

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	1-2
<i>HACCP Requirements</i>	1-3
Definitions	1-4
Introduction to the Preliminary Steps	1-5
Introduction to the 7 HACCP Principles	1-6

Section 2 - The Preliminary Steps

Introduction	2-1
Step 1 -Assemble the HACCP Team	2-2
Step 2 -Identify Products/Processes to be Covered.....	2-4
Step 3 - Develop a Complete List of Ingredients, Materials, Equipment and Recipes/Formulations	2-5
Steps 4 and 5 -Develop and Verify a Process Flow Diagram	2-8
Conclusion	2-10

Section 3 -Utilizing the 7 Principles of HACCP

Understanding Hazards and Controls	3-1
Principle 1 -Conduct a Hazard Analysis	3-7
Principle 2 -Identify Critical Control Points	3-15
Principle 3 -Establish Critical Limits for Each Control Point	3-20
Principle 4 -Establish Monitoring Procedures	3-23
Principle 5 -Establish Corrective Actions -	3-26
Principle 6 -Establish Record Keeping Procedures	3-29
Principle 7 -Establish Verification Procedures	3-31

Section 4 - Food Code Requirements

Introduction	4-1
Contents of a HACCP Plan	4-2
Compliance with the HACCP Plan	4-3
Variances and the HACCP Plan	4-3
Reduced Oxygen Packaging	4-5

Section 5 -Sample HACCP Forms

Appendix

Uniform Minnesota Food Code	i
Common Foodborne Bacterial Pathogens	vii
Sample Plan	xv

Section 1: Introduction to Food Safety Systems

About HACCP

What is HACCP?

The **Hazard Analysis Critical Control Point** 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 than 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.

Verification procedures help makes the HACCP plan work correctly.

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 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
<i>Also list procedures for producing the product.</i>

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 ___ oz. Pepper (black) ___ oz. Soy Sauce	___ oz. Sodium Nitrite	
Liquid	Packaging Materials	Other
___ lb. Tap Water	Vacuum Plastic Pouch 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

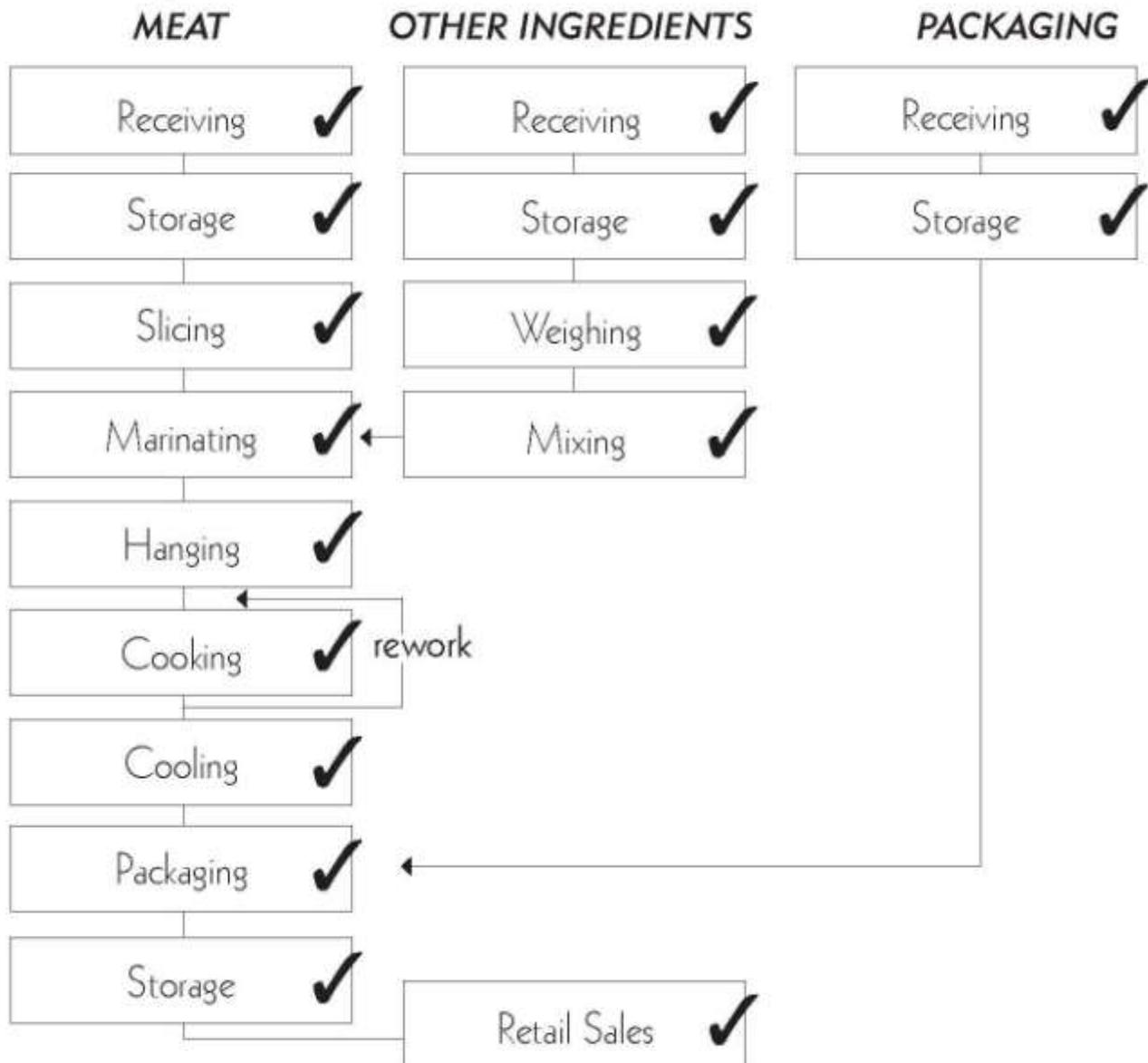
The Example Facility divided their flow diagram into three paths. Each of these paths represents one or more ingredients or raw materials. It made sense to combine certain categories. They grouped all meat items into "Meat", all-nonmeat food ingredients such as spices and preservatives into "Other Ingredients", 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:

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

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.

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 (°F)	pH	Minimum Water Activity (A_w)
<i>Bacillus cereus</i>	39 – 131	4.3 – 9.3	0.92
<i>Campylobacter jejuni</i>	86 – 113.7	4.9 – 9.5	0.99
<i>Clostridium botulinum</i>	38 – 118	A: 4.5 E: 5.9	A: 0.94 E: 0.97
<i>Clostridium perfringens</i>	50 – 125	5.0 – 9.0	0.93
<i>Escherichia coli</i>	45 – 121	4.0 – 9.0	0.95
<i>Listeria monocytogenes</i>	31 – 113	4.4 - 9.4	0.92
<i>Salmonella</i>	41 – 115	3.7 – 9.5	0.94
<i>Shigella</i>	43 – 117	4.8 – 9.3	0.96
<i>Staphylococcus aureus</i>	45 – 122	4.0 – 10	0.83
<i>Vibrios</i>	41 – 111	4.8 – 11	0.94 – 0.97
<i>Yersinia enterocolitica</i>	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 -preservatives (high level of nitrates) -flavor enhancers -color additives
	Indirect food additives -boiler water additives -peeling aids -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 preventative 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.]

Preventive Measures:

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

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.

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.

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.

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: <i>Pesticides</i>	<i>Pathogens</i>	<i>Plastic</i>
<i>Hormones</i>		<i>Bone Fragments</i>

Is the hazard reasonably likely to occur?
 Yes No Yes No Yes No

What is the basis for your decision?

<i>No evidence of any historical occurrence at this facility.</i>	<i>Loss of control in time/temp can promote harmful bacteria growth.</i>	<i>No evidence of any historical occurrence at this facility from this product/source.</i>
-------------------------------------------------------------------	--------------------------------------------------------------------------	--------------------------------------------------------------------------------------------

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

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:		
<i>Residues of sanitizing chemicals</i>	<i>Pathogen survival and growth in finished product.</i>	<i>(None Identified)</i>
Is the hazard reasonably likely to occur?		
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>(None Identified)</i>
What is the basis for your decision?		
<i>Proper use will address this issue.</i>	<i>Loss of control in time/temp or moisture level can promote harmful bacteria growth.</i>	<i>(None Identified)</i>

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

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.

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:

<i>(None Identified)</i>	<i>Pathogen cross-contamination</i>	<i>Plastic</i>

Is the hazard reasonably likely to occur?

Yes No

Yes No

Yes No

(None Identified)

What is the basis for your decision?

<i>(None Identified)</i>	<i>SSOP's for separation</i>	<i>No evidence of any historical occurrence at this facility.</i>

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

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