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.

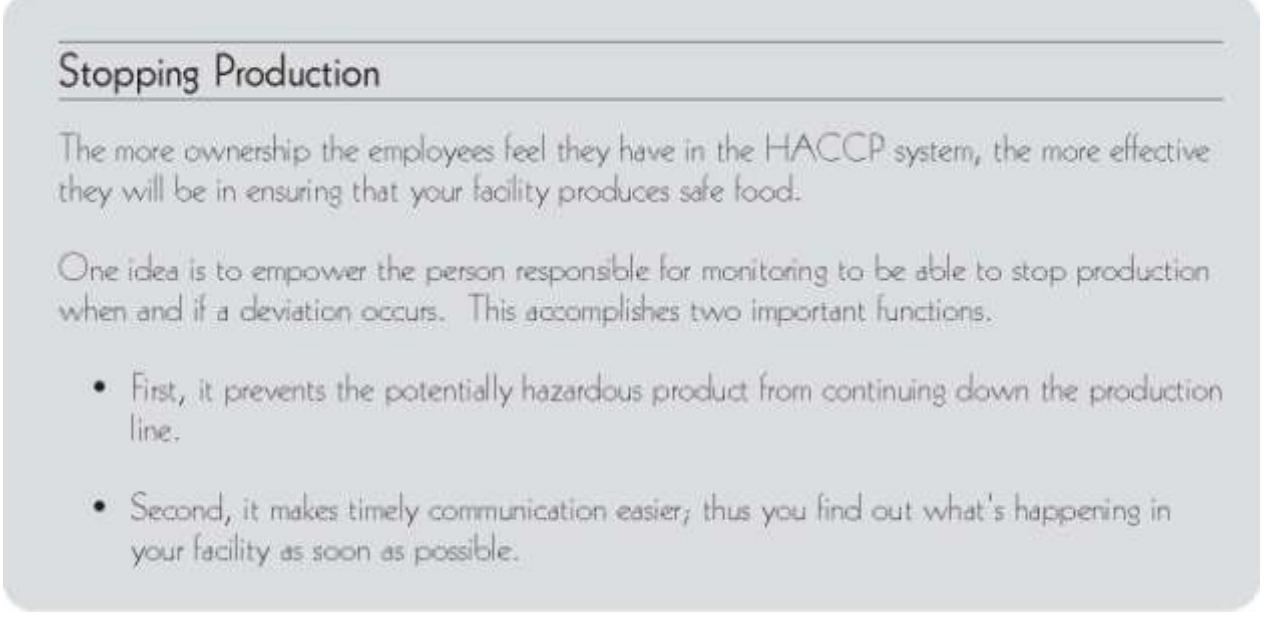
- **Under the "Problem" heading.**
  They state the critical limit that has been established for this CCP.

- **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 Location: Office File Cabinet	Name: HACCP Plan Review Sheet - For each CCP Location: Oven Room Wall	Name: Monitoring Log - For each CCP Location: Oven Room Wall
Name: Deviation / Corrective Action Log Location: Oven Room Wall	Name: Process - Monitoring Equipment Calibration Log - For each CCP Location: Oven Room Wall	Name: Verification Procedures & Results Log - For each CCP 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.

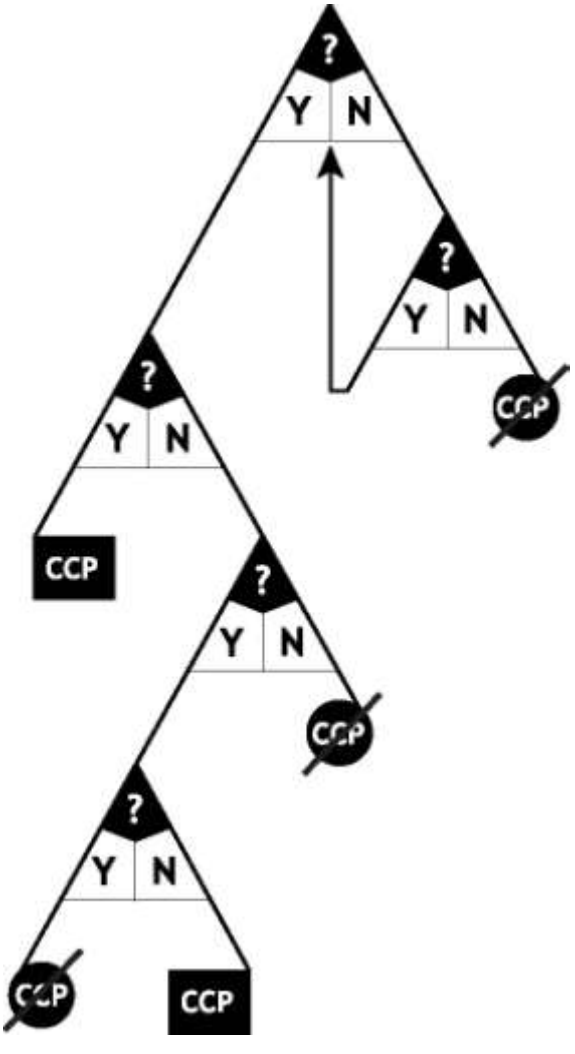
If "yes" - go to Question 4.

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 CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL 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

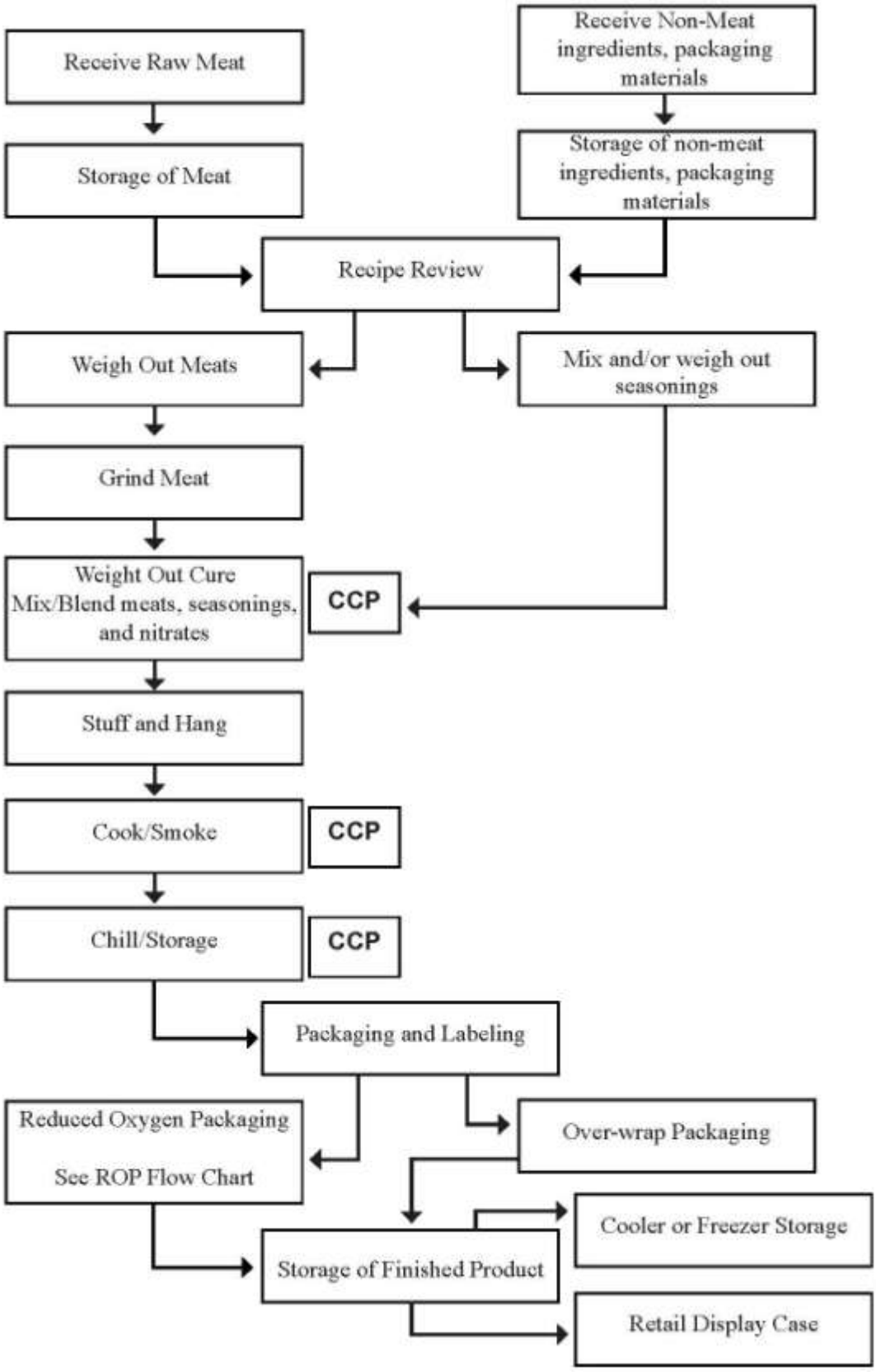
Full batch
- 50 pounds pork trim
- 50 pounds beef trim 6.5 (1 full packet) pounds of XYZ brand Bologna Seasoning
- 4 oz (1 full packet) of Quick Cure 10 pounds water

- 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.