of pathogens. | CCP | Temperature must be maintained at 40°F or below. Products will be considered temperature-abused if they are exposed to temperatures above 40°F for more than six hours. | Check and record display case temperature every four hours. | Lower the thermostat. Discard any temperature-abused products. |

| PROCESS STEP | FOOD SAFETY HAZARD | REASONABLY LIKELY TO OCCUR | JUSTIFICATION FOR DECISION | IF YES IN COLUMN 3 What measures could be applied to prevent, eliminate, or reduce the hazard to an accepable level? | IS THE STEP A CRITICAL CONTROL POINT (CCP)? |
|---|---|---|---|---|---|
| **Receive meat form raw, not ground HACCP Plan** | B — None | B: — No | | | |
| | C — None | C: — No | | | |
| | P— None | P: — No | | | |
| **Storage of meat** | B — Pathogen Growth | B — Yes | Proper storage temperature suffiecient to prevent pathogen growth. | Temperature control to reduce a potential risk of pathogenic growth. | Yes (CCP 1B Holding Cooler) |
| | C — None | C — No | | | |
| | P — Foreign Materials (ex. overhead contamination) | P — None | Preventive maintenance and sanitation SOP's to prevent contamination. | | |
| **Receiving from chill** | B — Pathogen Growth | B — No | Proper storage temperature sufficient to prevent pathogen growth. | | |
| | C — Pathogen Growth | C — No | | | |
| | P — Foreign Materials (ex. overhead contamination) | P — No | Preventive maintenance and sanitation SOP's to prevent contamination | | |
| **Receive packaging supplies** | B — Microbial Spores | No | Letters of guarantee are on file for all packaging supplies and ingredients. | | |
| | C — None | | | | |
| | P — Foreign Materials | No | Letters of guarantee are on file for all packaging supplies and ingredients. | | |
| **Receive non-meat ingredients** | B — Microbial Spores | No | Letters of guarantee are on file for all packaging supplies and ingredients. | | |
| | C — None | | | | |
| | P — Foreign Materials | No | Letters of guarantee are on file for all packaging supplies and ingredients. | | |
| **Storage of packaging supplies** | B — Microbial Spores | B — No | Letters of guarantee are on file for all packaging supplies and ingredients | | |
| | C — None | C — No | Letters of guarantee are on file for all packaging supplies and ingredients. GMP's, routine samition, visual observation for container integrity. | | |
| | P — Foreign Materials | P — No | | | |
| **Receive non-meat ingredients** | B — Microbial Spores | No | Letters of guarantee are on file for all packaging supplies and ingredients | | |
| | C — None | | | | |
| | P — Foreign Materials | No | Letters of guarantee are on file for all packaging supplies and ingredients | | |

| PROCESS STEP | FOOD SAFETY HAZARD | RESEASONABLY LIKELY TO OCCUR | JUSTIFICATION FOR DECISION | IF YES IN COLUMN 3 What measures could be applied to prevent, eliminate, or reduce the hazard to an accepable level? | IS THE STEP A CRITICAL CONTROL POINT (CCP)? |
|---|---|---|---|---|---|
| **Storage of non-meat ingredients** | B — Micobial Spores | No | Letters of guarantee are on file for all packaging supplies and ingredients. | | |
| | C — None | | | | |
| | P— None | No | Letters of guarantee are on file for all packaging supplies and ingredients. | | |
| **Formulate non-meat ingredients** | B — Pathogen Introduction | B — No | Responsible employee prepares according to formulation. | | |
| | C — None | C — No | | | |
| | P — Foreign Materials (ex. metal) | P — No | Plant history indicated that metal contamination is not likely to occur. | | |
| **Mix brine** | B — Pathogen Introduction | B — No | Sanitation SOP's to prevent cross-contamination. | | |
| | C — Nitrate | C — No | Responsible employee prepares according to formulation. | | |
| | P — Foreign Materials (ex. overhead contamination) | P — No | Plant history indicated that metal contamination is not likely to occur. | | |
| **Inject/pump** | B — Pathogen Introduction | No | Sanitation SOP's to prevent cross-contamination. | | |
| | C — Excessive Nitrate | | Proper pump % for appropriate formulation. | | |
| | P — None | No | | | |
| **Tumble** | B — Microbial Spores | No | Sanitation SOP's to prevent cross-contamination. | | |
| | C — None | | | | |
| | P — None | No | | | |
| **Net/stuff/ hangrack** | B — Microbial Spores | B — No | Sanitation SOP's to prevent cross-contamination. | | |
| | C — None | C — No | | | |
| | P — None | P — No | | | |
| **Storage of meat cure** | B — Pathogen Growth | B — Yes | Proper storage temperature sufficient to prevent pathogen growth. | Temperature control to reduce a potential risk of pathogenic growth. | Yes (CCP 2B cured meat cooler) |
| | C — None | C — No | | | |
| | P — None | P — No | | | |
| **Cook/smoke** | B — Pathogen Reduction | Yes | Potential survivor and/or growth of pathogens with improper cooking. | | Yes (CCP 3B) |
| | C — None | | | | |
| | P — None | | | | |

| PROCESS STEP | FOOD SAFETY HAZARD | REASONABLY LIKELY TO OCCUR | JUSTIFICATION FOR DECISION | IF YES IN COLUMN 3 What measures could be applied to prevent, eliminate, or reduce the hazard to an accepable level? | IS THE STEP A CRITICAL CONTROL POINT (CCP)? |
|---|---|---|---|---|---|
| **Chill/storage** | B — Pathogen Growth | B — Yes | Potential survival and/or growth of pathogens with improper chilling. Improper storage temperature can provide ambient temperature for both spoilage and pathogenic growth. | Temperature control to reduce a potential risk of pathogenic growth. | Yes (CCP 4B smoked meats cooler) |
| | C — None | C — No | | | |
| | P— Foreign Materials | P — No | Container integrity. | | No |
| **Fabricate** | B — Pathogen Contamination (*Listeria monocytogenes*) | No | Potential contamination form envimmental sources. Pre-operational and operation sanitation can reduce the risk of contamination from the environment and cross-contamination between products. | | No |
| | C — None | C — No | | | |
| | P — None | P — No | | | |
| **Package and label** | B — Pathogen Contamination | B — No | Sanitation Standard Operating Procedures are in place to prevent contamination. | . | No |
| | C — Nitrate | C — No | | | |
| | P — None | P — No | | | |
| **Storage of finished product** | B — Pathogen Growth | B — No | Improper storage temperature can provide ambient temperature for both pathogenic growth. | Temperature control to reduce a potential risk of pathogenic growth. | Yes (CCP 5B holding cooler) |
| | C — None | C — No | | | |
| | P — Foreign Materials | P — No | Container integrity. | | No |
| **Ship** | B — Pathogen Growth | B — No | Low risk, temperature abuse is unlikely to occur, since truck temperatures are sufficient to prevent pathogen growth. | | No |
| | C — None | C — No | | | |
| | P — Foreign Materials | P — No | Container integrity. | | |

| CCP | CRITICAL LIMITS | MONITORING PROCEDURES & FREQUENCIES | MONITORING RECORDS | CORRECTIVE ACTIONS | VERIFICATION PROCEDURES & FREQUENCIES | VERIFICATION RECORDS |
|---|---|---|---|---|---|---|
| CCP 1B Holding Cooler<br><br>Hazard: Pathogen Growth | The cooler temperature is not to exceed 40°F except for periods of defrost. | The temperature of the raw meat storage areas will be taken continuously by a computerized data recorder with an alarm. | Bi-weekly or as necessary a printout of the plant temperatures.<br><br>Non-compliance Log | See the Corrective Action Report for the specific actions taken to bring the CCP under control. Corrective actions may include but are not limited to; Plant management will immediately notify maintenance personnel to repair the cooler. The temperature of the cooler will be brought into compliance as soon as possible. If the increased temperature effects product temperature, the product will be temporarily relocated in another cooler or freezer, a hold may be placed on the cooler to prevent cold air from escaping. | Thermometers. Alarms will be checked and if necessary calibrated on a monthly basis. | Thermometer Calibration Log<br><br>Monthly Verification Log |
| CCP 2B Cured Meat Cooler | Same as CCP1B | The temperature of the cured meat storage areas will be taken continuously by a computerized data recorder with an alarm. | Same as CCP1B | Same as CCP1B | Same as CCP1B | Same as CCP1B |
| CCP 3B Internal Product Temperature | The minimal internal temperature must reach 148°F. | At the end of the cooking, the oven operator or designee will take and record the internal temperature per each product in the oven. The temperature will be taken with a calibrated thermometer. | Smokehouse Log<br><br>Non-compliance Report | Specific corrective actions will be recorded for each deviation from the critical limit. Corrective actions may include but are not limited to: holding in the oven until the temperature is reached, recooking the product, reworking the product, or disposing of the product. | Thermometers will be calibrated on a monthly basis or as necessary.<br><br>Daily review of production records by management Visual Observations of procedures will be conducted on a monthly basis or as necessary. Findings will be recorded on the Monthly Verification Log. | Thermometer Calibration Log<br><br>Monthly Verification Log |
| CCP 4B Smoked Meat Cooler | Same as CCP1B | The temperature of the smoked meat storage areas will be taken continuously by a computerized data recorder with an alarm. | Same as CCP1B | Same as CCP1B | Same as CCP1B | Same as CCP1B |
| CCP 4B Holding Cooler | Same as CCP1B | The temperature of the finished and packaged product areas will be taken continuously by a computerized data recorder with an alarm. | Same as CCP1B | Same as CCP1B | Same as CCP1B | Same as CCP1B |