United States
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Agriculture

Guidebook For The Preparation Of HACCP Plans

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TABLE OF CONTENTS

Preface C-1

Developing A HACCP Plan C-2

Step 1 - Assemble The HACCP Team C-2
Step 2 - Describe The Product and Its Method Of Distribution C-3
Step 3 - Develop a Complete List of Ingredients and Raw Materials C-4
Step 4 - Develop A process Flow Diagram C-4
Step 5 - Meet the Regulatory Requirements for Sanitation Standard Operating Procedures C-5

PRINCIPLE 1 - Conduct A Hazard Analysis C-5
Biological Hazards C-6
Chemical Hazards C-7
Physical Hazards C-8
Conducting A Hazard Analysis C-8
Steps In Conducting A Hazard Analysis C-10
First - Evaluate your operation for hazards C-10
Second - Observe the actual operating practices in your operation C-12
Preventive Measures C-13

PRINCIPLE 2 - Identify Critical Control Points C-14
Steps In Identifying Critical Control Points C-15
CCP Decision Tree C-16

PRINCIPLE 3 - Establish Critical Limits C-17
Steps In Establishing Critical Limits C-18

PRINCIPLE 4 - Establish Monitoring Procedures C-19
Steps in Establishing Monitoring Procedures C-20

PRINCIPLE 5 - Establish Corrective Actions C-20
Steps in Establishing Corrective Actions C-22

PRINCIPLE 6 - Establish Record keeping Procedures C-22
Steps in Establishing Record keeping Procedures C-23

PRINCIPLE 7 - Establish Verification Procedures C-24
Steps in Establishing Verification Procedures C-24

Appendix 1 - Critical Control Point Decision Tree C-28

Appendix 2 - HACCP Plan Checklist C-29

Appendix 3 - Internet Home Pages C-34

Appendix 4 - References C-35

Attachment 1 - Process Description Form C-37

Attachment 2 - Process Description Form Example for
Beef Slaughter C-38

Attachment 3 - Process Description Form Example for
Ground Beef C-39

Attachment 4 - Product and Ingredients Form C-40

Attachment 5 - Product and Ingredients Form Example for
Beef Stew C-41

Attachment 6 - Process Flow Diagram for
Ground Beef (Raw, Ground) C-37

Attachment 7 - Process Flow Diagram for Beef Slaughter C-37

Attachment 8 - Hazard Identification/Preventive Measures Blank C-44

Attachment 9 - Hazard Identification/Preventive Measures
Ground Beef (Raw, Ground) C-45

Attachment 10 - Hazard Analysis C-37

Attachment 11 - Critical Control Point Determination Form C-37

Attachment 12 - Critical Control Point Determination Form
Raw Ground C-37

Attachment 13 - Critical Control Point Determination Form
for Beef Slaughter C-37

Attachment 14 - HACCP Plan Form C-37

Attachment 15 - HACCP Plan C-37

Attachment 16 - Ground Beef C-37

PREFACE

The Hazard Analysis Critical Control Points (HACCP) system is a logical, scientific system that can control safety problems in food production. HACCP is now being adopted worldwide. It works with any type of food production system and with any food. It works by controlling food safety hazards throughout the process. The hazards can be biological, chemical, or physical.

This guidebook was developed to help meat and poultry establishments prepare HACCP plans. The steps in developing a HACCP plan can be used by all establishments, large or small, complex or simple. The guidebook identifies additional sources of information, so that small operators won't have to "go it alone."

The forms shown in this guidebook are examples only. Think of this as a self-help guide or a do-it-yourself manual. There are many ways to get to the final product--a good HACCP plan. So, choose the examples that work best in your establishment.

The guidebook can be used to complement HACCP training. You may also wish to use it in conjunction with a video about HACCP. The guidebook will provide the basics. When you are ready to move on, there are more specialized documents. FSIS is also publishing the *Meat and Poultry Products Hazards and Control Guide*. It explains in detail the biological, chemical, and physical hazards that can occur at different steps of meat and poultry slaughter and processing and provides some examples of controls for those hazards. In addition, there will be a series of Generic Models for different meat and poultry processes, to be used as examples. You will probably want to look at the models for processes that you use in your establishment. There will be model plans for the following 13 processes:

Generic HACCP Model for Beef Slaughter
Generic HACCP Model for Poultry Slaughter
Generic HACCP Model for Pork Slaughter
Generic HACCP Model for Raw, Not Ground Meat and Poultry Products
Generic HACCP Model for Raw, Ground Meat and Poultry Products
Generic HACCP Model for Mechanically Separated (Species)/Mechanically Deboned Poultry
Generic HACCP Model for Heat Treated Not Fully Cooked, Not Shelf Stable Meat and Poultry Products
Generic HACCP Model for Meat and Poultry Products with Secondary Inhibitors, Not Shelf-Stable
Generic HACCP Model for Not Heat Treated, Shelf-Stable Meat and Poultry Products
Generic HACCP Model for Fully Cooked, Not Shelf-Stable Meat and Poultry Products
Generic HACCP Model Heat Treated, Shelf-Stable Meat and Poultry Products
Generic HACCP Model for Thermally Processed Commercial Sterile Meat and Poultry Products
Generic HACCP Model for Irradiation

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 guidebook explains how to write a HACCP plan in five preparatory steps and then the seven HACCP principles.

The five preliminary steps in this guidebook are:

1. Bring together your HACCP resources/assemble the HACCP team.
2. Describe the food and its method of distribution.
3. Identify the intended use and consumers of the food.
4. Develop a process flow diagram.
5. Verify the diagram in the operation it is meant to represent.

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

Applying the seven HACCP principles make up the major steps to 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.

As you read this guidebook and look at the examples, the process for writing a HACCP plan should become clearer. This first section of the guidebook explains the five preliminary steps. The next seven sections cover each of the HACCP principles that you will need to follow to develop a HACCP plan.

STEP 1 - BRING TOGETHER YOUR HACCP RESOURCES-ASSEMBLE THE HACCP TEAM

The first step is to assemble your 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, you probably have access to more HACCP resources than you think! In a small establishment, this might mean bringing together one or two employees, one of whom has had HACCP training. Your HACCP resources may include outside expertise. You can get this expertise through your local Extension Office, a trade or professional association, or a contractor of your choice. 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 employees.

The employee or employees writing the HACCP plan should understand some basic things about the establishment: The technology and equipment used in your processing lines; the practical aspects of food operations; and the flow of the process in your plant. It will be a bonus for your 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 or the use of guidance materials or technical literature.

STEP 2 - DESCRIBE THE PRODUCT AND ITS METHOD OF DISTRIBUTION-INCLUDING THE INTENDED USE AND CONSUMERS OF THE FOOD

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

To describe your product, you might ask the following questions 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 to wholesale, retail or institutions?

6. Labeling instructions?
   "Keep Refrigerated" would be a common labeling instruction for meat and poultry products.

7. How is the product(s) distributed?

   For instance, should the product be kept refrigerated at or below 40°F?

8. Who is the consumer and how will the product be used by the consumer?

A blank Process Description Form is included (Attachment 1). It is an example. You may take it and tailor it to your own establishment or use a similar form containing all the necessary information. An example of a complete Process Description Form for beef slaughter (Attachment 2) and ground beef (Attachment 3) are included. These examples are taken from the FSIS Generic Models. The remaining HACCP Generic Models developed for 13 different process will give you more examples of product descriptions.

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. You can write this on a very simple form, (see Attachment 4). You 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(s)/process covered by the plan. Attachment 5 shows a sample Product and Ingredients Form for beef stew. Again, the forms included in the Guidebook are only examples to get you started. You may wish to have more elaborate forms for your establishment. The important thing is to list all ingredients that go into each product! It is also helpful to include the form of the ingredients for processed products. Is the meat frozen or fresh? Are the spices used in a premix?

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 your process to the end. The flow diagram may also include steps that occur before or after the processing occurs in the establishment.

You will want to verify the process flow diagram. You do this by actually walking through the plant to make sure that the steps listed on the diagram describe what really occurs in producing the product.

An example process flow diagram for ground beef /raw ground is included as attachment 6. It is a very simple form on which you may want to draw the flow freehand. If you have a computer, you can make a fancier form, with arrows leading from step to step.

An example of a Process Flow Diagram for beef slaughter is included as attachment 7. The HACCP team in this case chose to construct a flow diagram for the slaughter process, that separates variety meats and final carcass fabrication. You will find additional examples of process flow diagrams for specific process in the HACCP Generic Models.

Remember, the purpose of this diagram is to find any place in your specific establishment where hazards could occur. (As with all HACCP planning forms, the responsible establishment official should sign and date the form, for your records).

STEP 5 - MEET THE REGULATORY REQUIREMENTS FOR SANITATION STANDARD OPERATING PROCEDURES

Good sanitation is the most basic way to ensure a safe product is produced. Maintaining good sanitation serves as an excellent and necessary foundation for building your HACCP plan. It also demonstrates that you have the commitment and resources to successfully implement your HACCP plan. Because it is so important, meeting the regulatory requirements for Sanitation Standard Operating Procedures (SSOPs) is a pre-HACCP requirement that must be carried out in all establishments. A separate guide and a model Sanitation SOP have been prepared and are available to help you with this activity. In addition to the SSOP's, other prerequisite programs for HACCP can be developed which are extremely useful, such as GMP's 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 you are ready to apply the seven principles that will produce a HACCP plan suited to your plant and your process. These principles and how to carry them out will be discussed in detail in the next seven sections of this guidebook.

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 your establishment.

Finally, this section will explain how you can apply preventive measures to the hazards you have identified, 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."

You will find a far more detailed listing of and discussion of hazards in the *Meat and Poultry Products Hazards and Control Guide*. The generic HACCP models discuss the hazards specific to various meat and poultry processes, such as raw, ground product or pork slaughter. In addition, the Reference Section of this guidebook list publications which can help you identify

hazards.

To identify biological, chemical, or physical hazards likely to occur, you need 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 applicable preventive measures are available. Hazards which 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*.

In the *Meat and Poultry Products Hazards and Control Guide*, you will find a brief description of the major microorganisms of concern in meat and poultry. Table 1 in that guide describes the temperature and pH ranges and the minimum water activity needed for each organism to grow. Table 4 lists some preventive measures for biological hazards. To thoroughly identify significant biological hazards in your establishment, you need to evaluate each specific ingredient and processing step in your operation.

CHEMICAL HAZARDS

Chemical hazards fall into two categories:

1. Naturally occurring poisons, chemicals, 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 poison chemicals or deleterious substances are those which 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, drug residues, 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, you first need to identify any chemical residues that might still be present in the animal tissue. To do this, think about the following:

- The types of drugs and pesticides routinely used in raising the animals which are the source of your 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.

You can use the following preventive measures to help ensure that animals entering your establishment are free of harmful residues:

- Require that the animals have been raised in conjunction 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 your own maximum allowable residue limits 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 you need to be aware that chemical hazards can occur at any of the following points:

- Prior to receiving chemicals at your 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 which 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 which cannot or do not cause illness or injury are not hazards, even though they may not be aesthetically pleasing to your 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, broken glass jars, 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 SOP's can be used to idenify and control cross contamination that is due to employee practices.

CONDUCTING A HAZARD ANALYSIS

Now that you have some understanding of the types of hazards that can occur and how to identify them, you are ready to conduct a hazard analysis for each process and/or product(s) covered in your HACCP plan.

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

Your hazard analysis needs to be very specific to your establishment and how you make your 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 experiences, knowledge, and attitudes.

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 (use flow

diagram) in the process from the receipt of raw materials to the release of the finished product. During brainstorming, the team need not be confined by the hazards likelihood of occurrence or its potential for causing disease. All potential hazards's 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.

You also need to review--and perhaps revise--your hazard analysis whenever you make any changes in: raw materials, raw material suppliers, product formulation, preparation procedures, production volume, processing methods, or systems, packaging materials or procedures, distribution, or intended use of the product or consumers.

A blank Hazard Identification/Preventive Measures form that you may wish to use for your hazard analysis is included as Attachment 8. Attachments 9 and 10 are examples of two completed forms identifying hazards that might exist in a specific establishment's process. The form contains space for the process step in which the hazards could occur, the specific hazard, and preventive measure taken to prevent the hazard from occurring. Attachment 9 included space for indicating the manner in which a hazard may be introduced. Remember, HACCP is a preventive system.

STEPS IN CONDUCTING A HAZARD ANALYSIS

To conduct a hazard analysis, you need to do the following:

First - Assure that the prerequisite program-SSOP's and others are in place.
Evaluate your operation for hazards.

1. Review the product description developed in Pre-HACCP Step 2 and determine how this information could influence your hazard analysis.

2. Look at all product(s) ingredients and incoming materials for the product(s). You developed this list in Pre-HACCP Step 3.

3. For each processing step identified in the process flow diagram, determine if a biological, chemical or physical hazard(s) could exist at that step.

4. To help identify hazards, you can 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, work in process, or finished product became contaminated with pathogens? or

   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's?

5. Fully describe the hazards identified for each step.

6. For each incoming ingredient and material, indicate if a biological, chemical and/or physical hazard exists.

7. To help identify hazards, you can ask the following questions about each ingredient:

   Could this ingredient contain any pathogenic microorganisms, toxins, chemicals or harmful 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. You can ask the following questions about the product/process in general:

Have any livestock entering the slaughter establishment been subjected 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 you assess the risk, severity, and significance of the hazards identified.

Second - Observe the actual operating practices in your operation

After describing the hazards you've identified with each step, you should:

1. Observe the actual operation in your 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.

4. Review any past incidents of physical, biological, or chemical contamination that have occurred to determine the frequency, significance, and nature of the occurrence(s).

For additional information about potential biological, chemical, and physical hazards, you may wish to consult Tables 8 through 12 in the *Meat and Poultry Products Hazards and Control Guide*. They can serve as a guide for identifying potential hazards in ingredients and at various steps in slaughter and processing. However, they do not address every ingredient and every processing step used in the meat and poultry industry.

Third - Evaluate the likelihood and severity of occurrence of the hazard

The hazard evaluation should be 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 severity or seriousness 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 the influence on food safety of the manner in which the food is likely to be stored and prepared and whether the food is specifically intended for consumption by a group which may be more susceptible to a particular agent.

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 which 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

You 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 your finished product. You are now ready to fill in the preventive measure(s) 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 of the measures you can use to prevent chemical hazards are:

- Use only approved chemicals.
- Have detailed product specifications for chemicals entering your plant.
- Maintain letters of guarantee from suppliers.
- Inspect trucks used to ship finished product.
- Properly label and store all chemicals.
- Properly train employees who handle chemicals.

In the *Meat and Poultry Products Hazards and Control Guide*, Table 5 lists some preventive measures for chemical hazards. For still more information, see the publication *HACCP - Establishing Hazard Analysis Critical Control Point Program*, Food Processors Institute, 1993.

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

- Make sure your plant specifications for building design and operation are accurate and updated regularly.
- Make sure your letters of guarantee 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.

To identify some preventive measures for physical hazards, see Table 6 in the *Meat and Poultry Products Hazards and Control Guide*.

Some other examples of preventive measures are:

- In beef slaughter a chemical hazard could be the result of animals having high levels of drug residues. A preventive measure would be to reject or cull animals from a supplier on the basis of presentation of residue certification for all line 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 (GMP's) 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. You could inspect the grinding equipment daily to ensure that it is assembled and operated correctly, is functioning properly, and is not worn or damaged. You could have an employee visually examine the product at the packaging step. Or you 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 requiring a letter of guarantee from the supplier assuring that the packaging materials are food grade.

Once you have identified your preventive measures and written them on your form, you are ready to go on to the next step in developing your 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 your HACCP plan, you have identified biological, chemical, and physical hazards in the raw materials and ingredients you use and in the steps of your process. You've also identified preventive measures for each hazard you identified. With this information, your 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 to an acceptable level. Then you 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 critical control points.)

Fortunately, a great deal of work has already been done for you 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 or antimicrobial interventions.

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 which 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

One good tool for identifying Critical Control Points is the CCP Decision Tree, (Appendix 1). The CCP Decision Tree was developed to help companies separate CCPs from other controls such as SSOP's, GMP's or other operating procedures. You will get the best results if you use the Decision Tree very methodically and use simple, descriptive, and familiar wording. You should apply the Decision Tree at each step in the process where you have identified a hazard.

You can use the blank Critical Control Point Determination Form, (Attachment 11), to record the results from your CCP Decision Tree work. Or, you may wish to design your own form. Examples of a filled-in Critical Control Point Determination Form for Raw Ground and Beef Slaughter are shown as Attachments 12 and 13.

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 you have identified a hazard.

2. In Column 2, write in the identified hazard(s), indicating whether it is biological, chemical or physical. Then take the information you wrote on your Hazard Identification/Preventive Measures form and answer the following questions for each hazard you 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 <u>not</u> 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 you have 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 hazard(s) 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 identified hazard(s) 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 identified hazard(s) 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, which occurs later, 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

You will find that many critical limits for your identified CCPs have already been established. You can find these limits in sources such as regulatory requirements, scientific literature, experimental studies, and through consultation with experts. Some examples of regulatory critical limits for CCPs in meat and poultry production are shown in Table 7 of the *Meat and Poultry Products Hazards and Control Guide*.

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

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

An example of a HACCP Plan Form can be seen in Attachment 14. You can use that form, or develop your own to use when completing this and the following two sections. You can find other examples of critical limits for specific processes in the HACCP Generic Models.

STEPS IN ESTABLISHING CRITICAL LIMITS

1. For each identified CCP, determine if there is a regulatory critical limit set for ensuring food safety. If so, write that critical limit--or an alternative one if the scientific basis exists to show the value is adequate to ensure food safety--into

the critical limit column of your form.

For example, the regulatory critical limit for cooked poultry is 160 degrees F. So, column two of your form would read: "Deep breast muscle temperature of 160 degrees F. as the products exits the fryer/oven/smokehouse."

2. If there are no regulatory critical limits for a CCP, you need to establish critical limits for the CCP that are adequate to maintain control and prevent a food safety hazard. That is the responsibility of each establishment. You may wish to obtain the assistance of outside HACCP experts to help you determine critical limits for your CCPs. Once you have identified critical limits, enter them into the critical limit column of your form.

3. You should also file, for future reference, any documentation such as letters from outside HACCP experts, processing authorities, or scientific reports supporting the critical limits you have identified. This documentation will help validate that the limits have been properly established. In addition, you should keep on file any test results that show your early experience in implementing the HACCP plan, to demonstrate you can implement what is written and make it work.

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 you if there is a trend towards loss of control, so that you can take action based on an analysis of the variation to bring your 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 toward 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.

The monitoring procedures you will establish at CCPs will generally relate to on-line processes. Monitoring may be continuous or non-continuous. 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 you can review and evaluate to ensure that the CCP is under control. However, you should regularly check continuous monitoring equipment for accuracy.

You should use non-continuous monitoring procedures when continuous monitoring is not feasible. Non-continuous monitoring can include: visual examinations; monitoring of ingredient specifications; measurements of pH, water activity (Aw), and product temperatures; attribute sampling; and the like. When you use non-continuous monitoring, you need to 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, you may have to perform tests at a CCP or use statistically based sampling.

Monitoring will go much more smoothly if you:

- Clearly identify the employee(s) responsible for monitoring.
- Train the employee(s) 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.
- Ensure that the employee(s) understand the purpose and importance of monitoring.

You can use the HACCP Plan Form shown in Attachment 14, or you can develop your own form.

STEPS IN ESTABLISHING MONITORING PROCEDURES

You can identify monitoring procedures for your 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 you need to do a chlorine check or a temperature measurement?

5. Identify and train the employee(s) responsible for monitoring.

6. Make sure that the employee doing the monitoring signs 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 your 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, you have to plan in advance to correct potential deviations from established critical limits. Once your HACCP plan is in place, any time a critical limit is not met, you will need to take corrective actions. Those corrective actions should include:

1. Determining the disposition of non-complying product;

2. Correcting the cause of the non-compliance to prevent a recurrence;

3. 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.);

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, you determine in advance what you will do when a critical limit is not met at a CCP. The employee(s) 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 the employee responsible for taking the corrective actions sign all

the documentation. Not all corrective actions can be anticipated. If a corrective action is taken which 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 plant's quality control manager, supervisor, other individual who is knowledgeable in HACCP, and/or the responsible establishment official.

- 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 you take, you need to keep records that include:

- The deviation that was identified.

- The 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.

You can use the HACCP Plan form (Attachment 14) or you can develop your own form.

STEPS IN ESTABLISHING CORRECTIVE ACTIONS

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. You may need 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 action(s) for each CCP in the corrective action column of the HACCP Plan 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 to you for the following reasons:

- Records serve as written documentation of your establishment's compliance with its HACCP plan.

- Records allow you to trace the history of an ingredient, in-process operations, or a finished product, should problems arise.

- Records help you identify trends in a particular operation that could result in a deviation if not corrected.

- If you were ever faced with a product recall, HACCP records could help you 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 the HACCP principles, your HACCP system should include records for CCPs, establishment of critical limits, handling of deviations, results of verification activities and your HACCP plan including the hazard analysis. Examples of these and other HACCP forms that may be useful in assembling the HACCP plan are located in the appropriate sections of this guidebook. For your review, these forms are:

Process Description Form
Product and Ingredients Form - Process Categories and Ingredients
Process Flow Diagram Form
Hazard Analysis/Preventive Measures Form - Hazard Analysis Worksheet
CCP Determination Form - Hazard Analysis Worksheet
HACCP Plan Form - HACCP Worksheet

In many cases, the records you currently maintain may be sufficient to document your 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; time of observation, a place for the reviewer's signature; and, an orderly manner for entering the required data.

An example of a blank HACCP Plan form is included as Attachment 14.

STEPS IN ESTABLISHING RECORDKEEPING PROCEDURES

1. Review the records you currently maintain and determine which ones adequately address the monitoring of the CCPs you have identified, or develop forms for this information.

2. Develop any forms necessary to fully record corrective actions taken when

deviations occur.

3. Develop forms to document your HACCP system. (This will be explained in the next section, on verification).

4. Identify the employees responsible for entering monitoring data into the records and ensure that they understand their roles and responsibilities.

5. Enter the record form name(s) on the appropriate HACCP Plan Form or HACCP Worksheet under column adjacent to the appropriate CCP. (Verification will be explained in the next section).

6. Enter the appropriate record form name(s) on the Recordkeeping and Verification Form under the verification procedures column adjacent to the appropriate CCP. (Verification will be explained in the next section).

PRINCIPLE 7 - ESTABLISH VERIFICATION PROCEDURES

HACCP Principle No. 7 states:

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

Verification

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, you need to verify that your HACCP system is working the way you expected it to work. Several areas are, but are not limited to, the calibration of process monitoring instruments at specified intervals, direct observation of monitoring activities, and corrective actions. These should be included in your HACCP plan in addition to the critical limits, monitoring, and corrective actions and should be defined at each CCP (see example from model). You should also make sure that employees are following your procedures for taking corrective actions when a critical limit is exceeded. Finally, you should routinely check to see that your employees are keeping specific, accurate, and timely HACCP records.

By doing these things, you will evaluate the day-to-day operation of your HACCP system. Don't be surprised if you find that you need to fine-tune your HACCP plan.

Some things you can do to verify your HACCP system are:

- Analytically test or audit your monitoring procedures;

- Calibrate your temperature/test equipment;
- Sample your product, including microbiological sampling;
- Review your monitoring records;
- Review your records of deviations and product dispositions;
- Inspect and audit your 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/or commercially feasible and appropriate level, identified microbiological, chemical, and/or physical hazards. Validation is exclusively the responsibility of the regulated industry. It is the process through which a company assembles data showing that 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 guarantee 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. It's levels can be correlated to the potential presence of other pathogenic organism such as *Salmonella.* When indicator organism are used, a decrease in the level of the indicator should be correlated to some expected effect on other pathogenic organisms which may be present at much lower levels or be difficult to ascertain. The present regulatory requirements for the production for the production of cooked bef, roast beef, and cooked corned beef (9 CFR 318.17) and for cooked, uncured beef patties (9 CFR 318.23) 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 any changes occur 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 assure process control over food safety hazards.

STEPS IN ESTABLISHING VERIFICATION PROCEDURES

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 your 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 YOUR HACCP PLAN

It is very important to validate your 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.” You will probably first want to review your HACCP plan to determine whether the CCPS and critical limits that you established are really the right ones and that you are controlling and monitoring them adequately.

Simply put, when you validate your HACCP plan, you demonstrate what you have written and put into place can actually prevent, eliminate, or reduce the levels of hazards you have identified.

To validate your HACCP plan, you need to assemble information to show that your HACCP plan will work to control the process and to prevent food safety hazards. There are two types of information that you will probably collect. First, you will likely gather 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/or results of test for residues. Second, you may wish to gather practical information, such as test results from products produced under your HACCP plan. An example of a test might be microbiological analysis of your 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 your 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 assure that the parameters stipulated in the HACCP system are adequate to ensure process control.

You have a great deal of flexibility in assembling the information to validate your 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 volatile 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 assures 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 analysis of carcasses for compounds of concern.

Validation is simpler for 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. Your HACCP plan would need only to reflect these regulatory requirements; additional information would be unnecessary. In this case, you could do a minimal number of product analysis to demonstrate that hazards of concern, such as *Salmonella*, were not found in the products produced under the HACCP plan.

It is important that you reassess your HACCP plan 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. You add new ingredients or change the ingredient supplier.

3. You change the process steps or procedures.

4. You introduce new or different processing equipment.

5. Production volume changes.

6. The end point consumer for the product or the distribution system changes.

7. Personnel changes.

FINISHING YOUR HACCP PLAN

Now you are ready to assemble all your information into one HACCP Plan. A sample HACCP Plan blank form is provided as Attachment 15. An example of a form filled in for one establishment's ground beef process is provided as Attachment 16. It is important for your records that you assemble all your information into a final HACCP plan. To make sure that your HACCP Plan is complete, you may want to check it against the checklist provided in the next section of this guidebook. The HACCP plan should be reviewed in its entirety and signed and dated by the responsible establishment official/approving employee. All pages of the HACCP plan should be dated and marked with a cross referencing identifier to assure the plan is the most recent. The identifier can be a plan name or number.

Now you are ready to put your HACCP Plan into action and make HACCP a reality in your establishment.

Appendix 1

CCP DECISION TREE

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

Q1. DO PREVENTIVE MEASURE(S) EXIST FOR THE IDENTIFIED HAZARD?

↓ ↓ ↑

YES NO MODIFY STEP, PROCESS OR PRODUCT

↓ ↓ ↑

↓ IS CONTROL AT THIS STEP NECESSARY FOR SAFETY?→ YES

↓ ↓

↓ NO→ NOT A CCP → STOP*****

Q2. DOES THIS STEP ELIMINATE OR REDUCE
THE LIKELY OCCURRENCE OF A HAZARD

TO AN ACCEPTABLE LEVEL? → → → → → → → → → → → → → → → → → → →
↓ ↓
NO YES
↓ ↓
↓
Q3. COULD CONTAMINATION WITH IDENTIFIED ↓
HAZARD (S) OCCUR IN EXCESS OF ACCEPTABLE ↓
LEVEL(S) OR COULD THESE INCREASE TO ↓
UNACCEPTABLE LEVEL(S)? ↓
↓ ↓ ↓
YES NO → NOT A CCP → STOP* ↓
↓ ↓
↓
Q4. WILL A SUBSEQUENT STEP ELIMINATE ↓
IDENTIFIED HAZARD(S) OR REDUCE THE ↓
LIKELY OCCURENCE TO AN ACCEPTABLE ↓
LEVEL? ↓ ↓
↓ ↓ ↓
YES → NOT A CCP → STOP* NO → → → → → → → → → CCP

* Proceed to the next step in the described process

Appendix 2

HACCP PLAN CHECKLIST

You can use the HACCP Plan Checklist provided in this section to ensure that your HACCP plan adequately addresses all seven HACCP principles.

When completing the checklist, if you answer "NO" to any question, you 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 you make major changes to the HACCP plan based upon product or process modifications, it would be advisable to review the checklist to ensure that the revisions are acceptable.

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

ESTABLISHMENT NO._____

PRODUCT/PROCESS _____

DATE_____

HACCP PLAN CHECKLIST

A. DESCRIBE THE PRODUCT **YES** **NO**

1. Does the HACCP plan include:

   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 for consumption and the intended consumer? **YES** **NO**

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?

B. CONDUCT A HAZARD ANALYSIS **YES** **NO**

1. Have all steps in the process been identified and listed where hazards of potential significance occur?

2. Have all hazards associated with each identified step been listed?

3. Has the likehood and severity of the risk for each hazard been assessed?

4. Have safety concerns been differentiated from quality concerns?

5. Have preventive measures to control the identified hazard been identified and listed?

C. IDENTIFY CRITICAL CONTROL POINTS **YES** **NO**

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?

    a. Have monitoring frequencies been established?

3. Have all significant hazards identified during the hazard analysis been addressed?

D. ESTABLISH CRITICAL LIMITS **YES** **NO**

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?

E. ESTABLISH MONITORING PROCEDURES **YES** **NO**

1. Have monitoring procedures been developed to assure 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 not possible, is the frequency of monitoring sufficiently reliable to indicate that the hazard is under control? **YES** **NO**

   a. Have monitoring frequencies been established?

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?

F. ESTABLISH CORRECTIVE ACTIONS **YES** **NO**

1. Have specific corrective actions been developed for each CCP?

2. Do the corrective actions address:

   a. Reestablishment of process control?

   b. Disposition of affected product?

   c. Procedures to correct the cause of non-compliance 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?

G. ESTABLISH RECORDKEEPING PROCEDURES **YES** **NO**

1. Have procedures been established to maintain the HACCP plan on file at the establishment?

2. Do the HACCP records include:
   Description of the product and its intended use?
   Flow diagram for the process,
   Preventive measures?
   Critical limits?
   Monitoring system:
   Corrective action plans for deviations from critical limits?
   Record keeping procedures for monitoring? Procedures for verification of the HACCP system?

H. ESTABLISH VERIFICATION PROCEDURES **YES** **NO**

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?

Appendix 3

INTERNET HOME PAGES

Agriculture Canada	http://aceis.agr.ca
Center for Disease Control	http://fftp.cdc.gov/pub/mmwr/MMWRweekly
Food Law Sites	http://www.fsci.umn.edu/FoodLaw/foodlaw.html
HACCP95	http://www.cvm.uiuc.edu/announcements/ haccp95/haccp95.html
International HACCP Alliance	http://aceis.agr.ca
Material Safety Data Sheets	http://listeria.nwfsc.noaa.gov/msds.html
U.S. Department of Agriculture	http://www.usda.gov
U.S. Food and Drug Administration/ Bad Bug Book	http://vm.cfsan.fda.gov/list.html

Appendix 4

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PROCESS DESCRIPTION

PRODUCT:

THE FOLLOWING QUESTIONS NEED TO BE ANSWERED 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?
CONSUMER?
INTENDED USE?

6. LABELING INSTRUCTIONS?

7. IS SPECIAL DISTRIBUTION
CONTROL NEEDED?

LIST PRODUCT CATEGORIES AND INGREDIENTS

PRODUCT CATEGORY: Beef Slaughter (includes:Steer/heifer/cow/bull carcasses, beef primals, trim, and variety meat)

WORKSHOP LOCATION: Kansas City, Missouri

MEAT AND MEAT BYPRODUCTS	NONMEAT FOOD INGREDIENTS	BINDERS/EXTENDERS
Live Cattle	**Tripe - variety meat has sodium hydroxide or hydrogen peroxide** **Potable water** **Carbon dioxide** **Chlorine may be used in some injected spray chill systems.**	
SPICES/FLAVORINGS	**RESTRICTED INGREDIENTS**	**PRESERVATIVES/ ACIDIFIERS**
OTHER		
Approved packaging material.		

Attachment 3

LIST PRODUCT(S) AND INGREDIENTS

PROCESS CATEGORY: RAW, GROUND

PRODUCT EXAMPLE: GROUND BEEF

MEAT

BEEF

PRODUCT AND INGREDIENTS **PROCESS CATEGORY:** **PRODUCT:**

LIST PRODUCT(S) AND INGREDIENTS

PROCESS CATEGORY: THERMALLY PROCESSED-COMMERCIALLY STERILE

PRODUCT EXAMPLE: BEEF STEW

MEAT*

FROZEN COOKED DICED BEEF

INGREDIENTS*

FROZEN SLICED CARROTS
FROZEN DICED POTATOES
FROZEN SLICED CELERY

REFRIGERATED ONION JUICE CONC.
REFRIGERATED GARLIC PUREE

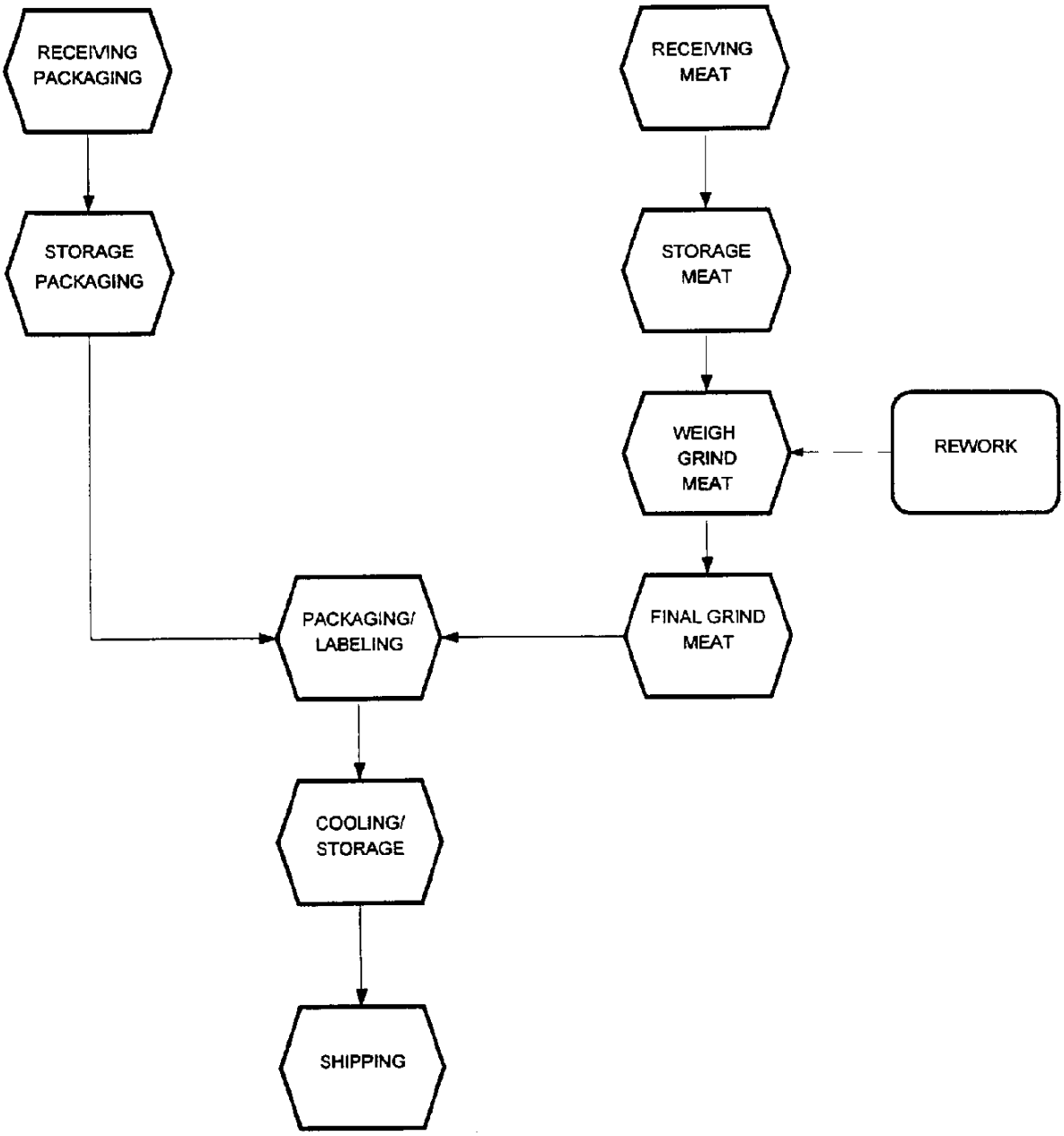
VEGETABLE OIL
STARCH
HVP
PLANT GUM
DEHY. BEEF STOCK
SALT
SPICE MIX
WORCESTERSHIRE SAUCE

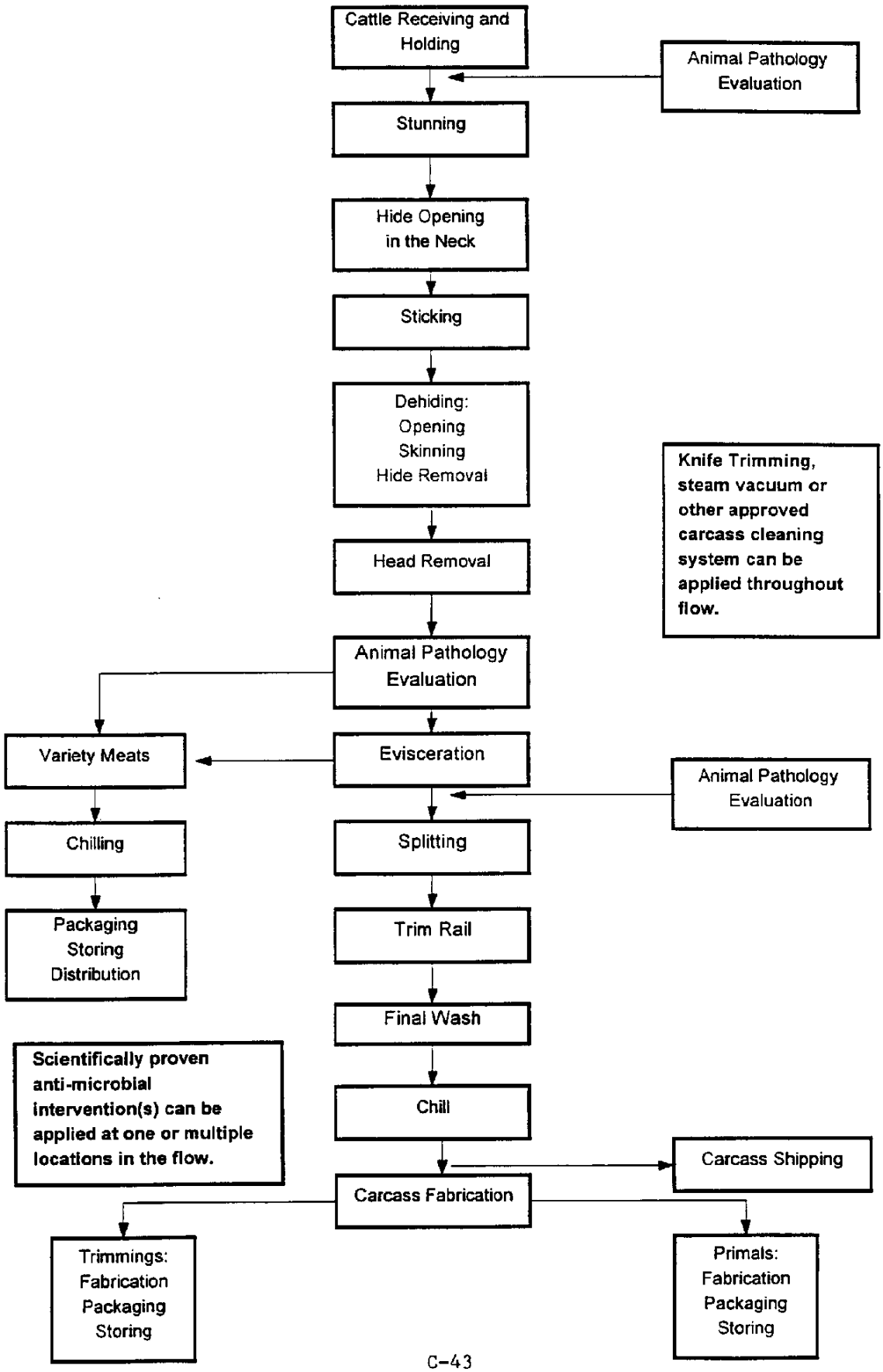
* The dice size of the ingredients should be listed in a specific plan if it is a critical formulation factor. Amounts of each ingredient may also be included.

PROCESS FLOW DIAGRAM

PROCESS CATEGORY: RAW, GROUND

PRODUCT: GROUND BEEF




Cattle Receiving and Holding
Animal Pathology Evaluation
Stunning
Hide Opening in the Neck
Sticking
Dehiding: Opening Skinning Hide Removal
Knife Trimming, steam vacuum or other approved carcass cleaning system can be applied throughout flow.
Head Removal
Animal Pathology Evaluation
Variety Meats
Evisceration
Animal Pathology Evaluation
Chilling
Splitting
Packaging Storing Distribution
Trim Rail
Final Wash
Scientifically proven anti-microbial intervention(s) can be applied at one or multiple locations in the flow.
Chill
Carcass Shipping
Carcass Fabrication
Trimmings: Fabrication Packaging Storing
Primals: Fabrication Packaging Storing

Attachment 8

HAZARD IDENTIFICATION/PREVENTIVE MEASURES

PRODUCT/PROCESS:

PROCESS STEP	HAZARD	PREVENTIVE MEASURE(S)

DATE: _____ APPROVED BY: _____

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures	Examples of How Hazard Is Introduced *
RECEIVING - MEAT	B (Microbial Growth) - Insufficient temperature control will result in unacceptable microbial growth. Ayers, J.C. 1979 B (Mishandling) - The integrity of the immediate container is compromised such that microbial contamination could occur. P (Foreign Material) - Visible foreign material that could compromise product safety. Meat and Poultry Products Hazards and Control Guide.	Maintain product temperature at a level sufficient to preclude bacterial growth. Visual inspection of containers to ensure that immediate container is not compromised. Visual inspection of a sufficient representative sample to ensure no foreign material is present.	B-Transport refrigeration unit is not functioning properly (out of freon). B-The shipping container (the cardboard combo bin) was crushed by a forklift and the immediate container (the film wrapped around the individual trays) was torn and punctured introducing harmful microbes into the product. P-Pieces of glass found in product from a broken light bulb, metal clips, knives, plastic, etc.
RECEIVING - NON-MEAT	C (Deleterious Chemicals) - Chemicals/non-meat ingredients/packaging materials, are acceptable for intended use. Should be food grade material approved for intended use. Bean, N.H. and P.M. Griffin 1990. P (Foreign Material) - Visible foreign material that could compromise product safety; rodent droppings, insects, etc.	Verify that the letter of guarantee is on file and appropriate for product use. Visual inspection of a sufficient representative sample to ensure no foreign material is present.	C-The new tray pack "diapers" ordered came in and the letter of guarantee is present with the shipment, however the letter states that of the diapers are acceptable for industrial use and not food grade. P-Black material that resembles rodent droppings are found on the surface of the styrofoam trays.
STORAGE - MEAT	B (Microbial Growth) - Insufficient temperature control could result in unacceptable microbial growth. Internal product temperature and environmental temperature must be monitored. Ayers, J.C. 1979, Bryan, F.L., 1988, Palumbo, S.A., et.al. 1994	Monitor the internal product temperature and environmental temperature (ex. cooler or freezer) to ensure that the meat does not exceed a level sufficient to preclude bacterial growth for more than 1 hour, and the temperature of the cooler or freezer does not exceed 50 °F for more than 2 hours.	B-Cooler generator breaks down and the ambient room temperature in the cooler increases above 50°F for 10 hours increasing product temperature above compliance permitting excessive bacterial growth.
STORAGE - NON-MEAT	P (Foreign Material/Adulteration) - All non-meat ingredients, packaging materials, etc. must be stored to prevent contamination due to foreign material. Meat and Poultry Products Hazards and Control Guide.	Visual inspection of storage area to ensure that materials are stored in a clean area, are covered, and not resting directly on the floor.	P-The product is stored directly against the walls which have visible debris on them. The debri falls into the packaging materials that contact product.
ASSEMBLE/ PRE-WEIGH/ PRE-GRIND/ RE-WORK FINAL GRIND MEAT	B (Microbial Growth) - Inadequate temperature control could result in unacceptable microbial growth. Internal product temperature and environmental temperature must be monitored. Ayers, J.C. 1979 P (Foreign Materials) - Visible foreign material that could compromise product safety; metal and plastic shavings, rubber gloves, bone, etc. Meat and Poultry Products Hazards and Control Guide.	Monitor ambient room temperature and product temperature to ensure that product temperature does not exceed a level sufficient to preclude bacterial growth for more than 2 hours and that room temperature does not exceed 50 °F for more than 4 hours. Visual inspection of all product as it is processed to ensure no foreign material is present.	B-As a result of a mechanical breakdown, the product movement into the cooling cycle was delayed 6 hours and the product temperature increases above 55°F due to exposure to ambient room temperature. P-Moving parts of the grinder are not set properly or are worn and grind together leaving pieces of ground metal into the product.

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures	Examples of How Hazard Is Introduced *
PACKAGING/ LABELING	P (Foreign Material)	Use of metal detectors on all packaged product.	Broken metal clips from chub pack in product.
COOLING AND STORAGE OF PRODUCT	B (Microbial Growth) - The potential for an increase in microbial growth if the product temperature is not maintained at temperature or below the level where pathogens survive and grow rapidly. Ayres, J.C. 1979, Johnston, R.W. et. al. 1982., Palumbo,S.A. et.al. 1994	Monitor the product temperature to assure that stored product is maintained at a level sufficient to preclude microbial growth. Monitoring the ambient room temperature to assure that it does not exceed 50 °F for more than 1 hour.	B-Continuous recording device has not been calibrated for weeks and is not recording actual ambient room temperatures. The actual ambient room temperature is 27 degrees higher than it should be, increasing product temperature to the point where bacteria can proliferate and/or spoilage can occur.
SHIPPING	B (Microbial Growth) - Potential for an increase in bacterial flora and other enteric pathogens that will proliferate to unsafe levels on the product if the temperature increases during transport. Ayres, J.C. 1979, Abdel-Rahman, H.T. El-Khaleib, and A.K. Timmawy. 1988.	Product must be 40 °F or less prior to leaving the establishment. Refrigerated transport.	Product was not ≤ 40 °F before it left the dock and microbial proliferation resulted during transport.

*** Not to be included in a plant specific HACCP plan.**

Attachment 11

CCP DETERMINATION
(A CRITICAL CONTROL POINT IS DEFINED AS A POINT, STEP OR PROCEDURE AT WHICH CONTROL CAN BE APPLIED AND A FOOD SAFETY HAZARD CAN BE PREVENTED, ELIMINATED, OR REDUCED TO ACCEPTABLE LEVELS)

PROCESS STEP	HAZARD(S) Biological - B Chemical - C Physical - P Hazard Description	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. 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=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP

Attachment 12

RAW GROUND
CCP DETERMINATION
(A CRITICAL CONTROL POINT IS DEFINED AS A POINT, STEP OR PROCEDURE AT WHICH CONTROL CAN BE APPLIED AND A FOOD SAFETY HAZARD CAN BE PREVENTED, ELIMINATED, OR REDUCED TO ACCEPTABLE LEVELS)

PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. *If yes=move to next questions.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURANCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes-CCP	Q3. COULD CONTANINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP *If yes=move to the nex question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURANCE TO AN ACCEPTABLE LEVEL? *If no=CCP *If yes=not a CCP.	#CCP
Receiving-Meat	B - Microbial Growth.	YES	YES			CCP1B
	C - N/A (Not Applicable)					
	P - Foreign Material	YES	YES			CCP 1P
Receiving-Non-Meat	B - N/A low risk					
	C - Deleterious Chemicals.	YES	YES			CCP 1C
	P- Foreign Material.	YES	YES			CCP 2P
Storage-Meat	B - Microbial Growth.	YES	YES			CCP 2B
	C - N/A					
	P - N/A low risk					
Storage-non-meat	B - Microbial Growth.					
	C - N/A					
	P - Foreign Material Material/Adulteration.	YES	YES			CCP 3P
Assemble/pre-weigh/re-work/final grind	B - Microbial growth	YES	YES			CCP 3B
	C - N/A					
	P - Foreign Material	YES	NO	YES	YES	CCP 4P

CCP DETERMINATION (A CRITICAL CONTROL POINT IS DEFINED AS A POINT, STEP OR PROCEDURE AT WHICH CONTROL CAN BE APPLIED AND A FOOD SAFETY HAZARD CAN BE PREVENTED, ELIMINATED, OR REDUCED TO ACCEPTABLE LEVELS)						
PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled *If yes=move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURANCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. 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=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURANCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP
Packaging	B - N/A Low Risk	Controlled at assembly & storage				
	C - N/A (Not Applicable)					
	P - Foreign Material	YES	NO	YES	NO	CCP 5P
Cooling and Storage of a Product	B - Microbial Growth.	YES	YES			CCP 4B
	C - N/A					
	P - N/A					
Shipping	B - Microbial Growth.	YES	YES			CCP 5B
	C - N/A					
	P - N/A					

Attachment 13

HAZARD ANALYSIS

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant? Risk:Severity	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Animal Receiving and Holding	C: Antibiotics, residues, pesticides P: Foreign material (needles, buckshot, etc.) B: Microbiological - bacterial pathogens	C: No P: No B: Yes	C: Low risk/low incidence, based on National Residue Monitoring Program (USDA, 1989) and Smith et al. (1994). P: Low incidence; based on National Beef Quality Audits conducted 1991 and 1995. B: Live animals are a known source of pathogens.	B: SOP should be written to define procedure for addressing fecal contamination on animals during receiving and holding (i.e., proper feed withdrawal to reduce gut fill, potential handling of animals to reduce mud/feces from mud-caked animals prior to entering the knocking shoot, etc.)	No
Stunning	C: Not applicable P: Not applicable B: Microbiological	B: No	Hemorrhagic tissue and brains contaminated with material are to be condemned (USDA, 1982) due to potential health hazards. Low risk.		No
Bleeding*	C: Not applicable P: Not applicable B: Not applicable				No

* Bleeding is for blood removal only. Opening the hide prior to bleeding is included in dehiding. If this process is not treated as two separate steps then it must be addressed and evaluated as one process. Also special procedures must be considered for Kosher slaughter.

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant? Risk:Severity	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Dehiding: Opening (only penetratin of the skin from the outside to the inside): Rip - leg, midline and fron shank Cap/bung Wet udder removal Foot removal Dehorning Head Skinning Skinning Rump Low Backing High Backing Flanking	P: Not applicable C: Not applicable B: Microbiological - bacterial pathogens	B: Yes	Hide contamination is a known source of pathogens. Low risk - when skining is properly performed, it is unlikely that external surface will contact the carcass to allow contamination. Corrective actions associated with Sanitation SOPs should address skinning defects.	The operational Sanitation Standard Operating Procedures (SSOPs) should address washing/sanitizing knife and hands between each hide-opening cut and/or prior to initiating skinning to preven contamination. (Example SSOP include in Appendix) Potential hazards should be controlled through the SSOPs, and the application of a microbiological intervention(s) later in process. Recommend that the establishment should develop a written SOP for the entire dehiding process to demonstrate the proper skinning procedure.	No *(If you do not have microbiological intervention(s) in place or methods for preventing/ reducing potential contamination at this step or at a later point in the process then you may determine this is a CCP).*

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant? Risk:Severity	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Dehiding: Hide Removal (any mechanical hide puller requires an evaluation of controbution to microbiological contamination). Slide puller Down Puller	C: Not applicable P: Not applicable B: Microbiological-bacterial pathogens	B: Yes	Exterior surface of the hide and the environment may be a source of pathogens. Proper operation of hide puller should preclude product contamination. Routine adjustments to the process should be conducted as needed to maintain proper conditions.	Recommend evaluating and controlling air flow to reduce aerosol contamination. Potential hazards should be controlled through the aplication of SSOPs designed to prevent direct contamination, and through the use of microbiological intervention(s) later in the process.	No *(If you do not have microbiological intervention(s) in place or methods for preventing/ reducing potential contamination at this step or at a later point in the process then you may determine this is a CCP).*

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant? Risk:Severity	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Head Removal	C: Not applicable P: Not applicable B: Microbiological - bacterial pathogens	B: No	B: Potential for introducing pathogens from GI tract onto the carcass when cutting esophagus (Rasmussen et al., 1993); however, risk is low.	Operational Sanitation Standard Operating Procedure (SSOP) should clearly address cleaning/sanitizing of knife to prevent cross contamination. *(Recommend rsearch should be initiated to evaluate additional interventions such as washing, organic rinse, etc. for heads)*	No
Evisceration: Brisket split Rod and secure weasand Bunging/Bagging Pre-gutting (bladder removal) Gastrointestinal (GI) tract removal Pluck removal Liver removall	C: Not applicable P: Not applicable B: Microbiological - bacterial pathogens	B: Yes	B: Contents of the gastrointestinal (GI) tract are potential source of enteric pathogens; however, sanitary dressing procedures should address contamination at this point.	Sanitary Dressing Procedures should be written to define procedures for properly eviscerating carcass to contain GI contents and addres potential mistakes (puncture/breakage) in the process which may cause carcass contamination. Apply approved intervention(s) to remove contamination (i.e.: trim cavity). Potential hazards should be controlled through proper evisceration and the application of microbiological intervention(s) later in the process. *Recommend:* *Brisket split - sanitize between carcasses; bunging/bagging -- bag and tie to prevent fecal contamination; pre-gutting - remove bladder to prevent spilling; evisceration -- to prevent puncture and breakage.*	No *(If the establishment does not have microbiological intervention(s) in place or methods for preventing/ reducing potential contamination at this step or at a later point in the process then you may determine this is a CCP).*

Attachment 14

HACCP PLAN FORM

PRODUCT:

PROCESS STEP/CCP	CRITICAL LIMITS	MONITORING PROCEDURES (WHO/WHAT/WHEN/HOW)	CORRECTIVE ACTIONS

DATE:_____ APPROVED BY:_____

HACCP PLAN

PRODUCT:

PROCESS STEP	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

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING - MEAT	B - Microbial Growth. B -Container Integrity P - Foreign Material.	1 B 1 B 1 P	Temperature within plant specifications.* Immediate container is intact. No visible hazardous non-food material. * Carcasses or red meat must be received at 40° F or below. *Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above will control quality and limt the growth rates of even psycotrophic spoilage organisms, Therefore, these parameters are more than sufficient to prevent growth of mesophillic enteric bacterial pathogens.	Internal temperature monitored when a shipment is received by the receiving personnel. Visual inspection of immediate container at the time a shipment is received and before processing by the receiving personnel. Record all findings in HACCP receiving log. Include lot #, date, condition, time of inspection and sign the record.	If product temperature is out of compliance, immediate container is compromised or foreign material is noted in/on the meat product, identify and control affected product for disposition; take corrective action to prevent reoccurrence. Notify plant designee. Receiving personnel documents actions taken in HACCP receiving log. Signs record and records time of observation.	Record all results and corrective action(s) in a plant specific log/record. Signs record and records time and date of observation. Corrective Action Log	Twice Weekly visual observation of product and receiving procedures, done by an individual who did not produce the records and who has successfully completed a course of instruction on HACCP, or the responsible establishment official. Audit to verify sampling techniques and accuracy of records; verify accuracy of temperature devices; determine in the Critical Limit corresponds to the plant records; check to see if Critical Limit is adequate for hazard; assure corrective actions are adequate; document findings. Weekly calibration of thermometers.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING-NON-MEAT	C - Deleterious Chemicals. P - Foreign Material.	1 C 2 P	Letters of guarantee are on file for all packaging materials/ non-meat supplies used by the establishment. Specific food contact acceptability must match that of the incoming shipment. No visible or detectable hazardous foreign material or matter.	Supervisory review of letters of guarantee for each new packaging material/non-meat supply not previously used by the establishment brought onto establishment premises. Check incoming material/ supplies to see if material identification matches the accompanying letter of guarantee for each shipment. Check letters of guarantee for materials, supplies used at the time each shipment is received and prior to release from the receiving area to assure that they are to be used as intended. Visual inspection of product when it is received and prior to use in or on product. Record all findings in HACCP receiving log. Signs record, dates and records time of observation.	Establish program through purchasing dept. to assure that letters of guarantee are on file prior to delivery. Notify plant designee. If process does not demonstrate control within written HACCP Plan procedures and letter of guarantee is not present or is unacceptable, do not allow packaging materials/non-meat supplies to enter establishment; take corrective action to prevent reoccurrence; designated receiving personnel documents actions taken in HACCP receiving log. Signs record, dates and records time of observation.	Record all results and corrective action(s) in a plant specific log/record. Signs record, date and records time of observation. Corrective Action Log.	Twice Weekly visual inspection of product and observation of receiving procedures, done by an individual who did not produce the records and who has successfully completed a course of instruction on HACCP, or the responsible establishment official. Audit by receiving manager to verify sampling techniques and accuracy of records; verify accuracy of temperature devices; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
STORAGE - MEAT	B - Microbial Growth.	2 B	*Product in storage not to exceed 40 °F. Environmental temperature within plant specifications. Carcasses or meat must be stored at 40° F or below. A maximum of 50° F maintained in product handling areas. Thermometers must be calibrated and accurate to within +/- 1 °F. *Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above will control quality and limt the growth rates of even psycotrophic spoilage organisms, Therefore, these parameters are more than sufficient to prevent growth of mesophillic enteric bacterial pathogens.	Environmental and internal temperature monitored twice daily by personnel responsible for the function through defined activities. Record all findings in HACCP storage log, sign, date, and record time of observation. Refrigeration operation and controls rountinely monitored by personnel responsible for the function. Thermometers are calibrated once a month and the results entered in a maintenance log, signed, time of caliration recorded and dated.	If process monitoring does not demonstrate control within written HACCP plan procedures, control affected product, evaluate operation for cause of deficiency; repair and/or readjust refrigeration device, cooler; rechill or condemn product; correct or adjust procedures; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP storage log. Notify plant designee.	Record all results and corrective action(s) in a plant storage or maintenance log/record, Sign record, date and record time of observation Corrective Action Log.	Twice Weekly visual inspection of thermometers and temperature records by an individual who did not produce the records and who has successfully completed a course of instruction on HACCP, or the responsible establishment official. Audit to verify sampling techniques and accuracy of records; verify accuracy of temperature devices; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings. Weekly evaluation of calibrations log and calibration of thermometers.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
STORAGE-NON-MEAT	P - Foreign Material/ Adulteration	3 P	No visible hazardous foreign material.	Visual inspection of storage room and non-meat supplies/ packaging materials prior to use in product by the individual releasing the packaging material or non-meat ingredient. Record all findings in HACCP records log, sign record, date and record time of observation.	If process monitoring does not demonstrate control within written HACCP plan procedures, control affected material, ingredient, or supply; rework if possible; correct or adjust procedures; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; document actions taken in HACCP storage or corrective action log. Sign record, date and record time of observation. Notify plant designee.	Record all results and corrective action(s) in a plant storage log/record and sign record. Corrective Action Log.	Twice Weekly visual inspection of product done by an individual who did not produce the records and who has successfully completed a course of instruction on HACCP, or the responsible establishment official. Audit records to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
ASSEMBLE/ PRE-WEIGH/ PRE-GRIND/ RE-WORK FINAL GRIND MEAT	B - Microbial Growth.	3 B	*Product temperature maintained at or below 40° F during handling for more than 3 hours. A maximum of 50° F maintained in product handling areas. Growth of L. monocytogenes Thermometers must be calibrated and accurate to within +/- 1 °F.	Product temperature monitored for each lot after final grind by personnel responsible for the function. Record all findings in HACCP processing log, sign record, date and record time of observation.	If process does not demonstrate control within written HACCP Plan procedures, identify and control affected product; correct or adjust procedures; recondition/rework product; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP processing log, signs record, dates and record time of observation/corrective action. Notify plant designee.	Record all results and corrective action(s) in a plant processing and microbiological testing log and/or corrective action log. Sign record, date nd record time of observation.	Twice Weekly measurement of product temperatures by an individual who did not produce the records and who has successfully completed a course of instruction on HACCP, or the responsible establishment official. Audit to verify sampling techniques and accuracy of records; verify accuracy of temperature devices; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings. Weekly calibration of thermometers and metal detectors.
	P - Foreign Material	4 P	No metal particles, visual inspection of each lot of product to exceed 1/32 inches. No visible foreign material. *Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above will control quality and limt the growth rates of even psycotrophic spoilage organisms, Therefore, these parameters are more than sufficient to prevent growth of mesophillic enteric bacterial pathogens.	All product is run through a detection device prior to packaging.	If foreign material is detected. Retain product for rework and retesting or condemn. Determine source of contamination through evaluation of the operation. Personnel responsible for the functiondocuments actions taken in HACCP records log, signs record, date, and record time of observation/corrective action.	Record all results and corrective/ preventive action(s) in a formulaiton log/record and/or corrective action log. Sign record, date and record time of observation.	

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
COOLING AND STORAGE OF PRODUCT	B - Microbial Growth.	4 B	*Product temperature maintained at or below 40° F. Environmental temperature does not exceed 50 °F for more than 2 hours. Thermometers must be calibrated and accurate to within +/- 1 °F. *Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above will control quality and limt the growth rates of even psycotrophic spoilage organisms, Therefore, these parameters are more than sufficient to prevent growth of mesophillic enteric bacterial pathogens.	Product temperatures, monitored prior to release for shipping or once per day. Environmental temperature monitored every 4 hours by personnel responsible for the function. Routine monitoring of refrigeration contols and operations by personnel responsible for the function. Record all findings in HACCP storage log. Sign record, date and and record time of observation.	If process monitoring does not demonstrate control within written HACCP plan procedures, control affected product, adjust, or repair refrigeration unit as required, rechill or condemn or cook product; correct or adjust procedures; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP records log. Sign record, date and record time of observation/ corrective action. Notify plant designee.	Record all results and corrective action(s) in a plant storage log/record and/or corrective action log. Sign record, date and record time of observation.	Twice Weekly measurement of product temperatures, of environmental temperatures done by an individual who did not produce the records and who has successfully completed a course of instruction on HACCP, or the responsible establishment official. Audit to verify sampling techniques and accuracy of records; verify accuracy of temperature devices; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings. Weekly calibration of thermometers.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
PACKAGING	P - Foreign Material	5 P	No visible foreign material present in product. Condemn product or remove particles 1/32" or larger	Packaging personnel will monitor the metal detector operation to assure that it is functioning as designed. Setting will be checked prior to shift start up. Record all findings on calibration chart, sign record, date and record time of observation. Automatic detectors are calibrated once month and the results entered in a maintenance log, signed, dated, and time of calibration entered.	If process is notin control within written HACCP plan procedures, control affected product,condemn, recalibrate equipment, reinpect product, and take action to prevent recurrence. Record actions taken in HACCP packaging log. Sign record, date and record time of observation/corrective action. Notify plant designee.	Record all results and corrective action(s) in a plant packaging log/record and/or corrective action log. Sign, record time of results and date record.	Weekly observation of procedures and/or visual inspection of product by an individual who did not produce the records and who has successfully completed a course of instruction on HACCP, or the responsible establishment official. Audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazards; assure corrective actions are adequate; document findings. Weekly calibration of metal detection device.

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PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
SHIPPING	B - Microbial Growth.	5 B	*Product must reach a temperature of $\leq$ 40 °F prior to leaving the establishment. *Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above will control quality and limt the growth rates of even psycotrophic spoilage organisms, Therefore, these parameters are more than sufficient to prevent growth of mesophillic enteric bacterial pathogens	Product will be maintained at or below 40 °F at the time of shipping. Truck temperature will not exceed 50 °F prior to loading. If plant owned truck, routine maintenence and monitoring of refrigeration unit operation and controls. Shipping personel will record all findings in HACCP shipping log,sign record and record lot # and time of observation.	If process does not demonstrate control within written HACCP plan procedures, control affected product, evaluate operation for cause of deficiency; rechill, rework or condemn product, reject transport; correct or adjust procedures; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP records log, signs record and records time of observation/corrective action. Notify plant designee.	Record all results and corrective action(s) in a plant specific shipping and or corrective action log/record. Sign record, and record time of observation.	Twice Weekly measurement of product temperatures, of environmental temperatures, and/or truck temperatures, done by an individual who did not produce the records and who has successfully completed a course of instruction on HACCP, or the responsible establishment official. Audit records to verify sampling techniques and accuracy of records; verify accuracy of temperature devices; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings. Weekly calibration of thermometers.