

Module 3: Steps in the Development of the HACCP System and Relationship of HACCP/CGMPs/SSOPs

Goal The goal of this module is for the trainee to have a working knowledge of HACCP systems development, and the relationship of CGMPs and SSOPs. Also, to impart understanding of the variety of ways that industry might approach regulatory compliance.

- Objectives** After completing this module, participants will be able to recognize how the industry may:
1. Evaluate a HACCP specific plan for the presence of “preliminary HACCP” steps used in the creation of the HACCP specific plan. They could include:
 - a. Bringing together HACCP resources.
 - b. Describing the product and its method of distribution.
 - c. Developing a complete list of ingredients and raw materials used in the product.
 - d. Developing a process flow diagram.
 - e. Meeting the regulatory requirements for Sanitation Standard Operating Procedures (SOPs).
 - f. Needing Hazard Analyses for specific processes.
 2. Use a scientific process to identify Critical Control Points (CCPs).
 3. Establish Critical Limits for each identified CCP.
 4. Establish monitoring procedures to ensure that preventive measures necessary for control at each CCP are maintained within the established critical limits.
 5. Establish specific corrective actions for each CCP.
 6. Establish recordkeeping procedures to verify that the HACCP plan is working.
 7. Establish procedures to verify that the HACCP plan is working correctly.
 8. Implement verification procedures to ensure that each CCP and critical limit is adequately controlled and monitored.

9. Implement, for each CCP, procedures to ensure that employees are following established procedures for handling product deviations and for recordkeeping.

Also, upon completion of the training, participants will be able to:

10. Describe how industry might incorporate quality/operating limits along with CCPs.
11. Differentiate between CGMPs, SSOPs, and HACCP.
12. State which are requirements, as opposed to recommendations.
13. Describe the variety of ways that industry may develop plans that meet regulatory requirements.

The guide that follows, "Steps in the Development of HACCP Systems," is a made-up example of the type of guide that establishments may encounter when they learn about HACCP. There are many others. There are also many consultants and organizations, both public and private, that offer seminars for developing HACCP plans. None of the sample forms are official or required forms. They are for teaching purposes only.

After viewing the videotape, the following questions will be discussed.

1. The five preliminary steps are:

- a. _____
- b. _____
- c. _____
- d. _____
- e. _____

2. The preliminary step that the establishment is required to do, is _____.

3. The seven HACCP principles are:

- a. _____
- b. _____
- c. _____
- d. _____
- e. _____
- f. _____
- g. _____

4. An example of a biological hazard is _____.

5. An example of a chemical hazard is _____.
6. An example of a physical hazard is _____.
7. Hazard analysis includes evaluating both the likelihood and _____ of the hazard.
8. Each hazard that is listed should also have a _____ measure identified.
9. When a logical decision process is applied to a process step at which a hazard exists, plus preventive measures can reduce or eliminate the hazard, then that step is a _____.
10. Different establishments preparing the same product can differ in the number and location of their critical control points.

_____ True _____ False
11. Some examples of critical limits are _____.
12. Companies are permitted to set a critical limit that is different from a regulatory requirement provided it is based on _____.
13. An example of continuous monitoring is _____.
14. An example of noncontinuous monitoring is _____.
15. The (establishment? or FSIS?) is responsible for establishing the monitoring frequency that ensures that the CCP is under control.
16. Corrective actions are planned in advance to correct deviations from _____.

17. Two examples of corrective actions are: _____
_____.
18. Two reasons why recordkeeping is important are: _____
_____.
19. Establishments may develop and use their own forms for the records they keep.
_____ True _____ False
20. Verification goes beyond monitoring to determine that the HACCP system is working as intended.
_____ True _____ False
21. Three examples of what the establishment may do to verify its plan are

_____.
22. At least annually, and any time changes occur that could alter the plan, the HACCP plan should be _____.

Steps in the Development of HACCP Systems

Table of Contents	Page
Developing a HACCP Plan	9
Pre-HACCP	
1. Bring Together the HACCP Resources	10
2. Describe the Product and Its Method of Distribution	11
3. Develop a Complete List of Ingredients and Raw Materials	13
4. Develop a Process Flow Diagram	14
5. Meet the Regulatory Requirements for Sanitation	16
Principle 1 Conduct a Hazard Analysis	17
Biological Hazards	17
Chemical Hazards	18
Physical Hazards	19
Conducting a Hazard Analysis	20
Steps in Conducting a Hazard Analysis	23
First Ensure that the prerequisite programs—SSOP and others—are in place	23
Second Observe the actual operating practices in the operation	25
Third Evaluate the likelihood and severity of the hazard's occurrence	25
Preventive Measures	26
Principle 2 Identify Critical Control Points	28
Steps in Identifying Critical Control Points	29
CCP Decision Tree	30
Principle 3 Establish Critical Limits for Each Critical Control Point	34
Steps in Establishing Critical Limits	36
Principle 4 Establish Monitoring Procedures	37

Table of Contents		Page
Principle 5	Establish Corrective Actions	39
	Steps in Establishing Corrective Actions	40
Principle 6	Establish Recordkeeping Procedures	41
	Steps in Establishing Recordkeeping Procedures	42
Principle 7	Establish Verification Procedures	43
	Reassessment	45
	Steps in Establishing Verification Procedures	47
	Validate the HACCP Plan	47
	Finishing the HACCP Plan	49
	HACCP Plan Checklist	50

Developing a HACCP Plan

The Hazard Analysis and Critical Control Points (HACCP) System is a logical, scientific approach to controlling safety problems in food production. When a company adopts HACCP, it puts controls in place at each point in the production system where safety problems could occur from biological, chemical, or physical hazards. To start a HACCP system, a company must first write a HACCP plan. This module explains how to write a HACCP plan in five preparatory steps and then applying the seven HACCP principles.

The five preliminary steps are:

1. Bring together the HACCP resources/assemble the HACCP team.
2. Describe the product and its method of distribution.
3. Develop a complete list of ingredients and raw materials used in the product.
4. Develop a process flow diagram.
5. Meet the regulatory requirements for Sanitation Standard Operating Procedures (SOPs)

The regulatory requirements for Sanitation Standard Operating Procedures (SOPs) must also be met as a prerequisite to HACCP.

Applying the seven HACCP principles is the most important step in writing a HACCP plan. They are:

1. Conduct a hazard analysis.
2. Identify critical control points.
3. Establish critical limits for each critical control point.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish recordkeeping procedures.
7. Establish verification procedures.

Pre-HACCP Step 1—Bring Together the HACCP Resources

The first step is to assemble the HACCP resources. When a company develops a HACCP plan, it is important to bring as much knowledge to the table as possible, including the direct involvement of top management. Actually, industry probably has access to more HACCP resources than they think! In a small establishment, this might mean bringing together one or two employees, one of whom has had HACCP training. The HACCP resources may include outside expertise. This expertise can be obtained through local Extension Offices, trade or professional associations, or a contractor. This will help to bring enough cross-functional expertise to this step to adequately analyze all biological, physical, and chemical hazards. A larger plant may wish to bring in employees from a number of departments, such as production, sanitation, quality control, and engineering, as well as employees directly involved in daily processing activities. There is no magic number of employees needed to write a HACCP plan. It could be one employee or, in a very large company, it could be seven or eight people.

The employee or employees writing the HACCP plan should understand some basic things about the establishment:

1. The technology and equipment used in processing lines;
2. The practical aspects of food operations; and
3. The flow of the process in the plant.

It will be a bonus to the HACCP plan if those employees have some knowledge of the applied aspects of food microbiology and of HACCP principles and techniques, although this knowledge can be supplemented by outside experts.

Pre-HACCP Step 2—Describe the Product and Its Method of Distribution

The second step is to describe completely each food product the plant makes. This can include a brief description of how the process occurs and/or how the product is produced/prepared. This will help identify hazards that may exist either in the ingredients or in the packaging materials.

To describe the product, you might ask the following questions might be asked about the product:

1. Common name?
For example, a cooked sausage could be called franks/hot dogs/wieners.
2. How is it to be used?
Categories might include "ready-to-eat," "to be heated prior to consumption," or "for further processing."
3. The type of package?
For example, is it modified atmosphere packaging?
4. Length of shelf life?
In the cooked sausage example, the length of shelf life might be 30 to 50 days for modified atmospheric packaging.
5. Where will it be sold?
For example, will it be sold wholesale, at retail, or to institutions?
6. Labeling instructions?
"Keep Refrigerated" would be a common labeling instruction for meat and poultry products.
7. How is the product distributed?
For instance, should the product be kept refrigerated at or below 40° F?

A blank sample Product Description Form is included. It can be tailored to any establishment.

PRODUCT DESCRIPTION

PRODUCT:

The following questions are appropriate when developing the product description.

1. Common name?
2. How is it to be used?
3. Type of package?
4. Length of shelf life,
at what temperature?
5. Where will it be sold?
6. Labeling instructions?
7. Is special distribution
control needed?

*Example only!
May vary by plant.*

DATE: _____ APPROVED BY: _____

Pre-HACCP Step 3—Develop a Complete List of Ingredients and Raw Materials

The third step is to develop a written list of ingredients and raw materials for each process/product. It can be written on a very simple form, as shown below. The establishment may wish to divide the ingredients into just two categories: meat (meat such as boneless beef or chicken parts with skin) and other ingredients (such as spices and preservatives). This is determined by the complexity of the product/process covered by the plan.

PRODUCT AND INGREDIENTS	
PRODUCT:	
<div style="border: 1px dotted black; padding: 10px;"><p><i>Example only!</i> <i>May vary by plant.</i></p></div>	

DATE: _____ APPROVED BY: _____

Pre-HACCP Step 4—Develop a Process Flow Diagram

The next step is to construct a process flow diagram that identifies all the steps used to prepare the product, from receiving through final shipment, that are directly under the control of the establishment. The diagram should not be so complex that it is difficult to follow and understand. The diagram must be complete from the beginning of the process to the end. The flow diagram may also include steps that occur before or after the processing occurs in the establishment.

The plant may choose to verify the process flow diagram. This is done by actually walking through the plant to make sure that the steps listed on the diagram describe what really occurs in producing the product.

A sample process flow diagram is included on the following page.

Remember, the purpose of this diagram is to find any places in the establishment at which hazards could occur. (As with all HACCP planning forms, the approving employee should sign and date the form for the records.)

PROCESS FLOW DIAGRAM

Product:

*Example only!
May vary by plant.*

DATE: _____

APPROVED BY: _____

Pre-HACCP Step 5—Meet the Regulatory Requirements for Sanitation

Standard Operating Procedures

Good sanitation is the most basic way to ensure that a safe product is produced. Maintaining good sanitation serves as an excellent foundation for building a HACCP plan. It also demonstrates that plant management has the commitment and resources to successfully implement the HACCP plan. Because it is so important, meeting the regulatory

requirements for Sanitation Standard Operating Procedures (SOPs) is a pre-HACCP requirement that must be carried out in all establishments. In addition to the SSOP's, other prerequisite programs for HACCP can be developed that are extremely useful, such as GMPs covering operating procedures and equipment maintenance. A written plan describing how a recall will be handled, if one is necessary, is also a valuable prerequisite to developing a HACCP plan.

Now the seven principles are ready to be applied to produce a HACCP plan suited to the plant and its process.

Principle 1—Conduct a Hazard Analysis

HACCP Principle No. 1 states:

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

The regulation defines a food safety hazard as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption."

This section will define the hazards and discuss in general where they may occur in meat and poultry production. It will then talk about identifying hazards in the establishment.

Finally, this section will explain how to apply preventive measures to the identified hazards and to ensure that the products are safe for consumers. A preventive measure is defined in the regulation as "physical, chemical, or other means that can be used to control an identified food safety hazard."

To identify biological, chemical, or physical hazards likely to occur, plant management needs to know about the chemical, physical, and microbiological characteristics of meat, poultry, and other ingredients, as well as how various processes affect those characteristics. You also need to understand the interactions among ingredients.

Evaluate each step in the process flow diagram to determine whether a biological, chemical and/or physical hazard may be introduced at that step and whether preventive measures are available. Hazards that are low risk and not likely to occur should be listed on the hazard analysis and the reason that no further consideration is needed should be stated. These determinations should be based on incidence evaluation and/or scientific data.

Biological Hazards

Biological hazards are living organisms, including microorganisms, that can put human health at risk. Biological hazards include bacteria, parasites, protozoa, viruses, and the like.

Agricultural products and food animals carry a wide range of bacteria. From a public health standpoint, most bacteria are harmless. Others—the pathogenic microorganisms—can cause illness or even death in humans. The numbers and types of bacteria vary from one food or animal species to another, from one geographic region to another, and with production and slaughter or harvesting methods. During production, processing, packaging, transportation, preparation, storage, and service, any food may be exposed to bacterial contamination. The most common biological hazards in meat and poultry are microbiological, although biological hazards may also be due to parasites or zoonotic disease processes.

Some of the major pathogenic bacterial organisms that can cause foodborne illness from eating meat or poultry are: *Salmonella*, *Clostridium perfringens*, *Listeria monocytogenes*, *Staphylococcus aureus*, *Campylobacter jejuni*, *Yersinia enterocolitica*, *Bacillus cereus*, *Clostridium botulinum*, and *Escherichia coli* O157:H7.

To thoroughly identify significant biological hazards in the establishment, management needs to evaluate each specific ingredient and processing step in the operation.

Chemical Hazards

Chemical hazards may also cause foodborne illnesses.

Chemical hazards fall into two categories:

1. Naturally occurring poisons or deleterious substances are those that are natural constituents of foods and are not the result of environmental, agricultural, industrial, or other contamination. Examples include aflatoxins, mycotoxins, and shellfish toxins.
2. Added poisonous or deleterious substances are those that are intentionally or unintentionally added to foods at some point in growing, harvesting, storage, processing, packing, or distribution. This group of chemicals can include pesticides, fungicides, insecticides, fertilizers, and antibiotics, as well as direct and indirect food additives. This group can also include chemicals such as lubricants, cleaners, paints, and coatings.

To identify any chemical hazards, plant management needs to determine any chemical residues that might be in the animal. To do this, management should consider:

- The types of drugs and pesticides routinely used in raising the animals that are the source of the meat and poultry ingredients.
- Feeds and supplements fed to the animals.
- Environmental contaminants the animals may have come into contact with. This includes both naturally occurring contaminants and added contaminants.
- Pesticides used on plants that may end up as residues in the animal.
- The source of the water the animals were allowed to drink.

The following preventive measures can be used to help ensure that animals entering the establishment are free of harmful residues:

- Require that the animals have been raised in accordance with the January 1994 FDA Compliance Policy Guidelines.

- Require written assurances from suppliers for each lot of animals, stating that the animals are free of illegal residues.
- Set a maximum allowable residue limit for specific drugs, pesticides, and environmental contaminants in animal urine or tissues as targets to ensure that FDA and EPA tolerances are met.
- Ensure that trucks used to ship the animals do not have chemical hazards that could contaminate the animals.

Most establishments use chemicals during processing and to keep their operations sanitary. Yet they need to be aware that chemical hazards can occur at any of the following points:

- Prior to receiving chemicals at the establishment.
- Upon receiving chemicals.
- At any point where a chemical is used during processing.
- During storage of chemicals.
- During the use of any cleaning agents, sanitizers, lubricants, or other maintenance chemicals.
- Prior to shipment of the finished product.
- In trucks used to ship finished product.

Physical Hazards

A physical hazard is any physical material not normally found in a food that causes illness or injury to the individual using the product. Physical hazards include a variety of foreign materials or objects, such as glass, metal, and plastic. However, foreign objects that cannot cause illness or injury are not hazards, even though they may not be aesthetically pleasing to customers.

A number of situations can result in physical hazards in finished products. They include, but are not limited to:

- Contaminated raw materials.

- Poorly designed or poorly maintained facilities and equipment. An example would be paint chips falling from overhead structures onto exposed product or pieces of metal from worn or improperly maintained equipment entering product.
- Improper procedures or improper employee training and practices. For example, by improper loading on the line by employees, or improper or inadequate condition examination, glass pieces from broken or chipped jars could be included when filling product containers.
- The Sanitation SOPs can be used to identify and control cross-contamination due to employee practices.

Conducting a Hazard Analysis

Once plant management has some understanding of the types of hazards that can occur and how to identify and prevent them, they are ready to conduct a hazard analysis for each process or product covered in the HACCP plan.

A hazard analysis is the identification of any hazardous biological, chemical, or physical property in raw materials and processing steps, and an assessment of their likely occurrence and potential to make food unsafe for consumption.

The hazard analysis needs to be very specific to the establishment and how it makes its product, since hazards may vary greatly from one establishment to another. This is due to differences in sources of ingredients, product formulations, processing equipment, processing methods, duration of the processes and storage, and employee experience, knowledge, and attitude.

One approach to hazard analysis divides it into two activities, brainstorming and risk assessment. Brainstorming should result in a list of potential hazards at each operational step in the process (use a flow diagram) from the receipt of raw materials to the release of the finished product. During brainstorming, the team need not be confined by the hazard's likelihood of occurrence or its potential for causing disease. All potential hazards must be considered. After brainstorming, the team conducts an analysis of the risks and severity of each of the hazards to determine the significance of the food safety hazards. This can be confusing, since it is easy to suggest that any hazard that compromises food safety should be controlled. However, HACCP focuses solely on significant hazards that **are reasonably likely to result in an unacceptable health risk to consumers**. Without this focus, it would be tempting to try to control too much and thus lose sight of the truly relevant hazards.

Plant management needs to review—and perhaps revise—the hazard analysis whenever they make any changes in raw materials suppliers, product formulation, preparation procedures, processing steps, packaging materials or procedures, distribution, or intended use of the product.

On the following page is a blank Hazard Identification/Preventive Measures form that the HACCP team may use for a hazard analysis. The form contains space for the process step in which the hazards could occur, the specific hazards, and preventive measures to keep that hazard from occurring. Remember, HACCP is a preventive system.

HAZARD IDENTIFICATION/PREVENTIVE MEASURES		
PRODUCT/PROCESS:		
PROCESS STEP	HAZARD	PREVENTIVE MEASURES

*Example only!
May vary by plant.*

DATE: _____

APPROVED BY: _____

Biological—B
Chemical—C
Physical—P

Steps in Conducting a Hazard Analysis

First—Ensure that the prerequisite programs—SSOPs and others—are in place. Evaluate the operation for hazards.

A possible plant management scenario is to:

1. Review the product description developed in Pre-HACCP Step 2 and determine how this information could influence a hazard analysis.
2. Look at all product ingredients and incoming materials for the product. This was developed in Pre-HACCP Step 3.
3. For each processing step identified in the process flow diagram, determine if a biological, chemical, or physical hazard could exist.
4. Ask the following questions at each processing step:

Could contaminants reach the product during this processing step? Possibilities include worker handling, contaminated equipment or materials, cross-contamination from raw materials, leaking valves or pipes, dead ends, splashing, etc.

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

Could this step create a situation where an ingredient in a process or finished product became contaminated with pathogens?

Could this step introduce a chemical hazard into the product?

Could this step introduce a physical hazard into the product?

Are the hazards addressed in the SSOP?

5. Fully describe the hazards identified for each step.
6. For each incoming ingredient and material, indicate if a biological, chemical, or physical hazard exists.

7. Ask the following questions about each ingredient:

Could this ingredient contain any pathogenic microorganisms, toxins, chemicals or physical objects?

If it became contaminated or were mishandled, could this ingredient support the growth of pathogenic microorganisms?

Are any hazardous chemicals used in growing, harvesting, processing, or packaging the ingredient?

Is this ingredient hazardous if used in excessive amounts?

If this ingredient were left out or used in amounts lower than recommended, could it result in microbial growth?

Are any chemical or physical hazards associated with this ingredient?

8. Ask the following questions about the product/process in general:

Have any livestock entering the slaughter establishment been exposed to hazardous chemicals?

Are any returned/reworked products used as ingredients? If so, could they cause a hazard?

Are preservatives or additives used in the product formulation to kill or inhibit the growth of microorganisms?

Do the amount and type of acid ingredients, and the resulting product pH, affect the growth/survival of microorganisms?

Does the water activity of the finished product affect microbial growth?

Should refrigeration be maintained for products during transit or in storage?

Are any chemical or physical hazards associated with any packaging materials?

9. Fully describe the hazards identified and assess the significance of the hazard based on available scientific and technical literature. This information can be obtained through public libraries, universities, trade associations, in-plant expertise, and/or extension services. This will help assess the risk, severity, and significance of the hazards identified.

Second—Observe the actual operating practices in the operation.

After describing the hazards identified with each step, plant management may:

1. Observe the actual operation in the establishment and be sure that it is the usual process or practice.
2. Observe employee practices where raw or contaminated product could cross-contaminate workers' hands, gloves, or equipment used for finished/post-process products.
3. Observe product handling past any kill step for potential cross-contamination. This includes studying traffic patterns in the establishment.

Third—Evaluate the likelihood and severity of an occurrence of the hazard.

The hazard evaluation is usually conducted after the list of potential hazards are assembled. During this stage, each hazard is evaluated based on **the likely occurrence of the hazard** and the severity of the consequences of exposure to the hazard. The estimate of **likelihood of occurrence** is usually based upon a combination of experience, epidemiological data, and information in the technical literature. When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and severity of the potential consequences if the hazard is not properly controlled. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage, and the nature of the consumers likely to purchase the product should be considered to determine how each of these factors may enhance or diminish the public health impact of the hazard being considered. The team must determine if the manner in which the food is likely to be stored and prepared or whether the food is specifically intended for consumption by a group that may be more susceptible to a particular agent will influence the safety of the food.

A summary of the HACCP team deliberations and the rationale developed during the hazard analysis should be kept for future reference. These documents provide information that will be useful during the periodic review and updating of the hazard analysis and the HACCP plan as well as for conducting a hazard analysis on a similar product.

Preventive Measures

The HACCP team should have identified all significant biological, chemical, and physical hazards for each processing step and each ingredient. Now it is time to identify measures to prevent hazards from compromising the safety of the finished product. The team is now ready to fill in the preventive measures column of the Hazard Identification/Preventive Measures Form.

Remember, HACCP defines a preventive measure as “physical, chemical, or other means that can be used to control an identified food safety hazard.”

Some examples of preventive measures are:

- Use only approved chemicals.
- Have detailed product specifications for chemicals entering the plant.
- Maintain letters of guaranty from suppliers.
- Inspect trucks used to ship finished product.
- Properly label and store all chemicals.

Measures to take to prevent physical hazards include, but are not limited to:

- Make sure the plant specifications for building design and operation are accurate and updated regularly.
- Make sure the letters of guaranty for ingredients and product supplies are accurate and updated regularly.
- Perform random visual examinations of incoming product and materials.
- Use magnets and metal detectors to help find metal fragments that would be a physical hazard.
- Use stone traps and bone separators to remove these potential physical hazards.
- Keep equipment well maintained.
- Train employees to identify potential problems.

Some other examples of preventive measures are:

- In beef slaughter, a chemical hazard could result from animals having high levels of drug residues. A preventive measure would be to reject or cull animals from a supplier on the basis of failure to present residue certification for all live animals presented for slaughter.
- In poultry slaughter, the venting, opening, and evisceration process could result in a biological hazard from cross-contamination by pathogenic microorganisms. Preventive measures for this hazard would be: use Good Manufacturing Practices (GMPs) at all times; properly maintain and operate equipment used to perform these tasks; and rinse food contact surfaces on equipment with chlorinated water between each carcass.
- In the grinding step for cooked sausage, a physical hazard could be metal fragments from the grinding equipment. There could be three different preventive measures for this hazard. The plant could inspect the grinding equipment daily to ensure that it is assembled and operated correctly, is functioning properly, and is not worn or damaged. It could have an employee visually examine the product at the packaging step. Or it could use a metal detector at the packaging step.
- In many operations, the packaging step could pose chemical hazards from the packaging materials. A preventive measure could be a letter of guaranty from the supplier that the packaging materials are all food grade.

Once the team has identified preventive measures and written them on the form, it is ready to go on to the next step in developing a HACCP plan.

Principle 2—Identify Critical Control Points

HACCP Principle No. 2 states:

"Identify the Critical Control Points (CCPs) in the process."

A Critical Control Point (CCP) 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."

So far, in developing a HACCP plan, the team has identified biological, chemical, and physical hazards in the raw materials and ingredients used, and in the steps of the process. It also identified preventive measures, if they exist, for each hazard identified. With this information, the next step is to identify the points in the process at which the preventive measures can be applied to prevent, eliminate, or reduce the hazard. Then it can use the CCP Decision Tree or other decision tree, or a logical process to assess each step in the process to determine whether it is a critical control point. The decision tree is applied only upon completion of the hazard identification and assessment. (Many control points may not be critical; often, companies starting out in HACCP identify too many control points.)

Fortunately, a great deal of work has already been done in identifying CCPs. Many CCPs are already recognized in various food processing and production systems. Some common CCPs are:

- Chilling, when appropriate.
- Cooking that must occur for a specific time and temperature in order to destroy microbiological pathogens.
- Product formulation controls, such as addition of culture or adjustment of pH or water activity.
- Certain processing procedures, such as filling and sealing cans.
- Certain slaughter procedures, such as evisceration.

These are just a few examples of measures that may be CCPs.

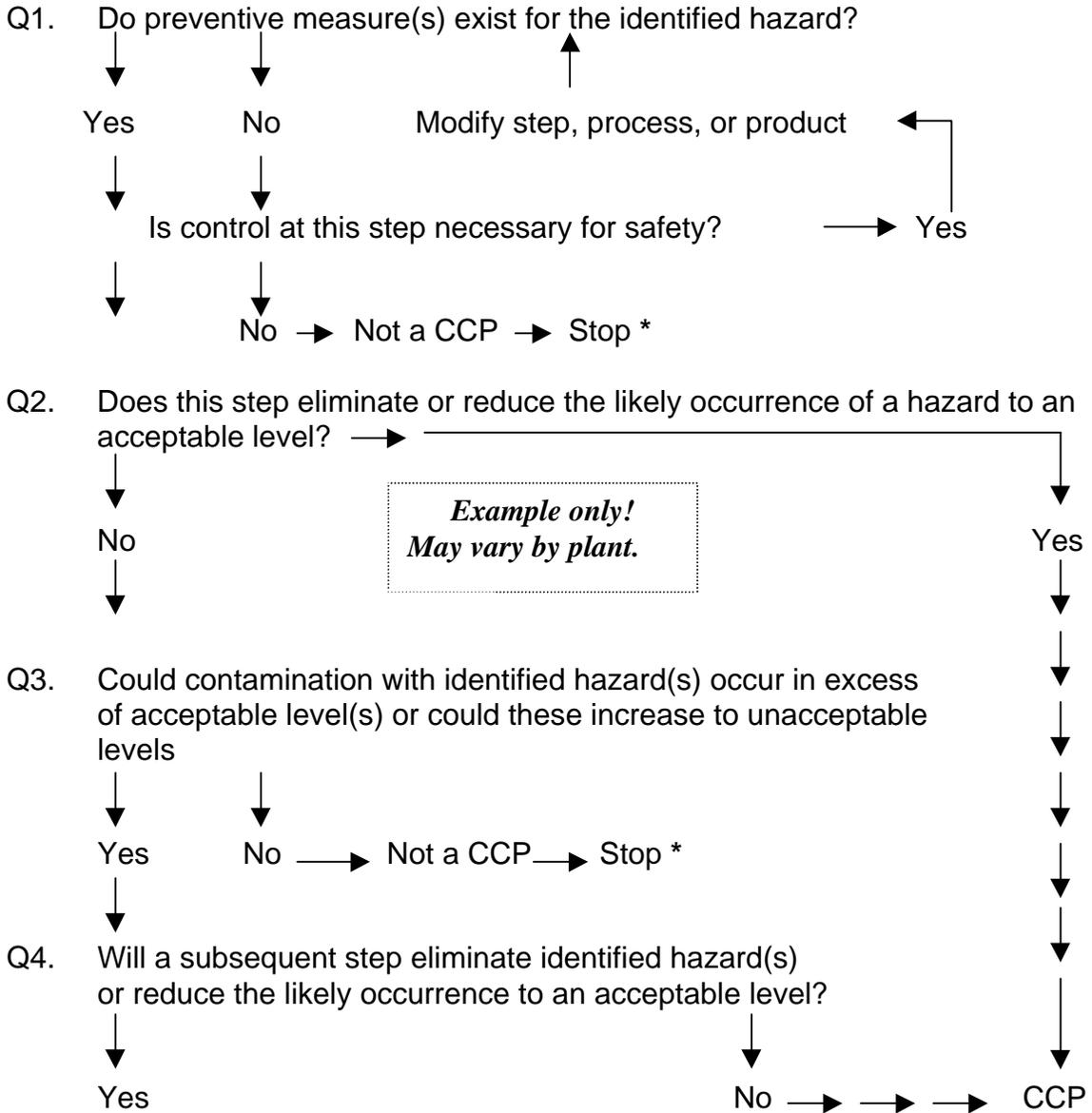
There are many more possibilities. Different facilities, preparing the same food, can differ in the number and location of hazards and the points, steps, or procedures that are critical control points. This is due, in part, to differences in plant layouts, equipment used, selection and sources of raw materials and ingredients, or the process that is used.

Steps in Identifying Critical Control Points

The Decision tree is an example of a tool that can be used for identifying Critical Control Points. The CCP Decision Tree was developed to help companies separate CCPs from other controls such as SSOP's, GMPs, or other operating procedures. The HACCP team will get the best results if it uses the Decision Tree very methodically and uses simple, descriptive, and familiar wording. The Decision Tree should be applied at each step in the process at which there is an identified hazard.

CCP DECISION TREE

(Apply at each step of the process with an identified hazard.)



* Proceed to the next step in the described process.

Determining whether a process step is a CCP is really a basic exercise of answering four questions. To use the form and the Decision Tree, follow the next six steps:

1. In Column 1 of the Critical Control Point Determination Form, write in each step in the process where there is an identified hazard.
2. In Column 2, write in each identified hazard, indicating whether it is biological, chemical, or physical. Then take the information written on the Hazard Identification/Preventive Measures form and answer the following questions for each hazard identified.
3. Question #1--Do preventive measures exist for the identified hazard?
{Note: From a regulatory standpoint, no further action is necessary if the hazard is not reasonably likely to occur.}

If the answer is yes, write "YES" and proceed to the next question.

If the answer is "NO," ask the question "Is control at this step necessary for safety?"

If control is not necessary at this step in the process, this process step is not a CCP. Write "NO" in Column 3 and write how and where this hazard will be controlled. Proceed to the next process step and identified hazard entered in Columns 1 and 2.

If control is necessary, in Column 3 explain how the step, process, or product will be modified to ensure safety.

Once the step, process, or product has been modified, return to Question #1.

4. Question #2--Does this step eliminate or reduce the likely occurrence of the hazards to an acceptable level?

If the answer is yes, write "YES" in Column 4 and identify the step as a CCP in Column 7.

If the answer is no, write "NO" in Column 4 and proceed to the next question.

5. Question #3--Could contamination with the identified hazards occur in excess of acceptable levels or could these increase to unacceptable levels?

If the answer is yes, write "YES" in Column 5 and proceed to the next question.

If the answer is no, write "NO" in Column 5, indicating that the step is not a CCP.

Then proceed to the next process step and hazard.

6. Question #4--Will a subsequent step eliminate the identified hazard or reduce the likely occurrence to an acceptable level?

If the answer is yes, write "YES" in Column 6, indicating that the step is not a CCP. Then write down which processing step will reduce the hazard to acceptable levels. Then proceed to the next process step and hazard.

If the answer is no, write "NO" in Column 6 and identify the step as a CCP in Column 7.

Principle 3—Establish Critical Limits for Each Critical Control Point

HACCP Principle No. 3 states:

"Establish critical limits for preventive measures associated with each identified CCP."

The regulation defines critical limit 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 are expressed as numbers or specific parameters based on visual observation, such as:

- Time/temperature
- Humidity
- Water activity
- pH
- Salt concentration
- Chlorine level

Many critical limits for identified CCPs have already been established. These limits are found in sources such as regulatory requirements, scientific literature, experimental studies, and through consultation with experts.

The HACCP team may wish to establish critical limits that differ from regulatory requirements. These limits must be based on sound scientific data. However, critical limits must always ensure that the result produces a safe/unadulterated product.

In some cases, more than one critical limit is needed to control a particular hazard. For example, the critical limits for cooked beef patties are time/temperature, patty thickness, and conveyor speed.

Critical Limits, Monitoring, and Corrective Actions			
Product:			
Process Step/CCP	Critical Limits	Monitoring Procedures (who/what/when/how)	Corrective Actions
		<div style="border: 1px dashed black; padding: 5px; display: inline-block;"> <i>Example only! May vary by plant.</i> </div>	

Date: _____

Approved by: _____

Steps in Establishing Critical Limits

1. For each identified CCP, plant management needs to establish critical limits that are adequate to maintain control and prevent a food safety hazard. This is the responsibility of each establishment. Plant management may wish to obtain the assistance of outside HACCP experts, use scientific reports, FSIS regulatory limits etc., to help determine critical limits for CCPs. Once critical limits are identified, enter them into the critical limit column of the form.
2. For future reference, any documentation such as letters from outside HACCP experts or scientific reports supporting the identified critical limits should be on file. This documentation will help validate that the limits have been properly established. In addition, the plant should keep on file any test results that show its early experience in implementing the HACCP plan, to demonstrate that what is written can be implemented and made to work.

NOTE: Plant management may decide to set an operating limit that is more restrictive than the critical limit. Normal deviations would then be less likely to pass the critical limit. For example, if the critical limit was to heat to at least 160° F, the operating limit might be set at 162° F.

Principle 4—Establish Monitoring Procedures

HACCP Principle No. 4 states:

"Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control."

Monitoring is 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.

Monitoring is essential to a HACCP system. Monitoring can warn the plant if there is a trend towards loss of control, so that it can take action to bring the process back into control before a critical limit is exceeded. For example, say that an establishment tests the pH of a batch of product at 6 a.m., 7 a.m., and 8 a.m. Each time, the pH is within acceptable limits, but it is steadily climbing towards the high end of the range. This information is showing a trend and the establishment should take action to prevent the pH from exceeding the critical limits.

Monitoring may be continuous or noncontinuous. Continuous monitoring at a CCP usually is done with measuring equipment, such as automatic time-temperature equipment used at a cooking step. Continuous monitoring is better because it results in a permanent record that can be reviewed and evaluated to ensure that the CCP is under control. However, the plant should regularly check continuous monitoring equipment for accuracy.

The plant should use noncontinuous monitoring procedures when continuous monitoring is not feasible. Noncontinuous monitoring can include visual examinations; monitoring of ingredient specifications; measurements of pH, water activity (A_w), and product temperatures; attribute sampling; and the like. When it uses noncontinuous monitoring, it must ensure that the frequency of monitoring is enough to ensure that the hazard is under control and that the monitoring is performed at random times. For instance, each plant needs to set its own times and frequency for checking the cooking time/temperature of products. This may vary from one establishment to another because of differences in plant size, plant layout, the type of product, the length of time for processing, and the product flow.

Each establishment has the responsibility to establish a frequency that ensures that the CCP is under control. In some cases, it may have to perform tests at a CCP or use statistically based sampling.

Monitoring will go much more smoothly if the plant:

- Clearly identifies employees responsible for monitoring.
- Trains employees monitoring the CCPs in the testing procedures, the critical limits established, the methods of recording test results, and actions to be taken when critical limits are exceeded.
- Ensures that the employees understand the purpose and importance of monitoring.

Steps in Establishing Monitoring Procedures

Plant management can identify monitoring procedures for the HACCP plan by doing the following:

1. For each CCP, identify the best monitoring procedure.
2. Determine the frequency of monitoring for each CCP.
3. Determine if the monitoring activity needs to be done randomly to get a good representation of the product throughout the day's production. If it does, decide how the random monitoring will be done.
4. Determine what testing procedures need to be done for each monitoring function. For example, will the plant need to do a chlorine check or a temperature measurement?
5. Identify and train employees responsible for monitoring.
6. Make sure that employees doing the monitoring sign all records and documents associated with CCP monitoring. Also make sure that the monitoring results are documented or recorded at the time the monitoring takes place.
7. Enter the above information in the monitoring column of the form.

Principle 5—Establish Corrective Actions

HACCP Principle No. 5 states:

"Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit."

The regulation defines corrective action as "procedures to be followed when a deviation occurs." A deviation is a failure to meet a critical limit.

Since HACCP is a preventive system to correct problems before they affect the safety of the food, plant management has to plan in advance to correct potential deviations from established critical limits. Once the HACCP plan is in place, any time a critical limit is not met, the plant will need to take corrective actions. Those corrective actions should include:

1. Determining the disposition of noncomplying product;
2. Correcting the cause of the noncompliance to prevent a recurrence;
3. Demonstrating that the CCP is once again under control by examining the process or product again at that CCP and getting results that are within the critical limits;
4. Maintaining records of the corrective actions. Not all deviations can be anticipated; therefore, it is recommend that the statement "other actions as appropriate" be included with the specific corrective action.

Under HACCP, plant management determines in advance what it will do when a critical limit is not met at a CCP. The employees monitoring CCPs should understand this process and be trained to perform the appropriate corrective actions. It is important that an establishment record all corrective actions and that employees responsible for taking the corrective actions sign all the documentation. Not all corrective actions can be anticipated. If a corrective action is taken that is not listed in the HACCP plan, this should be recorded on the appropriate document.

In some cases, the product in question will be held for further investigation of the deviation. This investigation may require a thorough record review, product testing, or consultation with a processing authority.

Some examples of corrective actions are:

- Immediately adjust the process and hold product for further evaluation and disposition.
- Empower employees to stop the line when a deviation occurs, hold all product not in compliance, and call in the quality control manager, supervisor, other individual.
- Rely on an approved alternate process that can be substituted for the one that is out of control at the specific critical control point. For example, if the in-line eviscerators in a poultry slaughter plant are malfunctioning, evisceration can be done by hand as long as Good Manufacturing Practices (GMPs) are followed.

Regardless of the corrective actions taken, the plant needs to keep records that include:

- Deviation that was identified.
- Reason for holding the product; the time and date of the hold; the amount of product involved; the disposition and/or release of product; and the individual who made the disposition decision.
- Actions to prevent the deviation from recurring. This may involve reassessment and/or revision of the HACCP plan.

Steps in Establishing Corrective Actions

Plant management must:

1. For each CCP, determine the corrective action to take if the critical limits are exceeded. Determine what should be done with the product if a deviation occurs at this step. There may be more than one corrective action for a CCP.
2. Develop the record form to capture all the necessary information on the deviation, and identify the employee responsible for maintaining and signing the record.
3. Ensure that employees conducting the monitoring at each CCP are fully trained and know the corrective actions to take if a deviation occurs.
4. Enter the appropriate corrective actions for each CCP in the corrective action column of the HACCP form and identify the record that will be maintained.

Principle 6—Establish Recordkeeping Procedures

HACCP Principle No. 6 states:

“Establish effective recordkeeping procedures that document the HACCP system.”

Maintaining proper HACCP records is an essential part of the HACCP system. Good HACCP records—meaning that they are accurate and complete—can be very helpful because:

- Records serve as written documentation of the establishment's compliance with its HACCP plan.
- Records allow the plant to trace the history of an ingredient, in-process operations, or a finished product, should problems arise.
- Records help identify trends in a particular operation that could result in a deviation if not corrected.
- If the event of a product recall, HACCP records could help identify and narrow the scope of such a recall.
- Well-maintained records are good evidence in potential legal actions against an establishment.

In accordance with HACCP principles, the HACCP system should include records for CCPs, establishment of critical limits, handling of deviations, results of verification activities, and the HACCP plan, including the hazard analysis.

In many cases, the records the plant currently maintains may be sufficient to document the HACCP system. Records must contain at least the following information: title and date of record; product identification; critical criteria or limits; a line for the monitor's signature; a place for the reviewer's signature; and an orderly manner for entering the required data.

Steps in Establishing Recordkeeping Procedures

Plant management may:

1. Develop any forms necessary to fully record corrective actions taken when deviations occur.
2. Develop forms to document the HACCP system.
3. Identify the employees responsible for entering monitoring data into the records and ensure that they understand their roles and responsibilities.
4. Enter the record form names on the appropriate HACCP Plan Form or HACCP worksheet under the column adjacent to the appropriate CCP.
5. Enter the appropriate record form names on the Recordkeeping and Verification Form under the verification procedures column adjacent to the appropriate CCP.

Principle 7—Establish Verification Procedures

HACCP Principle No. 7 states:

"Establish procedures to verify that the HACCP system is working correctly."

After a HACCP plan has been put into place, verification activities occur on an ongoing basis. Verification entails the use of methods, procedures, or tests in addition to those used in monitoring, to determine whether the HACCP system is operating as intended.

Simply stated, the plant needs to verify that the HACCP system is working the way it is expected to work. Several examples are the calibration of process monitoring instruments at specified intervals, direct observation of monitoring activities, and corrective actions. These should be included in the HACCP plan in addition to the critical limits, monitoring, and corrective actions and should be defined at each CCP. Plant management should also make sure that employees are following the procedures for taking corrective actions when a critical limit is exceeded. Finally, plant management should check to see that the employees are keeping specific, accurate, and timely HACCP records.

By doing these things, the plant will evaluate the day-to-day operation of the HACCP system. Plant management shouldn't be surprised to find that it needs to fine-tune the HACCP plan.

Some things it can do to verify the HACCP system are:

- Analytically test or audit the monitoring procedures;
- Calibrate the temperature equipment;
- Sample the product, including microbiological sampling;
- Review the monitoring records;
- Review the records of deviations and product dispositions;
- Inspect and audit the establishment's operations;
- Sample for environmental and other concerns.

Validation of a Hazard Analysis Critical Control Point (HACCP) plan is the process by which an establishment demonstrates that what is written in the HACCP plan and implemented in the establishment actually prevents, eliminates, or reduces to a regulated and commercially feasible and appropriate level, identified microbiological, chemical, and physical hazards. Validation is exclusively the responsibility of the regulated industry.

It is the process through which a company assembles data showing the HACCP plan it will use will work to control the process and prevent food safety hazards.

Data assembled to validate a HACCP plan may be derived from various sources, including the scientific literature, product testing results, experimental research results, scientifically based regulatory requirements, official Agency guidelines, computer modeling programs, and data developed by process authorities. Companies have considerable flexibility in assembling data to validate a HACCP plan, both with regard to the sources and the quantity of such data. Data can be derived from a combination of published scientific studies on a specific process that include the results of microbiological testing in conjunction with the results of at least three in-plant validation studies. A combination of the results of process procedures from a processing authority could also be used in conjunction with in-plant testing and letters of guaranty for equipment specifications on the tolerance for detecting physical hazards. However, FSIS believes that validation data for any HACCP plan needs to include results reflecting actual hazard characteristics of product produced using the HACCP plan. For example, validation data supporting a HACCP plan for slaughter should include some data about the generic *E. coli* levels in the product. *E. coli* serves as a useful and effective indicator organism. Its levels can be correlated to the potential presence of other pathogenic organisms such as *Salmonella*. When indicator organisms are used, a decrease in the level of the indicator should be correlated to some expected effect on other pathogenic organisms that may be present at much lower levels or be difficult to ascertain. The present regulatory requirements for the production of cooked beef, roast beef, and cooked corned beef and for cooked uncured beef patties illustrate scientifically based processing times, temperatures, and conditions for these processes that can serve as a basis for validation. In slaughter operations, data to substantiate the use and efficacy of trisodium phosphate or chlorine in chiller water also illustrate the types of data that can be used to validate critical limits at identified critical control points in a process.

Reassessment

In addition to the on-going validation activities that are conducted, reassessment to determine that HACCP system is adequate should be done by each establishment at least annually.

Reassessment of the HACCP plan is necessary when potential new hazards have been identified that may be introduced into the process or product via emerging pathogens; new ingredients; new, different, or additional process steps or procedures; or the introduction of new or different processing equipment.

Reassessment of the HACCP plan and system should also occur when there are changes in the process, ingredients, raw materials or source of raw materials, formulation, production volume, personnel, packaging, finished product distribution, or any other change that could effect the hazard analysis or that was not included in the original hazard analysis.

The reassessment should be performed by someone who is trained in HACCP. The reassessment should cover a review of the existing HACCP plan and system including the hazard analysis, critical control points, critical limits, monitoring procedures, record keeping, and corrective actions to determine that they still ensure process control over food safety hazards.

Recordkeeping and Verification		
Product:		
Process Step/CCP	Records	Verification Procedures

*Example only!
May vary by plant.*

Date: _____ Approved by: _____

Steps in Establishing Verification Procedures

The plant may:

1. Determine the appropriate verification procedure to ensure that each CCP and critical limit is adequately controlled and monitored.
2. For each CCP, determine procedures to ensure that employees are following the established procedures for handling product deviations and for recordkeeping.
3. Identify the frequencies for conducting any verification checks and the records where the results will be recorded.
4. Enter the details on the appropriate verification form for future reference.

Validate the HACCP Plan

It is very important to validate the HACCP plan. The regulation defines validation as "the scientific and technical process for determining that the CCPs and associated critical limits are adequate and sufficient to control likely hazards." Plant management will probably first want to review the HACCP plan to determine whether the CCPs and critical limits established are really the right ones and that they are controlled and monitored adequately.

Simply put, when plant management validates its HACCP plan, it demonstrates what it has written and put into place can actually prevent, eliminate, or reduce the levels of hazards that it has identified.

To validate the HACCP plan, plant management needs to assemble information to show that the HACCP plan will work to control the process and to prevent food safety hazards. There are two types of information that should be collected. First, gather likely supporting scientific information, such as studies that establish the time and temperatures necessary to kill certain harmful bacteria, results of past instances of physical contamination, and results of test for residues. Second, gather practical information, such as test results from products produced under the HACCP plan. An example of a test might be microbiological analysis of the finished, ready-to-eat products or periodic indicator testing to confirm the anti-microbial interventions in slaughter plants are effective. There are many sources of information to validate the HACCP plan, including the scientific literature, product testing results, experimental research results, scientifically based regulatory requirements, official FSIS guidelines, or information developed by process authorities. Remember, the purpose of the validation is to ensure that the parameters stipulated in the HACCP system are adequate to ensure process control.

Plant management has a great deal of flexibility in assembling the information to validate the plan, in terms of both source and quantity of information. For example, a slaughter plant should validate that its plan ensures residue control to prevent violative levels of

chemicals, animal drugs, or pesticides in carcasses. A slaughter plant might choose to purchase animals only from suppliers who provide veterinary certifications that the animals have been raised under a program that ensures that all animal drugs, pesticides, and other chemicals are properly used. In this situation, the establishment could validate this critical control point with the following information: a copy of the residue prevention program under which the producer is certified; a report of an on-site visit to the feedlot; and results of analyses of carcasses for compounds of concern.

Validation is simpler in HACCP plans for products such as cooked beef, roast beef, or cooked corned beef. Current regulatory requirements for these products include scientifically based processing times, temperatures, and handling requirements. The HACCP plan would need only to reflect these regulatory requirements; additional information would be unnecessary. In this case, a minimal number of product analyses to demonstrate that hazards of concern, such as *Salmonella*, were not found in the products produced under the HACCP plan need be taken.

It is important that the HACCP plan is reassessed at least once a year. Some changes that will require reassessment are listed below. Changes other than those listed may also compel reassessment.

1. Potential new hazards are identified that may be introduced into the process for the product.
2. New ingredients may be added or the ingredient supplier changed.
3. The process steps or procedures may change.
4. New or different processing equipment are introduced.
5. Production volume changes.
6. The end point consumer for the product or the distribution system changes.
7. Personnel changes.

Finishing the HACCP Plan

Plant management is now ready to assemble all the information into one HACCP Plan. It is important for the records that plant management assemble all its information into a final HACCP plan. A tool that plant management may choose to use to make sure the HACCP plan is complete is the checklist provided in the next section. The HACCP plan should be reviewed in its entirety and signed and dated by the responsible establishment official/approving employee.

Now plant management is ready to put its HACCP plan into action and make HACCP a reality in its establishment.

HACCP Plan Checklist

Plant management might use a HACCP Plan Checklist similar to the one provided in this section to ensure that its HACCP plan adequately addresses all seven HACCP principles.

When completing the checklist, if the answer to any question is "NO," plant management needs to reevaluate that section of the HACCP plan and make whatever modifications are necessary. Some modifications may require the assistance of recognized HACCP experts.

Any time major changes to the HACCP plan based upon product or process modifications are made, it would be advisable to review the checklist to ensure that the revisions are acceptable.

Plant management can keep the HACCP Plan Checklist as part of the HACCP plan for future reference and to provide documented evidence that the HACCP plan addresses all seven HACCP principles.

ESTABLISHMENT NO. _____

PRODUCT/PROCESS _____

DATE _____

Checklist

HACCP Plan		
<p>A. DESCRIBE THE PRODUCT</p> <ol style="list-style-type: none"> 1. Does the HACCP plan include: <ol style="list-style-type: none"> a. The producer/establishment and the product name? b. The ingredients and raw materials used along with the product receipt or formulation? c. The packaging used? d. The temperature at which the product is intended to be held, distributed, and sold? e. The manner in which the product will be prepared for consumption? 2. Has a flow diagram for the production of the product been developed that is clear, simple, and descriptive of the steps in the process? 3. Has the flow diagram been verified for accuracy and completeness against the actual operating process? 	YES	NO
<p><i>Example only! May vary by plant.</i></p>		
<p>B. CONDUCT A HAZARD ANALYSIS</p> <ol style="list-style-type: none"> 1. Have all steps in the process been identified and listed at which hazards of potential significance occur? 2. Have all hazards associated with each identified step been listed? 3. Has the likelihood and severity of the risk for each hazard been assessed? 4. Have preventive measures to control the identified hazard been identified, if they exist, and listed? 	YES	NO
<p>C. IDENTIFY CRITICAL CONTROL POINTS</p> <ol style="list-style-type: none"> 1. Has the CCP Decision Tree been used to help determine if a particular step is a CCP for a previously identified hazard? 2. Have the CCPs been entered on the forms? 3. Have monitoring frequencies been established? 4. Have all significant hazards identified during the hazard analysis been addressed? 	YES	NO
<p>D. ESTABLISH CRITICAL LIMITS</p> <ol style="list-style-type: none"> 1. Have critical limits been established for each preventive measure at each CCP? 2. Has the validity of the critical limits to control the identified hazard been established? 3. Were critical limits obtained from the regulations, processing authority, etc.? 4. Is documentation attesting to the adequacy of the critical limits maintained on file at the establishment? 	YES	NO
<p>E. ESTABLISH MONITORING PROCEDURES</p> <ol style="list-style-type: none"> 1. Have monitoring procedures been developed to ensure that preventive measures necessary for control at each CCP are maintained within the established critical limits? 2. Are the monitoring procedures continuous or, where continuous monitoring is 	YES	NO

HACCP Plan		
<p>not possible, is the frequency of monitoring sufficiently reliable to indicate that the hazard is under control?</p> <ol style="list-style-type: none"> 3. Have procedures been developed for systematically recording the monitoring data? 4. Have employees responsible for monitoring been identified and trained? 5. Have employees responsible for reviewing monitoring records been identified and trained? 6. Have signatures of responsible individuals been required on the monitoring records? 7. Have procedures been developed for using the results of monitoring to adjust the process and maintain control? 		
<p>F. ESTABLISH CORRECTIVE ACTIONS</p> <ol style="list-style-type: none"> 1. Have specific corrective actions been developed for each CCP? 2. Do the corrective actions address: <ol style="list-style-type: none"> a. Reestablishment of process control? b. Disposition of affected product? c. Procedures to correct the cause of noncompliance and to prevent the deviation from recurring? 3. Have procedures been established to record the corrective actions? 4. Have procedures been established for reviewing the corrective action records? 	YES	NO
<p>G. ESTABLISH RECORDKEEPING PROCEDURES</p> <ol style="list-style-type: none"> 1. Have procedures been established to maintain the HACCP plan on file at the establishment? 2. Do the HACCP records include: <ul style="list-style-type: none"> Description of the product and its intended use? Flow diagram for the process, indicating CCPs? Preventive measures? Critical limits? Monitoring system: Corrective action plans for deviations from critical limits? Recordkeeping procedures for monitoring? Procedures for verification of the HACCP system? 	YES	NO
<div style="border: 1px dashed black; padding: 5px; display: inline-block;"> <p><i>Example only! May vary by plant.</i></p> </div>		
<p>H. ESTABLISH VERIFICATION PROCEDURES</p> <ol style="list-style-type: none"> 1. Have procedures been included to verify that all significant hazards were identified in the HACCP plan when it was developed? 2. Have procedures been included to verify that the critical limits are adequate to control the identified hazards? 3. Are procedures in place to verify that the HACCP system is functioning properly? 4. Are procedures in place to reassess the HACCP plan and system on a regular basis or whenever significant product, process, or packaging changes occur? 5. Are procedures in place for HACCP plan validation? 6. Are procedures in place for HACCP plan reassessment? 	YES	NO

HACCP PLAN

Product: _____

Process Step	Hazards Biological—B Chemical—C Physical—P Hazard Description	CCP	Critical Limits	Monitoring Procedures/ Frequency/ Person Responsible	Corrective/Preventive Action/Person Responsible	HACCP Records	Verification Procedures/Person Responsible
				<div data-bbox="1104 829 1432 948" style="border: 1px dotted black; padding: 5px;"> <p><i>Example only! May vary by plant.</i></p> </div>			

Date: _____ Approved by: _____