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HACCP-6

Generic HACCP Model for Mechanically Separated (Species)/ Mechanically Deboned Poultry

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Introduction

The Hazard Analysis Critical Control Points (HACCP) concept is a systematic, scientific approach to process control. The Food Safety and Inspection Service (FSIS) views HACCP as a means of preventing the occurrence of health and safety hazards in plants producing meat and poultry and in their products. It does this by ensuring that controls are applied at any point in a food production system where hazardous situations could occur. These hazards may include biological, chemical, or physical adulteration of food products.

The United States Department of Agriculture (USDA) published a final rule in July 1996 mandating that HACCP be implemented as the system of process control in all USDA-inspected meat and poultry plants. As part of its effort to assist establishments in the preparation of plant-specific HACCP plans, FSIS determined that a generic model for each process defined in the regulation will be made available for use by the regulated industry.

In addition to the generic model, background information on HACCP is included to assist an establishment in conducting a hazard analysis and developing a plant-specific plan.

The regulation includes specific references to the development and maintenance of standard operating procedures for sanitation, and these standard operating procedures should be in place before a HACCP system is implemented. For this reason, principles of good sanitation are not included as part of the HACCP plan.

Principles of HACCP

The foundation of HACCP can be found in the seven principles that describe its functions. These seven principles are:

Principle No. 1: Conduct a Hazard Analysis. Prepare a list of steps in the process where significant hazards can occur, and describe the preventive measures.

Principle No. 2: Identify the Critical Control Points (CCP's) in the process.

Principle No. 3: Establish critical limits for preventive measures associated with each identified CCP.

Principle No. 4: Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.

Principle No. 5: Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.

Principle No. 6: Establish effective recordkeeping procedures that document the HACCP system.

Principle No. 7: Establish procedures to verify that the HACCP system is working correctly.

Definitions

Some definitions of commonly used HACCP terms are included below to clarify some of the terms used in reference to HACCP, hazard analysis, model development, and the development of the specific plan.

Corrective action. Procedures to be followed when a deviation occurs.

Criterion. A standard on which a judgement or decision can be based.

Critical Control Point (CCP). 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.

Critical limit. 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.

Deviation. Failure to meet a critical limit.

HACCP. Hazard Analysis and Critical Control Point. A process that identifies specific hazards and preventive and control measures to ensure the safety of food.

HACCP Plan. The written document that is based upon the principles of HACCP and that delineates the procedures to be followed to ensure the control of a specific process or procedure.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard (Food Safety). Any biological, chemical, or physical property that may cause a food

t o
b e
u n s
a f e
f o r
h u
m a
n
c o n
s u
m p
t i o
n.

Hazard Analysis. 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.

Monitor. To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food health hazard.

Process. A procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products wherein all CCP's, such as packaging, may be applied to one or more of those products within the group.

Development of the Plant Specific HACCP Plan

The National Advisory Committee for Microbiological criteria for Foods (NACMCF) has 12 steps (five preliminary steps listed below and the seven principles from page 1) in developing a HACCP plant specific plan.

PRELIMINARY STEPS

- 1) 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 flow diagram which describes the process.
- 5) Verify the flow diagram.

Then apply the seven principles from page 1 beginning with conducting a hazard analysis.

Remember a Sanitation SOP is a prerequisite for developing a HACCP plan.

There are certain elements required of a HACCP plan developed for a specific inspected establishment. Keep these in mind when proceeding with the steps in plan development. The following steps are all a part of developing your plant-specific plan:

Description of the Product: This is the first step in the development of the model for your process. It will aid you in describing your product(s) so that you may progress through the remainder of model development. The section listing special handling considerations may not be applicable to your particular process and thus may not need to be completed.

Process Flow Diagram: This form should be completed for your process following the completion of the product(s) description. This step includes the course of the process as the product(s) moves from receiving to finished product shipping. It is helpful to complete this portion of your plan while actually walking through your plant and following the production steps involved in the particular product or process.

Hazard Analysis: The Hazard Analysis is a critical step in the development of a plant-specific HACCP plan. This portion of plan development must take into consideration the risk or likelihood of occurrence, and the severity of each hazard. In order to be considered, an identified hazard must be "of such a nature that its prevention, elimination, or reduction to an acceptable level is essential to the production of a safe food." * Hazards that are not significant or not likely to occur will not require further consideration. The potential significance of each hazard should be assessed according to its frequency, risk, and severity. "Risk is an estimate of the likely occurrence of a hazard. The estimate of risk is usually based on a combination of experience, epidemiological data, and information in the technical literature."¹ For example, it is well documented that during the process of poultry slaughter, *Salmonella* is an organism of public health significance that constitutes a risk of sufficient severity for inclusion into a HACCP plan for identification and description of preventive measures. If the plan does not take into consideration the points at which the growth and proliferation of this organism can occur, and identify appropriate preventive measures, a safe food will not be produced.

Remember that in your hazard analysis there are three categories of hazards to consider: chemical, biological, and physical. Appendix 2 includes a table of hazards that are controlled in a HACCP

program. Each process step will be evaluated to determine if significant hazards from one or more of these categories are present. The hazards will be listed at each process step along with the specific preventive measures that can control the hazard. For example, if your plant-specific HACCP plan identifies foreign material as a physical hazard for receiving non-meat ingredients, a preventive measure must be included ensuring that the materials are handled and stored in a manner so as not to contaminate the product.

If conclusive epidemiological data are available, this information should be used to determine the appropriate preventive measure: cooking or cooling temperatures, use of antimicrobial rinses, etc.

Identify the processing steps that present significant hazards and any preventive measures on the Hazard Analysis/Preventive Measures Form. These will be derived from the process steps on your flow diagram. This activity is one of the major portions of the Hazard Analysis. The use of technical literature, epidemiological data, and assistance from an individual with HACCP training at least as described in 9CFR 417 is crucial at this point to ensure that adequate preventive measures have been identified and significant hazards have been addressed.

Critical Control Point (CCP) Determination: Identification and description of the CCP for each identified hazard is the next step in plan development. The CCP determination significance of identified hazards, a determination on the information and data you recorded on the Hazard Analysis/Preventive Measures form will be needed for completion of this portion of the plan.

HACCP Plan Development: This portion of the plan development will be used to designate the specific activities, frequencies, critical limits, and corrective actions that ensure that your process is under control and adequate to produce a safe product. This part will include all the information gathered to this point in your plan development process steps. In addition, the HACCP plan will include specification of critical limits. These limits will be identified after the identification of the CCP's for the process and will be listed in the HACCP Plan. The critical limit must include at a minimum the regulatory requirement for that specific process step.

The following will be identified or described in the HACCP plan: the establishment monitoring procedure or device to be used; the corrective action to be taken if the limit is exceeded; the individual responsible for taking corrective action; the records that will be generated and maintained for each CCP; and the establishment verification activities and the frequency at which they will be conducted. A blank example HACCP plan format has been included at the end of the generic model.

A copy of the Decision Tree developed by the NACMCF is included at the end of this section. The use of the Decision Tree is optional. The questions in the Decision Tree are listed

at the top of each page of the CCP Determination form of the generic model. These questions should be answered when identifying critical control points for your HACCP plan. Remember that the HACCP plan should cover health and safety CCP's, not economic and quality concerns.

A CCP should be identified when it presents a significant hazard and has a significant likelihood of occurrence. Hazards that are unlikely to occur or do not present significant hazards will not be considered during Hazard Analysis and, therefore, will not be identified as a CCP.

Remember that HACCP is a system of process control for the plant and not an inspection system. The creation of the plant-specific plan and its successful operation is the responsibility of each establishment. The plant-specific plan that you have developed will be used to help you monitor your process. The plan should be reassessed routinely by the plant to determine if updates are needed. Such cases may include, but are not limited to: new products are added; a process undergoes substantial changes such as changes in raw materials or their source; product formulation; processing or slaughter methods or systems; production volume; packaging; finished product distribution systems; the intended use or consumers of the finished product; or it is determined that the plan does not adequately ensure process control, defined as when critical limits are not being met. Revision of the HACCP plan should be conducted with the advice and assistance of the HACCP-trained individual.

The generic models use examples of products within the specific process category. The information for your plant-specific plan, and the products covered by the process, may differ and therefore will require different CCPs. There are two plans included in the handbook to help illustrate how two products can fit into the same generic process model.

Specific information related to regulatory requirements for HACCP can be found in Part 417 of the regulations. The 1992 paper on HACCP by the NACMCF contains important information on HACCP plan development, and is a recommended reference tool for use when creating your plant-specific plan.

Steps for Selecting a Generic Process Model

Process Platform for Use of Generic Models

Each generic model was developed by a committee of experts to serve as a guide for creating HACCP plans for various processes. Each generic model can be used as a starting point for the development of your plant-specific plan reflecting your plant environment and the specific processes conducted. The generic model is not intended to be used "as is" for your plant-specific HACCP plans.

The generic models designed by FSIS for use in developing a plant-specific HACCP plan are defined according to process. In order to select the model or models that will be most useful for the activities performed in your plant, the following steps should be taken.

If a model for a slaughter operation is required, select the model for the appropriate species. If a model for a processed product or products is required, proceed as directed in the steps below. If an establishment is a combination plant, i.e. conducting both slaughter and processing activities, the two models can be merged into a plant-specific plan. In this case, overlapping critical control points (CCP's) can be combined as long as all significant hazards are addressed.

- 1) Make a list of all products produced in the plant. Examine the list and group all like products according to common processing steps and equipment used. Compare these to the list of Process Models in Appendix 1. After reviewing and grouping the products produced, you will know the number of models that are needed to develop your plant-specific plans.
- 2) Refer to the process control flow chart (Appendix 3). This will show which process models will fit your product(s) groups most closely. To use the flow chart effectively, move in a step-by-step fashion by asking yourself these questions:

Is the product(s) shelf stable? Some questions that will determine if a process fits one of the shelf stable categories are:

Does the process result in a product sterilized in a sealed package?

Does the process dry the product(s) to an acceptable water activity?

Does the process result in a product(s) that need not be refrigerated?

Does the process acidify the products(s) to an acceptable pH, or is there a combination of the activities listed above resulting in a shelf stable product(s)?

If so, proceed to the categories listed for shelf stable processes.

Is the product(s) not shelf stable? Some questions that will help with this determination are:

Does the process result in a product(s) that must be kept refrigerated, frozen, or at an acceptable holding (heat) temperature?

If so, proceed through the remaining steps, for example:

If a product is not shelf stable but fully cooked, then the "Fully Cooked-Not Shelf Stable" model will be most useful. "Fully cooked" implies that the process includes an acceptable heat treatment that renders a final product ready to eat without further cooking, although the product may be warmed or reheated by the consumer.

If a product is not shelf stable and not fully cooked, but receives other processing that does not involve a heat treatment, the model "Not Shelf Stable with Secondary Inhibitors" will be most useful. If some heat treatment is involved in the process that does not result in a fully cooked product - for example, a cold smoke - the generic model "All Other Not Shelf Stable, Heat Treated" will be most useful.

If a product is not shelf stable and is raw, the "Raw, Ground" or "Raw, Other" models will be most useful. Products in the "Raw, Other" category may contain process steps in addition to cutting, boning, or breaking, but should not contain a process step that significantly alters the raw nature of the product. Products in the "Raw, Ground" process category are subjected to the grinding process and may include products such as fresh sausage.

After the correct generic model has been selected, you should proceed through the steps outlined in the model. The same generic process model may include diverse products, so it is important that you identify and group all products covered by the process model in order to correctly identify the hazards, create a representative flow diagram, identify all critical control points and critical limits, etc. The similarities within groupings will be confirmed as you work through the hazard analysis, flow diagram, and process flow. Not all steps will be common to all products grouped in the process model, but if you have grouped correctly you will see that the steps involved are very similar. If you find that a product has been mis-grouped, repeat the steps outlined above to determine if another generic process model is more appropriate.

Now you are ready to develop your plant-specific HACCP plan(s) according to the procedures shown in the generic process model(s).

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

Model Plan for Mechanically Separated/Deboned

Hazard Analysis

Conducting an analysis of the physical, chemical, and biological hazards associated with a process is a critical first step in the effective development and implementation of the plant-specific HACCP plan. The information gathered should focus on addressing points of public health significance associated with the manufacture of those products by a particular process used in your plant. **The hazard analysis must be conducted as a starting point in the development of the plant-specific plan. Information for a hazard analysis can be obtained from a local public library, community college or university library, the extension service, scientific publications, FDA guidelines, USDA Guidebook Appendix C - Guidebook for the Preparation of HACCP Plans and Appendix D - Meat and Poultry Products Hazards and Control Guide, or other sources that are available to the general public. It is important to include as much information relevant to the public health hazards associated with your process as possible, including information on suppliers performance at meeting public health related specifications, in-plant incidents of contamination or adulteration, and product recalls.** This will ensure that process hazards are recognizable as you proceed through the remaining steps of creating the plant-specific HACCP plan. An example of information needed for an analysis of the hazards associated with a specific process follows on the next few pages. Included along with this information should be your experience with, and knowledge of the process, and how it occurs in your plant.

There are a few important aspects to note when reviewing the information over the next few pages. Every establishment should validate the HACCP plans adequacy in controlling the food safety hazards identified during the hazard analysis, and should verify that the plan is being effectively, implemented. Each establishment should maintain records documenting the establishment's HACCP Plan, including references to all supporting documentation.

Epidemiological information is used to assess the public health significance of the known hazards associated with the specific process. These include the types and severity of diseases and injury caused by the occurrence of microbiological, physical, and chemical contamination. It also will assist you when you are ready to use the decision tree to determine the validity, existence, and appropriateness of a critical control point. This information can aid in determining a **significant** hazard from an insignificant one based on the frequency, severity, and other aspects of the risk.

The biological, chemical, or physical hazard information gathered will aid in determining where a hazard may occur in the process, what could cause the hazard, how it can be prevented, and actions to be taken if conditions which could result in a hazard occur. Information on physical hazards may be more general and may consist simply of items found in foods that are injurious to human health such as glass, metal, needles, etc. The evaluation of physical hazards should include the suppliers utilized and their ability to provide products, ingredients, or materials that meet the food safety requirements of the plant. Past incidents of physical contamination occurring in the plant should also be a consideration when determining the significance of a hazard and the likely occurrence of a similar or related deviation. If specific chemical hazards exist that are associated with the process, these should also be considered as part of the hazard analysis. Examples may be residues from veterinary drugs or zoonotic diseases present in animals at the time of slaughter natural toxins, or pesticides present in non-meat ingredients. Contamination from chemicals used for cleaning, equipment maintenance or upkeep are also of concern.

Creating a bibliography of the sources used will help document and provide the scientific basis for considering a hazard and determining its significance. It will also be useful when a plan is validated, reassessed, or when the hazard analysis is reassessed. Although a bibliography is a useful tool, it is not a regulatory requirement.

Preparing Your HACCP Plan

Assemble the HACCP team.

Your HACCP team should be composed of a HACCP trained individual and other member(s) who are familiar with the product and the process as it is conducted in your plant. There is no set number of participants. This will be determined by each individual establishment.

All team members should receive at least a basic introduction to HACCP. Training can be formal classroom training, on-the-job training, information from college courses and/or HACCP books or manuals.

Some textbooks and journal articles that are recommended for all HACCP model teams are:

1. HACCP in Meat, Poultry and Fish Processing. 1995. eds. Pearson and Dutson. Blackie Academic and Professional, Glasgow.
2. HACCP in Microbiological Safety and Quality. 1988. ICMFS. Blackwell Scientific Publications, Oxford.
3. An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients. 1985. National Research Council, National Academy Press, Washington, D.C.
4. Microorganisms in Foods, Vol 5. ICMSF. Blackwell Scientific Publications, Oxford.

All forms used in the model are examples for guidance only. Other forms a plant may wish to use are also appropriate if the information required in 9 CFR part 417 is included.

Process Description Form

The Process Description Form may be used to describe each food product included in each process category that is manufactured in the establishment. The description(s) answers the following questions: 1) Common name of product; 2) How is it to be used (the intended use of the food by end users or consumers (the intended consumers may be the general public or a particular segment of the population such as infants, the elderly, immune-compromised individuals) or another inspected establishment for further processing; 3) Type of packaging used (plastic bag/vacuum packed); 4) Length of shelf life, and appropriate storage temperature; 5) Where it will be sold (retail/wholesale); 6) Labeling instructions (keep frozen/keep refrigerated, thawing and cooking instructions); and 7) Special distribution controls (keep frozen/keep refrigerated).

Questions 6 and 7 are optional if there are no specific labeling or special instructions.

This form describes the food and its method of distribution. This information is important when determining whether a significant hazard exists and how/where it can be controlled.

PROCESS DESCRIPTION

PROCESS CATEGORY : RAW, GROUND

PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN

THE FOLLOWING QUESTIONS NEED TO BE ANSWERED WHEN DEVELOPING THE PRODUCT DESCRIPTION:

- | | | |
|----|--|--|
| 1. | COMMON NAME? | MECHANICALLY DEBONED CHICKEN |
| 2. | HOW IS IT TO BE USED? | AS MEAT INGREDIENT IN FRANKFURTERS,
SAUSAGES |
| 3. | TYPE OF PACKAGE? | BULK-PACKED (E.G., PLASTIC BAG, VACUUM
PACKED) |
| 4. | LENGTH OF SHELF LIFE,
AT WHAT TEMPERATURE? | 3 - 6 MONTHS AT 0°F OR BELOW
7 DAYS AT 40°F |
| 5. | WHERE WILL IT BE SOLD?
INTENDED USE
CONSUMERS? | WHOLESALE
USE AS AN INGREDIENT IN FURTHER
PROCESSED PRODUCTS
GENERAL PUBLIC |
| 6. | LABELING INSTRUCTIONS? | KEEP FROZEN; KEEP REFRIGERATED |
| 7. | IS SPECIAL DISTRIBUTION
CONTROL NEEDED? | KEEP FROZEN, KEEP REFRIGERATED |

Product and Ingredients Form

The Product and Ingredients Form consists of a full description of the food including the recipe or formulation used. This should include the meat and any edible casings and all added ingredients such as water, spices, restricted ingredients, etc. The formulation may be included and should indicate the amount or percentage of each ingredient in the formulation.

This form is only needed if there is more than one ingredient.

LIST PRODUCT AND INGREDIENTS

PROCESS CATEGORY: RAW, GROUND

PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN

MEAT

CHICKEN FRAMES

Process Flow Diagram

The Process Flow Diagram is used to provide a simple description of the steps involved in the process. The diagram will be helpful to the HACCP Team in the preparation of a HACCP plan and will also serve as a future guide for regulatory officials who must understand the process for their verification activities.

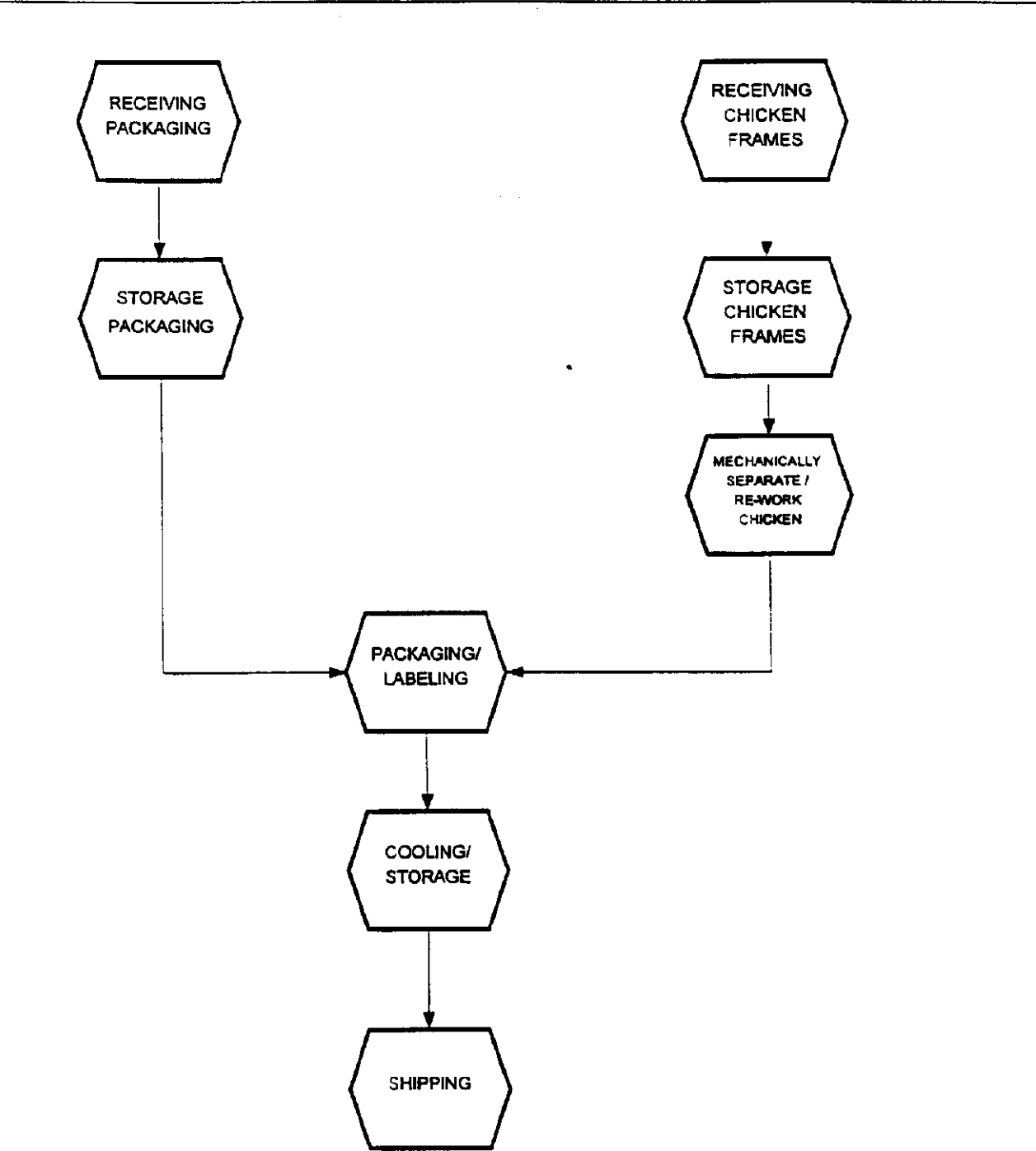
The flow diagram must cover all the steps in the process which are directly under the control of the establishment. It can also include steps in the food chain which are before and after the processing that occurs. For the sake of simplicity, the flow diagram should consist solely of words, not engineering drawings.

Member(s) of the HACCP Team should use the draft flow diagram and walk through the plant to follow the actual process flow as it occurs and make any adjustments, as necessary.

PROCESS FLOW DIAGRAM

PROCESS CATEGORY: MECHANICALLY DEBONED

PRODUCT: MECHANICALLY DEBONED CHICKEN



Hazard Analysis/Preventive Measures Form

The Hazard Analysis/Preventive Measures Form is used to take the steps listed in the Process Flow Diagram and identify where significant hazards could occur and describe the preventive measures, if they exist. A hazard is defined as a **biological, chemical, or physical** property that may cause a food to be unsafe for consumption. The hazard must be of such a nature that its prevention, elimination or reduction to acceptable levels is essential to the production of a safe food. Hazards of low risk and not likely to occur would not require further consideration.

The Hazard Analysis consists of asking a series of questions which are appropriate to the specific food process and establishment. It should question the effect of a variety of factors upon the safety of the food. Factors must be considered that may be beyond the control of the processor. During the Hazard Analysis, safety concerns must be differentiated from quality concerns. Each step in the process flow will be evaluated to determine if any significant hazards should be considered at that step. Examples of questions to be considered during hazard analysis have been included as Attachment 1.

The potential significance of each hazard should be assessed by considering its risk and severity. Risk is an estimate of the likely occurrence of a hazard. Risk is usually based upon a combination of experience, epidemiological data, and information in the technical literature. Severity is the seriousness of the hazard.

Preventive Measures, if they exist, must also be identified. A preventive measure is a physical, chemical, or other factor which can be used to control an identified health hazard.

The fourth column on the Hazard Analysis/Preventive Measures form is for illustrative purposes only and not included in a plant specific HACCP plan.

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN

Process Step	HAZARDS Chemical © Physical (P) Biological (B) INCLUDING MICROBIOLOGICAL	Preventive Measures	Examples of How Hazard Is Introduced *
RECEIVING - MEAT	<p>B (Microbial Growth) - Insufficient temperature control will result in unacceptable microbial growth.</p> <p>B (Mishandling) - The integrity of the immediate container is compromised such that microbial contamination could occur.</p> <p>P (Foreign Material) - Visible foreign material that could compromise product safety.</p>	<p>Maintain product temperature at less than or equal to 50°F or a level sufficient to preclude microbial growth.</p> <p>Baseline micro sampling</p> <p>Visual inspection to ensure that immediate container is not compromised.</p> <p>Visual inspection to ensure no foreign material.</p>	<p>B-Transport refrigeration unit is not functioning properly (out of freon).</p> <p>B-The shipping container (the cardboard combo bin) was crushed by a forklift and the immediate container (the plastic wrap inside the combo) was torn and punctured introducing harmful microbes into the product.</p> <p>P-Pieces of glass found in product from a broken light bulb, metal clips, knives, bone, etc.</p>
RECEIVING PACKAGING MATERIALS	<p>C (Deleterious Chemicals) - Packaging material, are acceptable for intended use. Should be food grade material approved for intended use.</p> <p>P (Foreign Material) - Visible foreign material that could compromise product safety; rodent droppings, insects, metal shavings, hair, dirt, wood slivers, etc.</p>	<p>Verify that the letter of guarantee is on file and appropriate for product use.</p> <p>Visual inspection to ensure no foreign material is present.</p> <p>Third party audit of supplier.</p>	<p>C-The new plastic lined combo bins ordered came in and the letter of guarantee is present with the shipment, however the letter states that the plastic liner is acceptable for industrial use and not food grade.</p> <p>P-Rodent droppings are found on the surface of the packaging material.</p>
STORAGE - MEAT	<p>B (Microbial Growth) - Insufficient temperature control could result in unacceptable microbial growth. Internal product temperature and environmental temperature must be monitored.</p>	<p>Monitor the temperature of the frames and environmental temperature (ex. cooler or freezer) to ensure that the frames do not exceed time and temperature requirements that would allow the growth of <i>L. monocytogenes</i>. Monitor the growth of <i>L. monocytogenes</i>.</p>	<p>B-Cooler generator breaks down and the ambient room temperature in the cooler increases above 50 °F for 10 hours increasing product temperature above 40 °F for 6 hours permitting excessive bacterial growth.</p>
STORAGE PACKAGING MATERIAL	<p>P (Foreign Material/Adulteration) - All packaging materials, must be stored to prevent contamination due to foreign material.</p>	<p>Visual inspection of storage area to ensure that materials are raised off the floor and covered.</p>	<p>P-The product is stored directly against the walls which have visible debris on them. The debris falls into the packaging materials that contact product.</p>
ASSEMBLE/ MECHANICALLY SEPARATE/ DEBONE POULTRY	<p>B (Microbial Growth) -Inadequate temperature control could result in unacceptable microbial growth. Internal product temperature and environmental temperature must be monitored.</p> <p>P (Foreign Materials) - Visible foreign material that could compromise product safety; metal and plastic shavings, rubber gloves, bone, etc.</p>	<p>Monitor ambient room temperature and product temperature to ensure that the poultry frames do not exceed a level sufficient to preclude microbial growth prior to processing and environmental temperatures do not exceed 50°F for more than 2 hours.</p> <p>Use manufacturer's guidelines to assure machine is assembled properly. Visual inspection to ensure no foreign material is present.</p> <p>Routine equipment maintenance.</p>	<p>B-As a result of 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 excess ambient room temperature.</p> <p>P-Moving parts of the deboner are not set properly or are worn and grind together leaving pieces of ground metal in the product.</p>

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY : RAW, GROUND

PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN

Process Step	HAZARDS Chemical © Physical (P) Biological (B) INCLUDING MICROBIOLOGICAL	Preventive Measures	Examples of How Hazard Is Introduced *
PACKAGING/ LABELING	P (Foreign Material)	Use metal detector on product packaging line.	Metal shavings in the product.
COOLING AND STORAGE OF PRODUCT	B (Microbial Growth) - The potential for an increase in microbial growth is significant if the product temperature is not maintained at or below the level where proliferation occurs, particularly <i>Listeria monocytogenes</i> and <i>Salmonella</i> growth.	<p>Monitor the product temperature to assure that stored product is maintained at a level sufficient to preclude microbial growth.</p> <p>Monitor the growth of <u><i>L. monocytogenes</i></u></p> <p>Monitor the ambient room temperature to assure that it does not exceed 50°F for more than one hour.</p> <p>Routine cooler maintenance.</p>	B-Continuous recording device has not been calibrated for months and is not recording actual ambient room temperatures. The actual ambient room temperature is 27°F higher than it should be, increasing product temperature to the point where bacteria can proliferate and/or spoilage occurs.
SHIPPING	B (Microbial Growth) - Potential for an increase in bacterial flora and other enteric pathogens that will proliferate on the product if the temperature increases above a certain level during transport.	<p>Product must be ≤ 40°F prior to leaving the establishment.</p> <p>Refrigerated transport.</p>	Product was not ≤ 40°F before it left the dock due to product standing on dock prior to loading and hazardous microbial growth resulted during transport.

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

CCP Determination Form

The Critical Control Point (CCP) Determination form is used to identify the critical control points in the process. 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 an acceptable level. All significant hazards identified in the hazard analysis must be addressed. Identification of each CCP can be facilitated by the use of a CCP Decision Tree (See Decision Tree). The Decision Tree asks a series of four yes or no questions to assist in determining if a particular step is a CCP for a previously identified hazard. These four questions are listed at the top of the CCP Determination form. Use this as a guide when determining if an identified significant hazard is a critical control point. **CCP's must be carefully developed and documented and must be for product safety only. Different facilities preparing the same food can differ in the risk of hazards and the points, steps, or procedures which are CCP's.** This can be due to differences in each facility such as layout, equipment, selection of ingredients, or the process that is employed.

In this document the CCP's that are identified are for illustrative purposes only. Your individual process will determine the CCP's identified. Remember that proper Sanitary Operating Procedures and maintenance programs are essential prerequisites to HACCP.

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 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
Receiving-Frames	B - Microbial Growth.	YES	YES			CCP 1B
	C - N/A	Controlled at slaughter facility				
Receiving Packaging Materials	P - Foreign Material	YES	YES			CCP 1P
	B - N/A	No significant risk of occurrence				
	C - Deleterious Chemicals.	YES	YES			CCP 1C
	P - Foreign Material.	YES	YES			CCP 2P
Storage-Frames	B - Microbial Growth.	YES	YES			CCP 2B
	C - N/A					
	P - N/A	Controlled at receiving				
Storage Packaging Materials	B - N/A					
	C - N/A					
	P - Foreign Material/Adulteration.	YES	YES			CCP 3P
Mechanically Debone	B - Microbial Growth.	YES	YES			CCP 3B
	C - N/A					
	P - Foreign Material.	YES	YES			CCP 4P
Packaging	B - N/A					
	C - N/A					
	P - Foreign Material	YES	YES			CCP 5P

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 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
Post Processing Cooling and Storage of Product	B - Microbial Growth.	YES	YES			CCP 4B
	C - N/A					
	P - N/A					
Shipping	B - Microbial Growth	YES	YES			
	C - N/A					
	P - N/A low risk	Controlled during processing step				CCP 5B

HACCP Plan Form

The HACCP Plan Form is used to develop a Plant Specific HACCP Plan. This plan can serve as a useful guide, however, it is essential that the unique conditions within each facility be considered during the development of the plant specific plan. The first three columns on the form are transferred from the CCP Determination Form. The fourth column is used to establish critical limits for preventive measures associated with each identified CCP.

A Critical Limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to assure prevention, elimination, or reduction of hazards to acceptable levels. Critical Limits may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental studies and subject matter or technical experts. The fifth column is used to establish monitoring requirements.

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 food safety management by tracking the HACCP system's operation. If monitoring indicates that there is a trend towards loss of control, then action can be taken to bring the process back into control before a deviation occurs. Monitoring provides written documentation for use in verification of the HACCP plan. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

Column six is used to establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit. Where there is a deviation from established critical limits, corrective action plans must be in place to: 1) determine the disposition of non-compliant product; 2) fix or correct the cause of non-compliant product to assure that the CCP is under control; and 3) maintain records of the corrective actions that have been taken where there has been a deviation from critical limits. Because of the variations in CCP's for different processes and the diversity of possible deviations, plant specific corrective actions must be developed for each CCP. The actions must demonstrate that the CCP has been brought under control. Documentation of the corrective actions taken must be signed by the individual responsible for taking corrective actions.

Column seven is used to establish effective recordkeeping procedures that document the HACCP system. The maintenance of proper HACCP records is an essential part of the HACCP system to document that each CCP is under control and to verify the adequacy of the HACCP plan. Records serve as: 1) a written documentation of the establishment's compliance with their HACCP plan; 2) the only reference available to trace the history of an ingredient, in-process operation or a finished product, should problems arise; 3) a ready source of information to identify trends in a particular operation that may result in a deviation if not properly corrected; and, 4) good evidence in potential legal actions. In accordance with the HACCP principles, HACCP records must include; records associated with establishing and monitoring CCP's and critical limits, records for the handling of deviations, and records associated with verification of the HACCP plan. It is also very important that all HACCP records dealing with plant operations

at CCP's and corrective actions taken, be reviewed on a daily basis by a designated individual who must sign or initial all records reviewed. The approved HACCP plan and associated records must be on file at the meat and/or poultry establishment.

Column eight of the HACCP plan establishes procedures for verification that the HACCP system is working correctly. The verification process is designed to review the HACCP plan; to establish whether the CCP's and critical limits have been properly established and are being adequately controlled and monitored; and to determine if the procedures for handling process deviations and recordkeeping practices are being followed.

The effective completion of this step is crucial since here is where you will define your critical limits that will be used to determine process control at a particular CCP.

HACCP PLAN

**PROCESS CATEGORY : RAW GROUND
PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN**

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING - FRAMES	B - Microbial Growth. B - Container Integrity. P - Foreign Material.	1 B 1 B 1 P	Temperature of frames at receipt $\leq 40^{\circ}$ F.* Immediate container is intact. No visible hazardous foreign non-food material (ie. glass); no metal contamination $\geq 1/32$ inch; no bone particles >0.8 inch (20mm).** *Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above and throughout this plan will limit the growth rates of even psychotropic spoilage organisms. Therefore the parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.	Internal temperature of a random sample of each lot of frames received is monitored by receiving personnel. Visual inspection of immediate containers at the time a shipment is received action by receiving personnel. Record all findings in HACCP receiving log and sign record, date, and include time of inspection.	If product temperature exceeds 40° F, immediate container is compromised, or foreign material is noted in/on the frames, identify and control affected product for disposition and condemnation; take corrective action to prevent recurrence. Condemn product or remove particles $1/32''$ or larger. Notify plant designee.	Record all results and corrective/preventive action(s) in a receiving log and/or corrective action log. Sign record and record the time of observation or corrective/preventive action.	Twice weekly visual observation of product and receiving procedures, done by an individual who did not produce the record(s) and who has successfully completed a course of instruction in 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 : MECHANICALLY DEBONED CHICKEN**

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING PACKAGING MATERIAL	<p>C - Deleterious Chemicals.</p> <p>P - Foreign Material.</p>	<p>1 C</p> <p>2 P</p>	<p>Letters of guarantee are on file for all packaging materials/ used by the establishment.</p> <p>No visible hazardous foreign non-food material (ie. glass, metal).</p>	<p>Receiving personnel reviews all letters of guarantee for each new packaging material/non-meat supply coming into or prior to delivery to the establishment.</p> <p>Check incoming material/ supplies to see if material identification matches the accompanying letter of guarantee.</p> <p>Check letters of guarantee at appropriate times for materials/supplies used on a continuous basis to assure compliance.</p> <p>Visual inspection of packaging material at appropriate times by qualified personnel.</p> <p>Record all findings in HACCP receiving log and sign record, date, and include time of action.</p>	<p>Establish program through purchasing dept. to assure that letters of guarantee are on file prior to delivery of packaging material.</p> <p>If process does not demonstrate control within written HACCP Plan procedures and letter of guarantee is not present or acceptable, do not allow packaging materials/non-meat supplies to enter establishment; take corrective action to prevent recurrence; plant designee documents actions taken in HACCP records log and signs record and include date and time of action.</p> <p>Notify plant designee.</p>	<p>Record all results and corrective/preventive action(s) in a receiving log and/or corrective action log. Sign, date, and record time of observation or corrective/preventive action.</p>	<p>Twice weekly visual inspection of product and observation of receiving procedures, done by an individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official.</p> <p>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.</p>

HACCP PLAN

**PROCESS CATEGORY : RAW GROUND
PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN**

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
STORAGE - FRAMES	B - Microbial Growth.	2 B	<p>Environmental temperature must not exceed 50°F for more than 4 hours.</p> <p>Frames must be stored at 40° F or below. A maximum of 50° F maintained in product handling areas.</p> <p>Less than 1 log growth of <i>L. monocytogenes</i>.</p>	<p>Environmental and internal temperature monitored every two hours by personnel responsible for the function.</p> <p>Routine monitoring of refrigeration operation and controls by personnel responsible for the function.</p> <p>Record all findings in HACCP receiving log. Sign record, date, and include time of action.</p> <p>Check to see if > 1 log growth of <i>Listeria monocytogenes</i>.</p>	<p>If process is not within written HACCP plan procedures, control affected product, rekill product; condemn product, correct or adjust procedures; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP receiving log and signs record, date and includes time of action.</p> <p>If microbial growth exceeds the critical limit, the frames are condemned.</p> <p>Notify the plant designee.</p>	<p>Record all results and corrective/preventive action(s) in a storage, micro log and/or corrective action log. Sign record and record time of observation or corrective/preventive action.</p>	<p>Twice weekly visual inspection of product done by an individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official.</p> <p>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.</p> <p>Weekly calibrations of thermometers.</p>

HACCP PLAN

**PROCESS CATEGORY : RAW GROUND
PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN**

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
STORAGE PACKAGING MATERIAL	P - Foreign Material/ Adulteration	3 P	No visible hazardous foreign non-food or food material (ie. glass,product residue).	Visual inspection of storage room and packaging materials daily at appropriate times by personnel responsible for the function. Record all findings in HACCP receiving log. Sign record, date, and include time of action.	If process is not within written HACCP plan procedures, control affected material, destroy or recondition affected material; 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 and signs record, date and include time of action. Notify plant designee.	Record all results and corrective/preventive action(s) in a storage log and/or corrective action log.. Sign record and reservation/corrective action.	Twice weekly visual inspection of product done by an individual who did not produce the record(s) and who has successfully completed a course of instruction in 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.

HACCP PLAN

**PROCESS CATEGORY : RAW GROUND
PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN**

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
MECHANICALLY DEBONING	B - Microbial Growth.	4 B	<p>Product temperature maintained at or below 40° F during process.*</p> <p>A maximum of 50° F maintained in product handling areas.</p>	<p>Product temperature monitored after exiting the deboner by qualified personnel.</p> <p>Record all findings in HACCP records log. Sign record and record time of observation.</p> <p>Room temperature monitored every 2 hours by personnel responsible for the function.</p>	<p>If process does not demonstrate control within written HACCP Plan procedures, identify and control or condemn affected product; correct or adjust procedures; recondition/rework product; evaluate operation for cause of deficiency; take corrective action to prevent recurrence; plant designee documents actions taken in HACCP records log and signs record, date and include time of action.</p> <p>If process is not within written HACCP Plan procedures, identify and control or condemn 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 records log and signs record, date and include time of action.</p> <p>Notify plant designee.</p>	<p>Record all results and corrective/preventive action(s) in a processing log and/or corrective action log. Sign record and record time of observation or corrective/preventive action.</p>	<p>Twice Weekly measurement of product temperatures by an individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official.</p> <p>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.</p> <p>Weekly calibration of thermometers.</p>
	P - Foreign material	4 P	<p>No visible foreign non-food material (ie. glass, plastic); no metal contamination > 1/32 inch; no bone particles >0.8 inch (20mm).**</p> <p>*Note:Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above and throughout this plan will limit the growth rates of even psychotrophic spoilage organisms. Therefore the parameters are more than sufficient to prevent growth of mesophilic enteric</p>	<p>Visual inspection of deboned poultry.</p> <p>Record all findings in HACCP records log. Sign record, date and include time of action.</p>			

HACCP PLAN

**PROCESS CATEGORY : RAW GROUND
PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN**

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	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	<p>Product temperature maintained at or below 40° F.*</p> <p>Environmental temperature shall not exceed 50°F for more than 4 hours.</p> <p>Less than 1 log growth of <i>L. monocytogenes</i>.</p> <p>*Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above and throughout this plan will limit the growth rates of even psychotropic spoilage organisms. Therefore the parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.</p>	<p>Product temperatures, monitored by cooler floor personnel as it is placed in the cooler.</p> <p>Environmental temperatures monitored every two hours by personnel responsible for the function.</p> <p>Refrigeration operation and controls routinely monitored by personnel responsible for the function.</p> <p>Record all findings in HACCP records log. Sign record, date and include time of action.</p> <p>Check to see if >1 log growth of <i>Listeria monocytogenes</i></p>	<p>If process does not demonstrate control within written HACCP plan procedures, control affected product, re chill product; correct or adjust procedures and/or refrigeration unit; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP records log and signs record, date and include time of action.</p> <p>Notify plant designee.</p>	<p>Record all results and corrective/preventive action(s) in a cooling log. Sign record and record time of observation or corrective/preventive action.</p>	<p>Twice weekly measurement of product temperatures, and environmental temperatures by an individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official.</p> <p>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.</p> <p>Weekly calibration of thermometers.</p>

HACCP PLAN

PROCESS CATEGORY : RAW GROUND
PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	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	<p>Product must not exceed a temperature of <math>40^{\circ}</math> F prior to leaving the establishment.*</p> <p>Truck temperature not to exceed <math>50^{\circ}</math> F prior to shipping product.</p> <p>*Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above and throughout this plan will limit the growth rates of even psychotropic spoilage organisms. Therefore the parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.</p>	<p>Product temperatures and truck temperatures, monitored for each lot shipped by shipping personnel.</p> <p>If truck is plant owned, routinely monitor operation and controls on refrigeration unit.</p> <p>Record all findings in HACCP records log. Sign record, date and include time of action.</p>	<p>If process does not demonstrate control within written HACCP plan procedures, control affected product, re chill product, reject transport; 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 and signs record, date and include time of action.</p> <p>Notify plant designee.</p>	<p>Record all results and corrective/preventive action(s) in a packaging log and/or corrective action log. Sign record and record time of observation or corrective/preventive action.</p>	<p>Twice weekly measurement of product temperatures. Weekly measurement of temperatures by an individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official.</p> <p>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.</p> <p>Weekly calibration of thermometers.</p>

HACCP PLAN

**PROCESS CATEGORY : RAW GROUND
PRODUCT EXAMPLE : MECHANICALLY DEBONED CHICKEN**

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
Packaging	P - Foreign Material	5P	No visible foreign material (i.e. glass).	Visible inspection of random sample of packaging material every 2 hours. Record all findings in HACCP packaging log. Sign, record, date, and record time of inspection.	If process does not demonstrate control within written HACCP plan procedures, control affected product, reject transport; correct or adjust procedures; evaluate operation for cause of deficiency; take corrective action to prevent recurrence; personnel responsible for action documents taken in HACCP packaging log and signs record, date and include time of action. Notify plant designee.	Record all results and corrective/preventive action(s) in a packaging log and/or corrective action log. Sign and date record and record time of observation or corrective/preventive action.	Twice weekly examination of a random sample of packaging material by an individual who did not produce the record(s) and who has successfully completed a course of instruction in 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.

Process Description Form

The Process Description Form may be used to describe each food product included in each process category that is manufactured in the establishment. The description(s) answers the following questions: 1) Common name of product; 2) How is it to be used (the intended use of the food by end users or consumers (the intended consumers may be the general public or a particular segment of the population such as infants, the elderly, immune-compromised individuals) or another inspected establishment for further processing; 3) Type of packaging used (plastic bag/vacuum packed)); 4) Length of shelf life, and appropriate storage temperature; 5) Where it will be sold (retail/wholesale); 6) Labeling instructions (keep frozen/keep refrigerated, thawing and cooking instructions); and 7) Special distribution controls (keep frozen/keep refrigerated).

Questions 6 and 7 are optional if there are no specific labeling or special instructions.

This form describes the food and its method of distribution. This information is important when determining whether a significant hazard exists and how/where it can be controlled.

PROCESS DESCRIPTION

PROCESS CATEGORY : RAW, GROUND

PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK

THE FOLLOWING QUESTIONS NEED TO BE ANSWERED WHEN DEVELOPING THE PRODUCT DESCRIPTION:

- | | |
|--|---|
| 1. COMMON NAME? | MECHANICALLY SEPARATED PORK |
| 2. HOW IS IT TO BE USED?
INTENDED USE? | AS MEAT INGREDIENT IN BOLOGNA,
FRANKFURTERS, SAUSAGES,
SECTIONED AND FORMED PRODUCTS |
| 3. TYPE OF PACKAGE? | BULK-PACKED (E.G., PLASTIC BAG,
VACUUM PACKED) |
| 4. LENGTH OF SHELF LIFE,
AT WHAT TEMPERATURE? | 3 - 6 MONTHS AT 0° F OR BELOW
7 DAYS AT 40° F |
| 5. WHERE WILL IT BE SOLD?
CONSUMER? | WHOLESALE
GENERAL PUBLIC; NO SPECIFIC AT
RISK POPULATION |
| 6. LABELING INSTRUCTIONS? | KEEP FROZEN; KEEP REFRIGERATED |
| 7. IS SPECIAL DISTRIBUTION
CONTROL NEEDED? | KEEP FROZEN, KEEP REFRIGERATED |

Product and Ingredients Form

The Product and Ingredients Form consists of a full description of the food including the recipe or formulation used. This should include the meat and any edible casings and all added ingredients such as water, spices, restricted ingredients, etc. The formulation may be included and should indicate the amount or percentage of each ingredient in the formulation.

This form is only needed if there is more than one ingredient.

LIST PRODUCT AND INGREDIENTS

PROCESS CATEGORY: RAW, GROUND

PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK

MEAT

PORK CARCASS PARTS

Process Flow Diagram

The Process Flow Diagram is used to provide a simple description of the steps involved in the process. The diagram will be helpful to the HACCP Team in the preparation of a HACCP plan and will also serve as a future guide for regulatory officials who must understand the process for their verification activities.

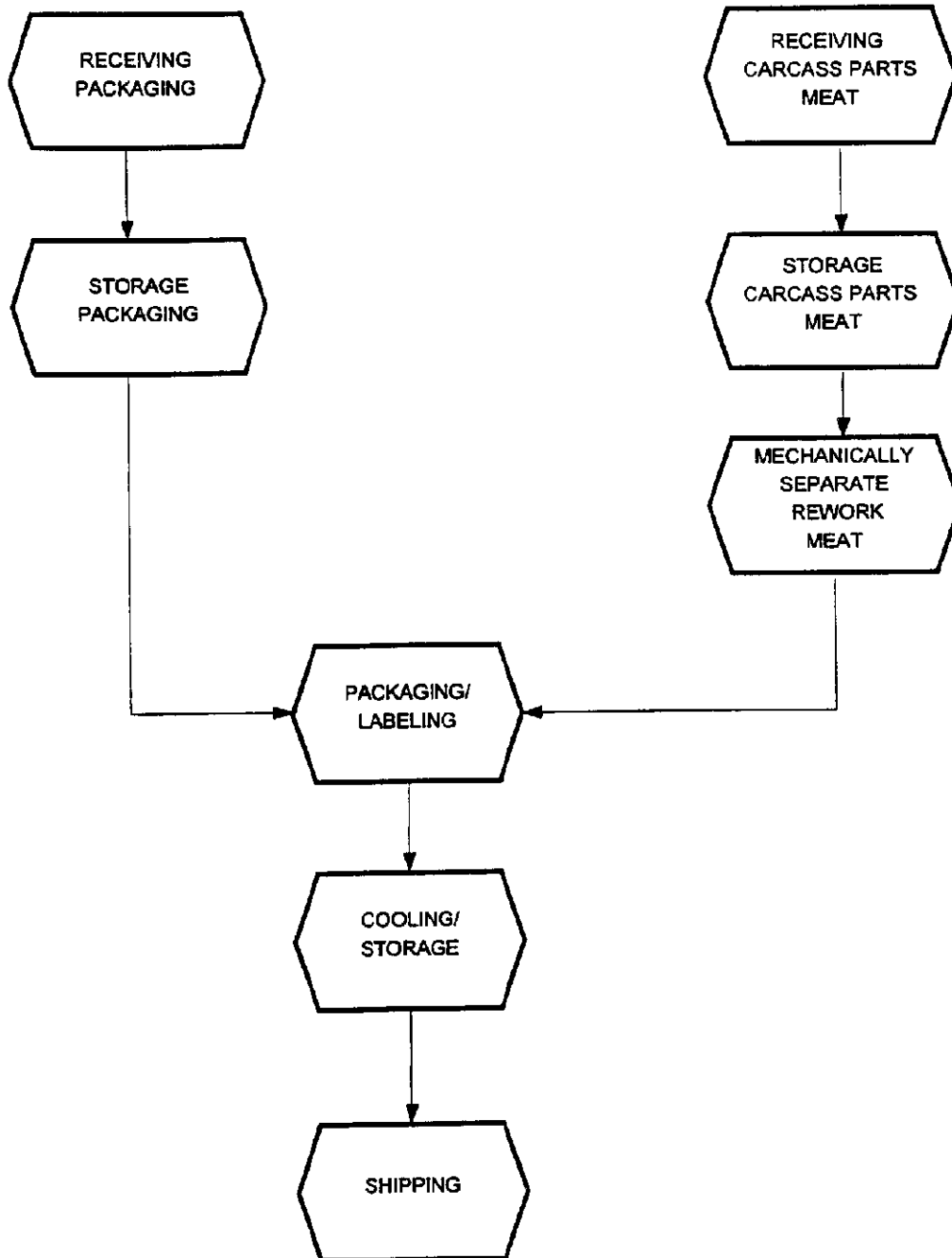
The flow diagram must cover all the steps in the process which are directly under the control of the establishment. It can also include steps in the food chain which are before and after the processing that occurs. For the sake of simplicity, the flow diagram should consist solely of words, not engineering drawings.

Member(s) of the HACCP Team should use the draft flow diagram and walk through the plant to follow the actual process flow as it occurs and make any adjustments, as necessary.

PROCESS FLOW DIAGRAM

PROCESS CATEGORY: MECHANICALLY SEPARATED

PRODUCT: MECHANICALLY SEPARATED PORK



Hazard Analysis/Preventive Measures Form

The Hazard Analysis/Preventive Measures Form is used to take the steps listed in the Process Flow Diagram and identify where significant hazards could occur and describe the preventive measures, if they exist. A hazard is defined as a **biological, chemical, or physical** property that may cause a food to be unsafe for consumption. The hazard must be of such a nature that its prevention, elimination or reduction to acceptable levels is essential to the production of a safe food. Hazards of low risk and not likely to occur would not require further consideration.

The Hazard Analysis consists of asking a series of questions which are appropriate to the specific food process and establishment. It should question the effect of a variety of factors upon the safety of the food. Factors must be considered that may be beyond the control of the processor. During the Hazard Analysis, safety concerns must be differentiated from quality concerns. Each step in the process flow will be evaluated to determine if any significant hazards should be considered at that step. Examples of questions to be considered during hazard analysis have been included as Attachment 1.

The potential significance of each hazard should be assessed by considering its risk and severity. Risk is an estimate of the likely occurrence of a hazard. Risk is usually based upon a combination of experience, epidemiological data, and information in the technical literature. Severity is the seriousness of the hazard.

Preventive Measures, if they exist, must also be identified. A preventive measure is a physical, chemical, or other factor which can be used to control an identified health hazard.

The fourth column on the Hazard Analysis/Preventive Measures form is for illustrative purposes only and not included in a plant specific HACCP plan.

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK

Process Step	HAZARDS Biological (B) Including Microbiological Chemical © Physical (P)	Preventive Measures	Examples of How Hazard Is Introduced *
RECEIVING - MEAT	<p>B (Microbial Growth) - Insufficient temperature control will result in unacceptable microbial growth. Ayres, J.C. 1979 Duitschaver, C.L. and C.I. Buteau, 1979.</p> <p>B (Mishandling) - The integrity of the immediate container is compromised such that microbial contamination could occur. USDA Guidebook, Hazards and Preventive Measures Guide.</p> <p>P (Foreign Material) - Visible foreign material that could compromise product safety. Hyman, F.N. et. al 1993</p>	<p>Maintain product temperature at a level sufficient to preclude microbial growth.</p> <p>Visual inspection to ensure that immediate container is not compromised.</p> <p>Visual inspection to ensure no hazardous foreign material.</p>	<p>B-Transport refrigeration unit is not functioning properly (out of freon).</p> <p>B-The shipping container (the cardboard combo bin) was crushed by a forklift and the immediate container (the plastic wrap inside the combo) was torn and punctured introducing harmful microbes into the product.</p> <p>P-Pieces of glass found in product from a broken light bulb, metal clips, knives, bone, etc.</p>
RECEIVING PACKAGING MATERIALS	<p>C (Deleterious Chemicals) - Packaging materials, are acceptable for intended use. Should be food grade material approved for intended use. Bean, N. Hand and P.N. Griffin. 1990</p> <p>P (Foreign Material) - Visible foreign material that could compromise product safety; rodent droppings, insects, metal shavings, hair, dirt, wood slivers, etc.</p>	<p>Verify that the letter of guarantee is on file and appropriate for product use.</p> <p>Visual inspection to ensure no hazardous foreign material is present.</p> <p>Third party audit of supplier.</p>	<p>C-The new plastic lined combo bins ordered came in and the letter of guarantee is present with the shipment, however the letter states that the plastic liner is acceptable for industrial use and not food grade.</p> <p>P-Hard, gritty, black material is found on the surface of the combo bins.</p>
STORAGE - MEAT	<p>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. Johnston, R.W. et.al. 1982</p>	<p>Monitor the temperature of the frames and environmental temperature (ex. cooler or freezer) to ensure that the frames do not exceed a level sufficient to preclude microbial growth and the cooler temperature does not exceed 50 °F for over 2 hours.</p> <p>Routine cooler/refrigeration maintenance.</p>	<p>B-Cooler generator breaks down and the ambient room temperature in the cooler increases above 50 °F for 10 hours increasing product temperature above 40 °F for 6 hours permitting excessive bacterial growth.</p>
STORAGE PACKAGING MATERIAL	<p>P (Foreign Material/Adulteration) - All packaging materials, must be stored to prevent contamination due to foreign material. USDA Guidebook. Hazards and Preventive Measures Guide.</p>	<p>Visual inspection of storage area to ensure that materials are raised off the floor and covered.</p>	<p>P-The product is stored directly against the walls which have visible debris on them. The debris falls into the packaging materials that contact product.</p>

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK

Process Step	HAZARDS Biological (B) Including Microbiological Chemical © Physical (P)	Preventive Measures	Examples of How Hazard Is Introduced *
ASSEMBLE/ MECHANICALLY SEPARATE PORK	<p>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. Comi, G., et. al 1992</p> <p>P (Foreign Materials) - Visible foreign material that could compromise product safety; metal and plastic shavings, rubber gloves, bone, etc. Surkeiwils, B.F. et. al. 1972, USDA Guidebook, Hazards and Preventive Measures Guide</p>	<p>Monitor ambient room temperature and product temperature to ensure that the carcass parts do not exceed a level sufficient to preclude microbial growth prior to processing and environmental temperatures do not exceed 50°F for more than 2 hours.</p> <p>Use manufacturer's guidelines to assure machine is assembled properly. Routine equipment maintenance. Visual inspection to ensure no hazardous foreign material is present.</p>	<p>B-As a result of 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> <p>P-Moving parts of the deboner are not set properly or are worn and grind together leaving pieces of ground metal into the product.</p>
PACKAGING/ LABELING	P (Foreign Material) Visible or detectable metal.	Use metal detector on product packaging line.	Metal shavings in the product from broken clips on the chub pack line.
COOLING AND STORAGE OF PRODUCT	<p>B (Microbial Growth) - The potential for an increase in microbial growth is significant if the product temperature is not maintained at or below the level where proliferation occurs, particularly <u>Salmonella</u> growth. Ayers, J.C. 1979 Buchanan, R.L. and L.A. Klawilter, 1992.</p>	<p>Monitor the product temperature to assure that stored product is maintained at a temperature sufficiently low to preclude microbial growth.</p> <p>Monitor the ambient room temperature to assure that does not exceed 50°F for more than one hour.</p> <p>Routine maintenance of refrigeration unit. (This may be covered using GMP's)</p>	B- Continuous recording device has not been calibrated for months and is not recording actual ambient room temperatures. The actual ambient room temperature is 27°F higher than it should be, increasing product temperature to the point where bacteria can proliferate and/or spoilage occur.
SHIPPING	<p>B (Microbial Growth) - Potential for an increase in bacterial flora and other enteric pathogens that will proliferate on the product if the temperature increases above a certain level during transport. Ayers, J.C. 1979.</p>	<p>Product must be at a temperature sufficiently low to preclude microbial growth (ex 40°F) prior to leaving the establishment.</p> <p>Refrigerated transport.</p>	Product was not ≤ 40°F before it left the dock due to product standing on dock prior to loading and hazardous microbial growth resulted during transport.

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

CCP Determination Form

The Critical Control Point (CCP) Determination form is used to identify the critical control points in the process. 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 an acceptable level. All significant hazards identified in the hazard analysis must be addressed. Identification of each CCP can be facilitated by the use of a CCP Decision Tree (See Decision Tree). The Decision Tree asks a series of four yes or no questions to assist in determining if a particular step is a CCP for a previously identified hazard. These four questions are listed at the top of the CCP Determination form. Use this as a guide when determining if an identified significant hazard is a critical control point. **CCP's must be carefully developed and documented and must be for product safety only. Different facilities preparing the same food can differ in the risk of hazards and the points, steps, or procedures which are CCP's.** This can be due to differences in each facility such as layout, equipment, selection of ingredients, or the process that is employed.

In this document the CCP's that are identified are for illustrative purposes only. Your individual process will determine the CCP's identified. Remember that proper Sanitary Operating Procedures and maintenance programs are essential prerequisites to HACCP.

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 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
Receiving-Pork	B - Microbial Growth.	YES	YES			CCP 1B
	C - N/A low risk - controlled by residue programs prior to slaughter					
	P - Foreign Material	YES	YES			CCP 1P
Receiving Packaging Materials	B - N/A not likely to occur					
	C - Deleterious Chemicals.	YES	YES**			CCP 1C
	P - Foreign Material.	YES	YES**			CCP 2P
Storage-Meat/Bones	B - Microbial Growth.	YES	YES			CCP 2B
	C - N/A - low risk					
	P - N/A - not likely to occur					
Storage Packaging Materials	B - N/A - no significant hazard					
	C - N/A - controlled at receiving					
	P - Foreign Material/Adulteration.	YES	YES (Note: This hazard may alternatively be controlled at the packaging step.)			CCP 3P
Assemble/Mechanically Separate Pork	B - Microbial Growth.	YES	YES			CCP 3B
	C - N/A					
	P - Foreign Material.	YES	YES			CCP 4P

*Establishment's only supplier has an effective operating HACCP plan for production and transport of meat products.

**This CP may not be identified as a CCP if the supplier has a HACCP plan or the hazard analysis shows that the incidence of contamination from a supplier does not present a significant hazard.

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 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
Post Processing Cooling and Storage of Product	B - Microbial Growth.	YES	YES			CCP 4B
	C - N/A					
	P - N/A					
Packaging Labeling	B - N/A					
	C - N/A					
	P - Foreign Material	YES	YES Note: This hazard may alternatively be controlled at the storage step			
B - Microbial Growth.	YES	YES				CCP 5B
	C - N/A					
	P - N/A					

HACCP Plan Form

The HACCP Plan Form is used to develop a Plant Specific HACCP Plan. This plan can serve as a useful guide, however, it is essential that the unique conditions within each facility be considered during the development of the plant specific plan. The first three columns on the form are transferred from the CCP Determination Form. The fourth column is used to establish critical limits for preventive measures associated with each identified CCP.

A Critical Limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to assure prevention, elimination, or reduction of hazards to acceptable levels. Critical Limits may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental studies and subject matter or technical experts. The fifth column is used to establish monitoring requirements.

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 food safety management by tracking the HACCP system's operation. If monitoring indicates that there is a trend toward loss of control, then action can be taken to bring the process back into control before a deviation occurs. Monitoring provides written documentation for use in verification of the HACCP plan. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

Column six is used to establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit. Where there is a deviation from established critical limits, corrective action plans must be in place to: 1) determine the disposition of non-compliant product; 2) fix or correct the cause of non-compliant product to assure that the CCP is under control; and 3) maintain records of the corrective actions that have been taken where there has been a deviation from critical limits. Because of the variations in CCP's for different processes and the diversity of possible deviations, plant specific corrective actions must be developed for each CCP. The actions must demonstrate that the CCP has been brought under control. Documentation of the corrective actions taken must be signed by the individual responsible for taking corrective actions.

Column seven is used to establish effective recordkeeping procedures that document the HACCP system. The maintenance of proper HACCP records is an essential part of the HACCP system to document that each CCP is under control and to verify the adequacy of the HACCP plan. Records serve as: 1) a written documentation of the establishment's compliance with their HACCP plan; 2) the only reference available to trace the history of an ingredient, in-process operation or a finished product, should problems arise; 3) a ready source of information to identify trends in a particular operation that may result in a deviation if not properly corrected; and, 4) good evidence in potential legal actions. In accordance with the

HACCP principles, HACCP records must include: records associated with establishing and monitoring CCP's and critical limits, records for the handling of deviations, and records associated with verification of the HACCP plan. It is also very important that all HACCP records dealing with plant operations at CCP's and corrective actions taken, be reviewed on a daily basis by a designated individual who must sign or initial all records reviewed. The approved HACCP plan and associated records must be on file at the meat and/or poultry establishment.

Column eight of the HACCP plan establishes procedures for verification that the HACCP system is working correctly. The verification process is designed to review the HACCP plan; to establish whether the CCP's and critical limits have been properly established and are being adequately controlled and monitored; and to determine if the procedures for handling process deviations and recordkeeping practices are being followed.

The effective completion of this step is crucial since here is where you will define your critical limits that will be used to determine process control at a particular CCP.

HACCP PLAN

PROCESS CATEGORY : RAW GROUND PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING - PORK CARCASS PARTS	<p>B - Microbial Growth.</p> <p>B - Container Integrity.</p> <p>P - Foreign Material.</p>	<p>1 B</p> <p>1 B</p> <p>1 P</p>	<p>Temperature of parts at receipt $\leq 40^{\circ}$ F.</p> <p>Immediate container is intact.</p> <p>No visible hazardous foreign non-food material (ie, glass); no metal contamination $\geq 1/32$ inch; no bone particles >0.8 inch (20mm).**</p>	<p>Internal temperature of a random sample of each lot of parts received is monitored by receiving personnel.</p> <p>Visual inspection of immediate containers at the time a shipment is received action by receiving personnel.*</p> <p>Record all findings in HACCP records log and sign record, date and include time of action.</p>	<p>If product temperature exceeds 40° F, immediate container is compromised, or foreign material is noted in/on the parts, identify and control affected product for disposition; take corrective action to prevent reoccurrence.</p> <p>Condemn product or remove particles $1/32''$ or larger.</p> <p>Plant designee documents actions taken in HACCP records log and signs record, date and include time of action.</p> <p>Notify plant designee.</p>	<p>Record all results and corrective/preventive action(s) in a receiving log and/or corrective action log. Sign record and record the time of observation or corrective/preventive action.</p>	<p>Twice weekly visual observation of product and receiving procedures, done by an individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official.</p> <p>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.</p> <p>Weekly calibration of thermometers.</p>

*This may be controlled through the plant's GMP's.

HACCP PLAN

PROCESS CATEGORY : RAW GROUND PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING PACKAGING MATERIAL	<p>C - Deleterious Chemicals.</p> <p>P - Foreign Material.</p>	<p>1 C</p> <p>2 P</p>	<p>Letters of guarantee are on file for all packaging materials/used by the establishment.</p> <p>No visible hazardous foreign non-food material (ie. glass).</p>	<p>Personnel responsible for the function reviews all letters of guarantee for each new packaging material/non-meat supply coming into or prior to delivery to the establishment.</p> <p>Check incoming material/supplies to see if material identification matches the accompanying letter of guarantee.</p> <p>Check letters of guarantee at appropriate times for materials/supplies used on a continuous basis to assure compliance.</p> <p>Visual inspection of packaging material at appropriate times by personnel responsible for the function.</p> <p>Record all findings in HACCP records log and sign record, date, and include time of action.</p>	<p>Establish program through purchasing dept. to assure that letters of guarantee are on file prior to delivery of packaging material.</p> <p>If process does not demonstrate control within written HACCP Plan procedures and letter of guarantee is not present or acceptable, do not allow packaging materials/non-meat supplies to enter establishment; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP records log and signs record, date, and include time of action.</p> <p>Notify plant designee.</p>	<p>Record all results and corrective/preventive action(s) in a receiving log or corrective/preventive action log.</p> <p>Sign record and record time of observation.</p>	<p>Periodic visual inspection of product and observation of receiving procedures, done by an individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official.</p> <p>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.</p>

HACCP PLAN

PROCESS CATEGORY : RAW GROUND PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
STORAGE - PORK CARCASS PARTS	B - Microbial Growth.	2 B	<p>Environmental temperature must not exceed 40°F for more than 4 hours.*</p> <p>Parts must be stored at 40° F or below. A maximum of 50° F maintained in product handling areas.</p> <p>*Note:Insufficient scientific data exist regarding the growth of pathogens during chilling. However the provided above and throughout this plan will limit the growth rates of even psychotropic spoilage organisms. Therefore the parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.</p>	<p>Environmental and internal temperature monitored every two hours by personnel responsible for the function.</p> <p>Routine monitoring of refrigeration unit operation and controls by personnel responsible for the function.</p> <p>Record all findings in HACCP receiving log. Sign record, date and include time of action. Check to see if >1 log growth of <i>Listeria monocytogenes</i>.</p>	<p>If process is not within written HACCP plan procedures, control affected product, re chill correct or adjust procedures; adjust or repair refrigeration/cooler; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP records log and signs record, date and include time of action.</p> <p>Notify plant designee</p>	<p>Record all results and corrective/preventive action(s) in a storage and/or corrective action log. Sign record and record time of observation or corrective/preventive action.</p>	<p>Twice weekly visual inspection of product done by an individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official.</p> <p>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.</p> <p>Weekly calibrations of thermometers.</p>

HACCP PLAN

**PROCESS CATEGORY : RAW GROUND
PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK**

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
STORAGE PACKAGING MATERIAL	P - Foreign Material/ Adulteration	3 P	No visible hazardous foreign non-food or food material (ie. glass, product residue).	Visual inspection of storage room and packaging materials daily at appropriate times by personnel responsible for the function. Record all findings in HACCP records log. Sign record, date and include time of action.	If process is not within written HACCP plan procedures, control affected material, destroy or recondition affected material; 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 and signs record, date, and include time of action. Notify plant designee.	Record all results and corrective/preventive action(s) in a storage log and/or corrective action log. Sign record and record time of observation/corrective action.	Twice weekly visual inspection of product done by an individual who did not produce the record(s) and who has successfully completed a course of instruction in 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.

HACCP PLAN

PROCESS CATEGORY : RAW GROUND PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURES/PERSON RESPONSIBLE
MECHANICAL SEPARATION	B- Microbial Growth	4 B	Product temperature maintained at or below 40°F during process.* A maximum of 50°F maintained in product handling areas.	Product temperature monitored after exiting the deboner by personnel responsible for the function. Routine monitoring of refrigeration unit operation and controls. Record all findings in HACCP records log. Sign, record date and include time of action. Check to see if > 1 log growth of <i>Listeria monocytogenes</i> . Visual inspection of deboned poultry. Record all findings in HACCP records log. Sign record, date and include time of action.	If process does not demonstrate control within written HACCP Plan procedures, identify and control or condemn affected product; correct or adjust refrigeration unit; recondition/rework product; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrences; plant designee documents actions taken in HACCP records log and signs record, date and include time of action. Note plant designee. If process is not within written HACCP Plan procedures, identify and control or condemn 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 records log and signs record date and include time of action. Notify plant designee.	Record all results and corrective/preventive action(s) in formulation log and/or corrective action log. Sign record and record time of observation or corrective/preventive action.	Twice weekly measurement of product temperatures by an individual who did not produce the record(s) and who has successfully completed a course of instruction in 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.
	P- Foreign material	4 P	No visible hazardous foreign non-food material (i.e. glass); no metal contamination ≥ 1/32 inch; no bone particles > 0.8 inch (20mm). *Note: Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above and throughout this plan will limit the growth rates of even psychrotrophic spoilage organisms. Therefore the parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.				

HACCP PLAN

PROCESS CATEGORY : RAW GROUND PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	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	<p>Product temperature maintained at or below 40° F.*</p> <p>Environmental temperature shall not exceed 50°F for more than 4 hours.</p> <p>*Note: Insufficient scientific data exist regarding the growth of pathogens during chilling. However the chilling parameters provided above and throughout this plan will limit the growth rates of even psychotrophic spoilage organisms. Therefore the parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.</p>	<p>Product temperatures, monitored by cooler floor personnel as it is placed in the cooler.</p> <p>Environmental temperatures monitored every two hours by qualified personnel.</p> <p>Routine monitoring of cooler operations and controls by personnel responsible for the function.</p> <p>Record all findings in HACCP records log. Sign record, date and include time of action.</p> <p>Check to see if >1 log growth of listeria monocytogenes.</p>	<p>If process does not demonstrate control within written HACCP plan procedures, control affected product, re chill product; correct or adjust procedures; repair or adjust cooling unit; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP records log and signs record, date and include time of action.</p> <p>Notify plant designee.</p>	<p>Record all results and corrective/preventive action(s) in cooling log and/or corrective action log. Sign record and record time of observation or corrective/preventive action</p>	<p>Twice weekly measurement of product temperatures, and environmental temperatures by an individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official.</p> <p>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.</p> <p>Weekly calibration of thermometers.</p>

HACCP PLAN

**PROCESS CATEGORY : RAW GROUND
PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK**

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
PACKAGING LABELING	P - Foreign Material	3P	No visible hazardous foreign non-food material (ie. glass).	<p>Visual inspection of mechanically separated pork. Weekly inspection of filters/screens by personnel responsible for the function.</p> <p>Record all findings in HACCP packaging log. Sign record, date, and include time of action.</p>	<p>If process is not written HACCP Plan procedures, identify and control or condemn affected product; correct or adjust procedures; recondition/rework product; evaluate operation for cause of deficiency; take corrective action to prevent recurrence; personnel responsible for the function documents action taken in HACCP packaging log and signs record, date, and includes time of action.</p> <p>Notify plant designee.</p>	<p>Record all results and corrective action(s) in packaging log and/or corrective action log. Sign and date record and record time of observation or corrective/preventive action.</p>	<p>Twice weekly measurement of temperatures and visual inspection of product by an individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official.</p> <p>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.</p> <p>Weekly calibration of thermometers and metal detectors.</p>

HACCP PLAN

**PROCESS CATEGORY : RAW GROUND
PRODUCT EXAMPLE : MECHANICALLY SEPARATED PORK**

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	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 not exceed a temperature of ≤40° F prior to leaving the establishment.* Truck temperature not to exceed 50° F prior to shipping product. *Note:Insufficient scientific data exist regarding the growth of pathogens during chilling. However the provided above and throughout this plan will limit the growth rates of even psychotropic spoilage organisms. Therefore the parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.	Product temperatures and truck temperatures, monitored for each lot shipped by shipping personnel. If truck is plant owned, routine monitoring of refrigeration unit operation and controls. (Alternatively this may be included in the plant GMP's.) Record all findings in HACCP records log. Sign record, date and include time of action.	If process does not demonstrate control within written HACCP plan procedures, control affected product, re chill product, reject transport; 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 and signs record, date and include time of action. Notify plant designee.	Record all results and corrective/pre-ventive action(s) in shipping log and/or corrective action log. Sign record and record time of observation or corrective/preventive action.	Twice weekly measurement of product temperatures. Weekly measurement of temperatures by an individual who did not produce the record(s) and who has successfully completed a course of instruction in 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.

Appendix 1 - List of Process Models

- **Slaughter**
 - Beef**
 - Pork**
 - Poultry**

- **Raw Product, Ground**
Mechanically Separated/ Deboned

- **Raw Product - Not Ground**
Irradiation

- **Thermally Processed/ Commercially Sterile**

- **Not Heat Treated, Shelf Stable**

- **Heat Treated, Shelf Stable**

- **Fully Cooked, Not Shelf Stable**

- **Heat Treated but Not Fully Cooked, Not Shelf Stable**

- **Product With Secondary Inhibitors, Not Shelf Stable**

FOOD SAFETY HAZARDS BEING CONTROLLED IN HACCP PROGRAM

PHYSICAL

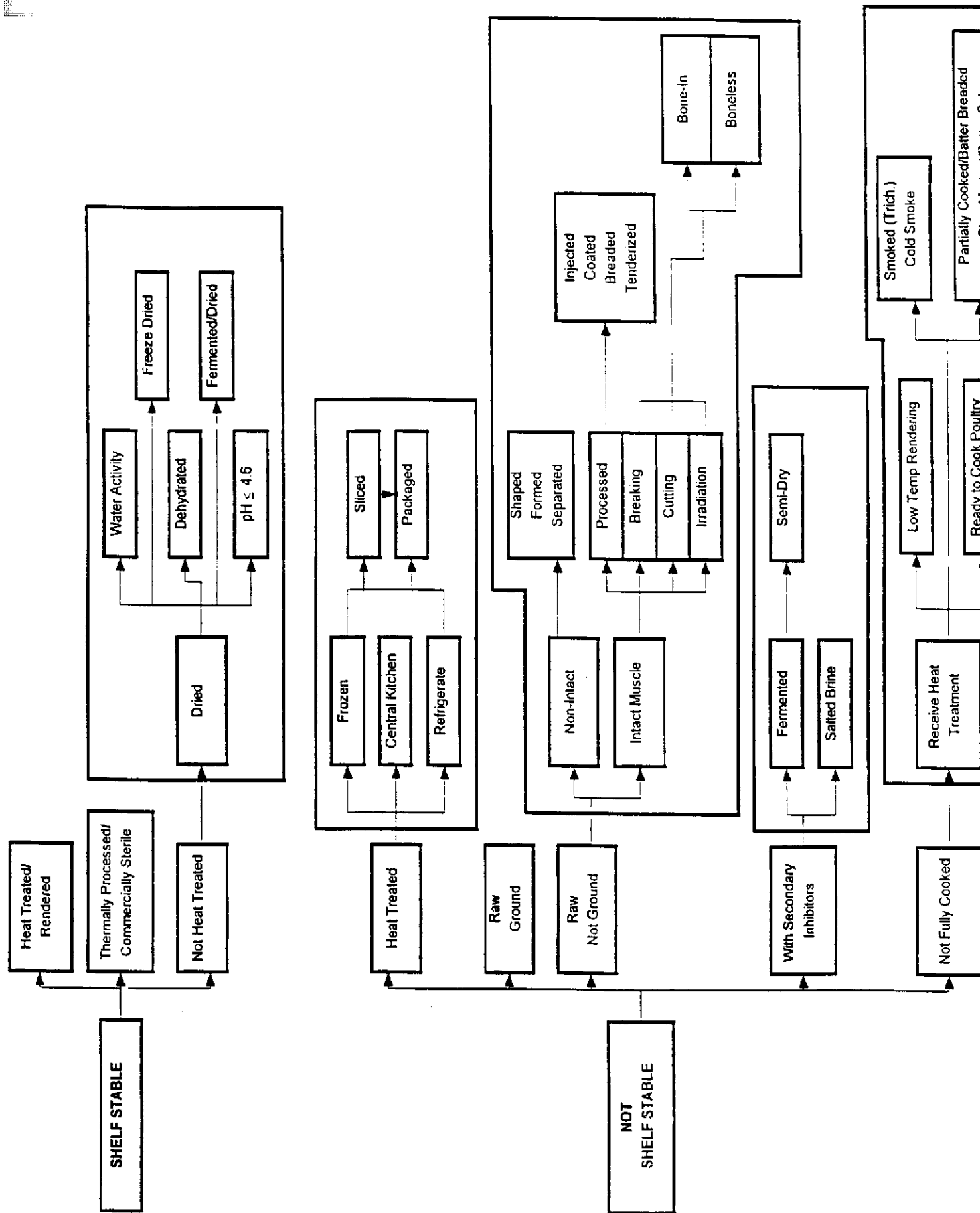
Glass
Metal
Other Foreign
Materials

CHEMICAL

Allergens
Animal Drug Residues
Cleaning Compound
Residues
Illegal Residues/Pesticides
- Packaging Materials
- Raw Ingredients
- Shipping Containers
Natural Toxins

BIOLOGICAL

Cross-Contamination
- Post Cooked
Pathogens
- Raw Ingredients
- Raw Storage



Sources for Epidemiology of Foodborne Illness

General

Bean, N. H. and P. M. Griffin. 1990. Foodborne disease outbreaks in the United States, 1973-1987: Pathogens, vehicles, and trends. *J. Food Prot.* 53(9):804-817.

The etiologic agents and food vehicles associated with the 7458 outbreaks (involving 237,545 cases) of foodborne disease reported to the Centers for Disease Control between 1973 and 1987 were examined. Bacterial pathogens accounted for 66% of outbreaks and 87% of cases, viruses 5 and 9%, parasites 5 and <1%, and chemicals 25 and 4%, respectively. *Salmonella* accounted for 42% of outbreaks and 51% of cases due to bacterial pathogens. When data from 1973-75 were compared to 1985-87, a 75% increase in the proportion of outbreaks and 130% increase in the proportion of cases due to *Salmonella* were observed; in particular, outbreaks due to *Salmonella* enteritidis increased markedly. The proportion of *Salmonella* outbreaks with a known vehicle that were associated with beef (the food most frequently associated with *Salmonella* outbreaks) peaked at 30% in 1981, dropped to 4% in 1982, and has since risen gradually. The proportion of *Salmonella* outbreaks due to chicken and eggs increased over the study period. Bacteria not previously recognized as important foodborne pathogens that emerged during the study period include *Campylobacter jejuni*, *Escherichia coli* O157:H7, and *Listeria monocytogenes*. Bacterial pathogens accounted for 90% of deaths, with *L. monocytogenes* (317/1,000 cases) and *Clostridium botulinum* (192/1,000 cases) having the highest death-to-case ratios. The proportion of outbreaks in which the food was prepared in a commercial or institutional establishment and the median outbreak size both increased. Investigation and analysis of foodborne disease outbreaks continue to play a key role in understanding foodborne illness and in designing and evaluating control measures.

Bryan, F. L. 1980. Foodborne diseases in the United States associated with meat and poultry. *J. Food Prot.* 43(2):140-150.

Surveillance data from 1968 to 1977 indicate that meat and poultry and products made from them were vehicles in over 50% of reported outbreaks of foodborne disease. The 3 most commonly identified vehicles were ham, turkey and roast beef. Ground (cooked) beef, pork, sausage and chicken were also frequently reported as vehicles. These foods were mishandled to the extent that outbreaks resulted in food service establishments (65%), in homes (31%) and in processing plants (4%). The most frequently identified factors that contributed to these outbreaks were improper cooling of cooked foods (48%), foods prepared a day or more before serving (34%), inadequate cooking or

thermal processing (27%), infected person touching cooked foods (23%), inadequate reheating of cooked and chilled foods (20%), improper hot storage of cooked foods (19%) and cross-contamination of cooked foods from raw foods (15%). Commonly reported foodborne diseases associated with these vehicles were *staphylococcal* intoxication, salmonellosis, *Clostridium perfringens* gastroenteritis, and trichinosis.

Bryan, F. L. 1988. Risks of practices, procedures and processes that lead to outbreaks of foodborne diseases. *J. Food Prot.* 51(8):663-673.

Factors that contributed to 766 outbreaks of foodborne disease in the USA between 1977 and 1982 are reported and tabulated. The main contributory factors include: inadequate or improper cooling, a time lapse of greater than or equal 12 h between preparation and eating, and contaminated raw food/ingredient; these factors were implicated in 40.9, 25.2 and 22.8% of outbreaks, resp. Additional contributory factors include inadequate heat processing, colonized persons handling implicated foods, improper cleaning of equipment and improper fermentation. Data accumulated from 1961 to 1982 (1918 outbreaks) are classified by disease (salmonellosis, staphylococcal food poisoning, botulism, *Clostridium perfringens* enteritis, shigellosis, typhoid fever, *Vibrio parahaemolyticus* gastroenteritis and *Bacillus cereus* gastroenteritis), and are grouped according to whether the factors affect contamination, survival or growth of the contaminant. The incidence of various contributory factors is also classified according to place where the implicated foods were mishandled (food service establishments, homes and food processing plants). The importance of distinguishing between frequently and rarely occurring contributory factors is emphasized so that priorities can be defined for preventative and control programs and critical control points indicated.

Doyle, M. P. 1992. A new generation of foodborne pathogens. *Dairy, Food and Environmental Sanitation* 12(8):490,492-493.

Pathogens that have been recognized in the last 10-15 yr as important causes of foodborne disease are discussed, including: *Campylobacter jejuni*; *Yersinia enterocolitica*; *Vibrio vulnificus*; *Listeria monocytogenes*; enterohaemorrhagic *Escherichia coli* O157:H7; and *Salmonella enteritidis* (ovarian-infecting). *C.jejuni* is associated with foods of animal origin producing illness with ingestion of only low numbers of infective cells. Outbreaks in the USA of *Y. enterocolitica* are few but symptoms are severe and include diarrhoea, fever, headache and intense abdominal pain. The organism grows at refrigeration temp. Raw oysters have been identified as the vehicle of infection for *V. vulnificus* causing severe illness. *L. monocytogenes* is of particular risk for immunocompromised individuals. The organism is present in low numbers in ready-to-eat meats, cooked poultry, milk and dairy products and vegetables. Low-acid soft cheeses are of particular concern to high-risk individuals. The organism can be ingested by most individuals in the population with no ill-effects.

Enterohaemorrhagic *E. coli* O157:H77 has been associated with undercooked ground beef, unpasteurized milk and person-to-person transmission. Illness from *S. enteritidis* has been principally associated with the use of uncooked eggs. *S. enteritidis* has been identified in ovarian tissue of hens, thus eggs laid by these hens are infected by the pathogen prior to purchase and consumption.

Gravani, R. B. 1987. The causes and costs of foodborne disease. *Dairy Food Sanitation* 7(1):20-25.

This article highlights the importance of food safety and discusses the prevalence and economic impact of foodborne diseases in the USA. Foods incriminated in foodborne illnesses are listed. Red meats, poultry, fish and shellfish, ethnic foods and salads account for the majority of cases of food poisoning, but dairy products have also been implicated. Factors contributing to outbreaks of foodborne illness are outlined.

McIntosh, W. A., et al. 1994. Perceptions of risks of eating undercooked meat and willingness to change cooking practices. *Appetite* 22(1): 83-96.

Knowledge and awareness of food safety issues relating to improperly cooked hamburger and willingness to change hamburger cooking practices were examined from a representative sample of 1004 adult Texans. Awareness of the danger of improperly cooked hamburger, knowledge of specific foodborne pathogens and knowledge of food safety practices had no effect on willingness to change behavior, but respondents who were better-educated, female and Hispanic and respondents who used newspapers/magazines or televisions were all more likely to report willingness to change their cooking practices.

Notermans, S. 1992. Existing and emerging foodborne diseases. *International J. Food Microbiology* 15(3/4):197-205.

Data recorded in different countries show that the incidence of some foodborne diseases due to microbial contamination has increased in recent years. Results of analysis of available data from several countries are discussed in terms of the frequency of foodborne diseases, causative agents and incriminated foods. Microorganisms responsible for existing foodborne diseases (*Salmonella*, *Campylobacter* and *Staphylococcus aureus*) and emerging foodborne diseases (*C.jejuni/coli*, *S. enteritidis*, pathogenic *Escherichia coli*, *Listeria monocytogenes*, *Aeromonas spp.*, *Yersinia enterocolitica* and molds) are addressed.

Schothorst, M. van and L. J. Cox. 1989. "Newer" or emerging pathogenic microorganisms in meat and meat products. *Proceedings, International Congress of Meat Science and Technology* No. 35, Vol. I(35):55-67.

This paper discusses the reasons for emergence of ‘new’ pathogens, i.e. changes in eating habits, changes in perception, awareness and interest, improvement of detection methods, improved epidemiology, changes in food production (raw materials), changes in food processing technology, changes in handling and preparation practices, demographic changes (the state of the population, mobility and social conditions) and changes in the behavior of microorganisms. ‘Newer’ foodborne pathogens are outlined (*Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Campylobacter jejuni*, *Yersinia enterocolitica*, *Vibrio vulnificus* and *Aeromonas hydrophila*) and future developments considered.

Steahr, T. 1994. Food-borne illness in the United States: geographic and demographic patterns. International J. Environ. Health Research 4(4):183-195.

Foodborne illness in the USA has been defined on the basis of List A (a listing of foodborne disease as classified by the International Classification of Diseases, 4th Edition, Clinical Modification (ICD-9-CM)). Geographical and demographic patterns are presented for foodborne illness in the USA based on national data for patients discharged from hospital by List A categorization of foodborne disease in 1990. Frequency of category types (e.g. cholera, shigellosis, staphylococcal food poisoning) is considered. Variations by age, sex, region and race based on hospital discharge, physician visit and mortality data are also presented. Benefits and limitations of the current method of determining the prevalence of foodborne illness are discussed and the need to establish the actual frequency of unreported cases of foodborne illness is stressed.

Todd, E.C.D. 1989. Costs of acute bacterial foodborne disease in Canada and the United States. International J. Food Microbiol 9(4):313-326.

Bacterial foodborne disease incidence is increasing in industrialized countries. In Canada and the USA many millions of cases are believed to occur each year. Economic impact of this is huge. Medical costs and lost income are easier to determine than losses to food companies, legal awards and settlements, value of lost leisure time, pain, grief, suffering and death. Evaluation of costs at the national level for Canada and the USA, based on all available costs for 61 incidents, showed that costs of company losses and legal action were much higher than medical/hospitalization expenses, lost income or investigational costs. It was reckoned that, on an annual basis, 1 million cases of acute bacterial foodborne illness in Canada cost nearly ‘ 1.1 billion and 5.5 million cases in the USA cost nearly 7 billion. The value of deaths was a major contributor to overall costs, especially for diseases like listeriosis, salmonellosis, *Vibrio* infections and hemorrhagic colitis. Salmonellosis was the most important disease in economic terms, because it affects all parts of the food system [and because proper control measures need to be implemented], unlike typhoid fever and botulism which are largely controlled by public health authorities and the food industry.

Todd, E. 1990. Epidemiology of foodborne illness: North America. *Lancet* 336(8718):788-790.

The epidemiology of foodborne diseases in Canada and the USA is discussed with reference to: surveillance (including the completeness and quality of the reports); estimated incidence and costs of foodborne disease; and recent foodborne disease concerns (salmonellosis, *Escherichia coli* O157:H7, campylobacteriosis, *Listeria monocytogenes*, *Vibrio* spp., staphylococcal toxins, botulism, paralytic shellfish poisoning).

Microorganisms

Abdel-Rahman, H., T. El-Khateib, and A. K. El-Timmawy. 1988. Spoilage and food poisoning organisms in frozen ground beef. *Fleischwirtschaft* 68(7):881-882.

50 packs of frozen ground beef from supermarkets in Egypt were studied for spoilage and pathogenic bacteria. Of 518 isolates of spoilage bacteria, 43.8% were *Enterobacteriaceae*, 30.9% were pseudomonads and 25.3% were lactobacilli. The incidence of individual sp. within these groups was considered. *Clostridium perfringens*, *Staphylococcus aureus* and *Shigella dysenteriae* were isolated from 34, 80 and 1.4% of samples, resp. *Salmonellae* were not detected in any sample.

Adesiyun, A. A. 1993. Prevalence of *Listeria* spp., *Campylobacter* spp., *Salmonella* spp., *Yersinia* spp. and toxigenic *Escherichia coli* on meat and seafoods in Trinidad. *Food Microbiology* 10(5):395-403.

Occurrences of species of *Listeria*, *Campylobacter*, *Salmonella*, *Yersinia* and *Escherichia coli* in raw meats (beef, ground beef, mutton, goat meat, pork and chicken) and seafoods (fish and shrimps) in Trinidad were studied. Toxigenicity and antibiograms of *E. coli* isolates were also established. 480 samples were studied, of these: 28 (5.8%) were positive for *Listeria* spp. (of which 9 (1.9%) and 14 (2.9%) were positive for *L. monocytogenes* and *L. innocua*, respectively); the highest prevalence (14.8%) was in fish. *L. monocytogenes* serotypes 4b and 1/2c were present in both locally produced and imported meats. 29 (6.0%) samples were positive for *Campylobacter*; 28 (96.6%) of positive samples were chickens and 1 (3.4%) was shrimps. 43 (9.0%) samples were positive for *E. coli*. All samples were negative for *Yersinia*. Only 2 (4.7%) of the positive *E. coli* samples produced verocytotoxins while 1 (2.3%) isolate produced heat labile toxin. 33 (76.7%) of the *E. coli* strains isolated were resistant to ≥ 1 antimicrobial agent(s). Frequency of contamination of meats and seafoods was low, as was the health risk to consumers. Based on the frequency of contamination and the large amounts of fish eaten in Trinidad, it is possible that seafoods may pose the greatest risk of listeriosis.

Chapman, P. A., et al. 1993. Cattle as a possible source of verocytotoxin-producing *Escherichia coli* O157 infections in man. *Epidemiology and Infection* 111(3):439-447.

In May-June 1992 cases of infection with verocytotoxin-producing (VT+) *Escherichia coli* O157 in South Yorkshire (UK) could have been associated with prior consumption of beef from a local abattoir. During investigation of the abattoir, bovine rectal swabs and samples of meat [meat trimmings from neck end of carcass] and surface swabs from beef carcasses were examined for *E. coli* O157, isolates of which were tested for toxigenicity, plasmid content and phage type. *E. coli* O157 was isolated from 84 (4%) of 2103 bovine rectal swabs; of these 84, 78 (93%) were VT+, the most common phage types being 2 and 8, the types implicated in the cluster of human cases. Positive cattle were from diverse sources within England. *E. coli* O157 was isolated from 7 (30%) of 23 carcasses of rectal swab-positive cattle and from 2 (8%) of 25 carcasses of rectal swab-negative cattle. The study has shown that cattle may be a reservoir of VT+ *E. coli* O157 and that contamination of carcasses during slaughter and processing may be the mechanism by which beef and beef products become contaminated and thereby transmit the organism to man.

Comi, G., et al. 1992. *Listeria monocytogenes* serotypes in Italian meat products. *Letters-in-Applied-Microbiology* 15(4): 168-171.

Listeria monocytogenes was isolated and enumerated in Italian fresh ground beef, fresh pork meat and industrial sausages. All samples contained less than 2000 *L. monocytogenes*/g of meat. The main serotype isolated was 1/2c (56.9%). Other serotypes isolated included 1/2a, 1/2b, 3c, 4b and 4c. A prevalence of less virulent serotypes over more virulent was thus noted. It seems that the low incidence of listeriosis from these products is related to the low concentration and virulence of *L. monocytogenes* present.

Doyle, M. P. 1991. *Escherichia coli* O157:H7 and its significance in foods. *International J. Food Microbiol* 12(4):289-301.

Escherichia coli O157:H7 was conclusively identified as a pathogen in 1982 following its association with 2 food-related outbreaks of an unusual gastrointestinal illness. The organism is now recognized as an important cause of foodborne disease, with outbreaks reported in the USA, Canada and the UK. Illness is generally quite severe, and can include 3 different syndromes, i.e., hemorrhagic colitis, haemolytic uraemic syndrome and thrombotic thrombocytopenic purpura. Most outbreaks have been associated with eating undercooked ground beef or, less frequently, drinking raw milk. Surveys of retail raw meats and poultry revealed *E. coli* O157:H7 in 1.5-3.5% of ground beef, pork, poultry and lamb. Dairy cattle, especially young animals, have been identified as a reservoir. The organism is typical of most *E. coli*, but does possess distinguishing characteristics. For example, *E. coli* O157:H7 does not ferment sorbitol within 24 h,

does not possess beta-glucuronidase activity, and does not grow well or at all at 44-45.5 degree C. The organism has no unusual heat resistance; heating ground beef sufficiently to kill typical strains of *Salmonellae* will also kill *E. coli* O157:H7. The mechanism of pathogenicity has not been fully elucidated, but clinical isolates produce 'sw1 verotoxin which are believed to be important virulence factors. Little is known about the significance of pre-formed verotoxins in foods. The use of proper hygienic practices in handling foods of animal origin and proper heating of such foods before consumption are important control measures for the prevention of *E. coli* O157:H7 infections.

Duitschaever, C. L. and C. I. Buteau. 1979. Incidence of *Salmonella* in pork and poultry products. *J. Food Prot.* 42(8):662-663.

223 retail samples of pork and poultry products were purchased in the Toronto area and analyzed for *Salmonella* contamination. Procedure used was lactose pre-enrichment incubation at 41 degree C, enrichment incubation in tetrathionate-novobiocin or selenite-cystine broth followed by plating onto *Salmonella-Shigella*, bismuth/sulphite or xylose/lactose/deoxycholate agar. Suspect colonies were transferred to triple sugar/Fe or lysine/Fe/agar slants or malonate broth and further identified using the API microscreening system. Confirmation was by serotyping. 36 of the 223 samples (16.14%) contained *Salmonella* sp.; for individual products results were: pork sausages 15 of 105 contained *Salmonellae*; turkey sausages 3 of 3; ground pork 5 of 25; pork chops 7 of 50; chicken parts 5 of 7; and barbecued back pork 1 of 33. A total of 37 isolates was obtained (1 pork sausage contained 2 spp.) which were classified into 10 serotypes; *Salmonella agona* (11 of 37) and *S. typhimurium* (8 of 37) predominated. Occurrence of *S. agona* in ready-to-eat barbecued pork indicates need for legislation on retail storage temp. of this product.

Johnston, R. W., et al. 1982. Incidence of *Salmonella* in fresh pork sausage in 1979 compared with 1969. *J. Food Science* 47(4):1369-1371.

A survey was conducted to determine incidence of *Salmonella* in fresh pork sausage. Retail size samples representing different days of production were collected from 40 federally inspected plants and analyzed for the presence of *Salmonellae*. The results obtained during the 1979 survey were compared to results obtained in a similar 1969 survey. *Salmonellae* were isolated from 162 of the 566 (28.6%) samples analyzed in 1969. For the samples analyzed in 1979, 74 of 603 samples (12.4%) were positive for *Salmonellae*. Ladiges, W. C., et al. 1974. Incidence and viability of *Clostridium perfringens* in ground beef. *J. Milk Food Technol.* 37(12):622-623. The incidence of *Clostridium perfringens* in 95 ground beef samples obtained from a retail store in Denver, Colorado was 47.4%. Although viability was not reduced after 24 h at - 20C, greater than 90% of the organisms usually could not be detected after frozen storage over a 4-month period.

Ladiges, W.C. and J. F. Foster. 1974. Incidence of *Salmonella* in beef and chicken. *J. Milk Food Technol.* 37(4): 213-214.

A survey was undertaken to determine the incidence of *Salmonella* in retail purchases of beef, ground beef, and chicken fryers. *Salmonella* were isolated from 3 of 36 (8.3%) fresh whole chicken fryers. No *Salmonella* were detected in 129 quarter of carcass beef or in 100 samples of ground beef. The failure to detect *Salmonella* in beef products is discussed.

Lior, H. 1994. *Escherichia coli* O157:H7 and verotoxigenic *Escherichia coli* (VTEC). *Dairy, Food and Environmental Sanitation* 14(7):378-382.

Infections caused by *Escherichia coli* O157:H7 and by verotoxigenic (*Shiga*-like toxin) producing *E. coli* are discussed. Aspects considered include: symptoms and pathogenesis of disease; foods associated with outbreaks (including beef mince [ground beef], turkey roll, and raw milk; identification of serotypes of *E. coli* responsible for the outbreaks; and methods of detection of *E. coli* verotoxins. Ways in which the risk of infection by these pathogens can be minimized are presented.

McLauchlin, J., et al. 1988. Listeriosis and food-borne transmission. *Lancet* I(8578):177-178.

Attention is drawn to increasing incidence of listeriosis in the UK (at least 1 case/230 000 of the population in England and Wales) due to *Listeria monocytogenes*, to the fact that its ubiquity and growth characteristics (resistance to nitrites and salt, growth at 4 degree C) favor food-borne transmission, and to the lack of knowledge on the scale of food-borne listeriosis. Epidemiological studies of outbreaks that may be food-borne are hindered as many strains of *L. monocytogenes* are not phage-typable. A DNA probe method, using cloned biotin-labelled DNA sequences from *L. monocytogenes* and the 'Blu-gene' biotin detection system (Gibco) was successfully used to type 24 epidemiologically unrelated strains, and revealed 8 distinct patterns. Improved typing systems will increase the understanding of listeriosis epidemiology.

Mermelstein, N. H. 1993. Controlling *E. coli* O157:H7 in meat. *Food Technol.* 47(4):90-91.

The improved inspection procedures and regulations imposed following a fatal food poisoning outbreak in the US caused by ingestion of undercooked hamburgers contaminated with *Escherichia coli* O157:H7 are described. Aspects considered include: the food poisoning outbreak; details of *E. coli* O157:H7; detection of the organism; recommendations to livestock operations, processors, ground beef producers and foods service and retail industries (to implement the HACCP system); recommendations for research into the ecology of *E. coli*; animal and carcass inspection; increased numbers of inspectors; and education of the consumer and foods service handlers to prevent

foodborne illness.

Read, S. C., et al. 1990. Prevalence of verocytotoxigenic *Escherichia coli* in ground beef, pork, and chicken in southwestern Ontario. *Epidemiol. Infect.* 105:11-20.

Samples of ground beef (225), pork (235) and chicken (200) were randomly selected from meat processing plants in the Southwestern Ontario area. Supernatants of broth cultures of the samples were tested for verocytotoxins using a Vero cell assay. Neutralization of cytotoxic activity using antisera specific for three types of verocytotoxin (Verotoxin 1, Verotoxin 2 and Shiga-like toxin II) was performed on positive samples. Isolation of verocytotoxigenic *Escherichia coli* (VTEC) was attempted from positive samples. VTEC were confirmed as *E. coli* biochemically, test for drug resistance, and serotyped. Based on neutralization studies, the prevalence of VTEC in beef and pork was at least 36.4% and 10.6%, respectively. This is much higher than has been reported from a survey of retail meats in which a method designed to detect only *E. coli* O157:H7 was used. Isolations of VTEC were made from 10.4% of the beef samples and 3.8% of the pork samples. No VTEC were recovered from the chicken samples. The majority of VTEC isolates were susceptible to commonly used antimicrobial agents. A number of the serotypes of the VTEC isolates recovered have been associated with human disease; however, no VTEC of serotype O157:H7 were isolated.

Rindi, S., D. Cerri, and B. Gerardo. 1986. [Thermophilic *Campylobacter* in fresh pork sausages.] *Industrie-Alimentari* 25(241):648-650.

2 spp. of *Campylobacter* were isolated from 200 samples of pork sausage: one belonged to the NARTC group of Skirrow & Benjamin [*Campylobacter*; *Epidemiology, Pathogenesis & Biochemistry* (1982); Ed. Newell, Lancaster], the other was identified as *C. jejuni* (resistant to nalidixic acid.)

Riley, L. W. 1987. The epidemiologic, clinical, and microbiologic features of hemorrhagic colitis. *Ann. Rev. Microbiol* 41:383-407.

Aspects of hemorrhagic colitis are reviewed; the disease is primarily food-borne (although person-to-person transmission is possible) and is associated most frequently with *Escherichia coli* serotype O157:H7. Cattle may be a reservoir of this serotype for human infection; *E. coli* O157:H7 has been isolated from cattle, hamburger meat is the food most frequently implicated in the disease, and consumption of raw milk has also been associated with hemorrhagic colitis. Other aspects of the epidemiology and clinical manifestations of the disease are described. The disease can result in serious complications and death. Microbiology of *E. coli* O157:H7 is also described; this strain can survive up to 9 months at -20 degree C in ground beef and grows poorly at 44-45.5 degree C, the temp. generally used to isolate *E. coli* from foods. Pathogenesis of the

disease is presently unknown; studies to establish the virulence mechanism are suggested.

Samadpour, M., et al. 1994. Occurrence of Shiga-like toxin-producing *Escherichia coli* in retail fresh seafood, beef, lamb, pork, and poultry from grocery stores in Seattle, Washington. *Appl. Environ. Microbiol.* 60(3):1038-1040.

Fresh meat, poultry, and seafood purchased from Seattle area grocery stores were investigated for the presence of Shiga-like toxin-producing *Escherichia coli* by using DNA probes for Shiga-like toxin (SLT) genes I and II. Of the 294 samples tested, 17% had colonies with sequence homology to SLT I and/or SLT II genes.

Schuchat, A., B. Swaminathan, and C. V. Broome. 1991. Epidemiology of human listeriosis. *Clin. Micro. Rev.* 4(2):169-183.

A review article discussing the current information on epidemic and sporadic disease caused by *Listeria monocytogenes* is presented. Recent developments in the microbiological detection and serotyping of *L. monocytogenes* are also discussed. Aspects considered include: microbiology of *L. monocytogenes*; *L. monocytogenes* in the environment; *L. monocytogenes* in animals; *L. monocytogenes* in humans; epidemiological patterns of disease; diagnosis, treatment, and prevention; and issues for the food industry.

Silas, J. C., et al. 1984. Update: prevalence of *Salmonella* in pork sausage. *J. Animal Science* 59(1):122-124.

175 samples of fresh pork sausage representing 35 different commercial brands from 6 different retail stores were examined for the presence of *Salmonellae* by standard enrichment, plating, biochemical and serological techniques. Contamination levels varied from 0 to 50% among stores and 0 to 28% among brands. Prior research implied reduced prevalence of *Salmonellae* in fresh pork sausage; however, these results indicate no variation in prevalence since 1969.

Surkiewicz, B. F., et al. 1972. Bacteriological survey of fresh pork sausage produced at establishments under federal inspection. *Appl. Microbiol.* 23(3):515-520.

At the time of manufacture, 75% of 67 sets of finished fresh pork sausage collected at 44 plants had aerobic plate counts in the range of 500,000 or fewer/g; 88% contained 100 or fewer *E. coli*/g; and 75% contained 100 or fewer *S. aureus*/g (geometric means of 10 samples). *Salmonella* were isolated from 28% of 529 samples of pork trimmings used for sausage, and from 28% of 560 finished sausage samples. Semiquantitative analysis revealed that *Salmonella* were at low levels; more than 80% of the *Salmonella*-positive samples were positive only in 25-g portions (negative in 1.0- and

0.1-g portions).

Surkiewicz, B. F., et al. 1975. Bacteriological survey of raw beef patties produced at establishments under federal inspection. *Appl. Microbiol.* 29(3):331-334.

At the time of manufacture, 76% of 74 sets of raw beef patties collected in 42 federally inspected establishments had aerobic plate counts of 1,000,000 or fewer/g; 84% contained 100 or fewer coliforms/g; 92% contained 100 or fewer *Escherichia coli*/g; and 85% contained 100 or fewer *Staphylococcus aureus*/g (geometric means of 10 patties/set). *Salmonella* were isolated from only three (0.4%) of 735 beef patties.

Tarr, P. I. 1994. Review of 1993 *Escherichia coli* O157:H7 outbreak: Western United States. *Dairy, Food and Environmental Sanitation* 14(7):372-373.

A description of the 1993 *Escherichia coli* O157:H7 outbreak in Washington, USA, is given and the investigation that followed is discussed. Within 1 wk, hamburgers consumed at multiple outlets of the same fast food restaurant chain had been implicated as the vehicle of infection, beef mince [(ground beef) from which the hamburgers had been made) was microbiologically tested, and incriminated lots were recalled. It is concluded that this epidemic demonstrates the value of baseline epidemiological surveillance data on this (and other) foodborne pathogens, combined with a rapid and thorough investigative response to an outbreak.

Vorster, S. M., et al. 1994. Incidence of *Staphylococcus aureus* and *Escherichia coli* in ground beef, broilers and processed meats in Pretoria, South Africa. *J. Food Prot.* 57(4):305-310.

Three types of processed meats (vienna sausages, shoulder ham, and cervelat), ground beef and broilers were purchased from 17 different supermarkets in the Pretoria area (South Africa) during 1991. The 232 samples were analyzed for the presence of *Escherichia coli* and *Staphylococcus aureus*, with the total aerobic plate counts (APCs) also being determined. *Escherichia coli* was found in 74.5% of the ground beef samples, in 79.1% of the broilers, and 27.7% of the processed meats. *Staphylococcus aureus* was found in 23.4% ground beef, 39.5% broiler and 7.1% processed meat samples. The total APCs ranged from as low as log₁₀ 1 CFU/g of sample (shoulder ham) to as high as log₁₀ 12.1 CFU/g (ground beef). No identifiable relationship between the total APCs and the occurrence of *E. coli* and/or *S. aureus* was evident. This study confirms the view that *E. coli* and *S. aureus* are frequent contaminants of meat, with South Africa being no exception.

Warnken, M. B., et al. 1987. Incidence of *Yersinia* species in meat samples purchased in Rio de Janeiro, Brazil. *J. Food Prot.* 50(7):578-579.

Twenty-five samples of several types of meat purchased at supermarkets in Rio de Janeiro were analyzed for presence of *Yersinia*. Species were isolated from 80% of beef and chicken giblets, 60% of ground beef and beef liver and 20% of pork. Fifteen strains were identified as *Yersinia intermedia*, 9 as *Y. enterocolitica*, 4 as *Y. kristensenii* and 1 as *Y. frederiksenii*. Two strains of *Y. intermedia*, serotype 0:13,7 were positive in both the autoagglutination and calcium-dependency tests. Two strains of atypical *Y. intermedia* (serotype 0:29 and one not typable) and one strain of atypical *Y. enterocolitica*, serotype 0:16, were positive only in the autoagglutination test. Seventeen strains isolated from meat produced heat stable toxin.

Weissman, M. A. and J. A. Carpenter. 1969. Incidence of *Salmonella* in meat and meat products. *App. Micro.* 17(6):899-902.

The incidence of *Salmonella* spp. in 50 pork carcasses from 5 abattoirs and 50 beef carcasses from 4 abattoirs was 56% and 74% respectively. The value for beef is higher than previously reported. Suggested areas for sampling are the cervical and anal areas of the carcass. *Salmonella* were detected in 38% of fresh pork sausage samples, 9% smoked pork sausage and in one sample of miscellaneous sausage products.

Factors Influencing/Controlling Microbial Growth

Ayres, J. C. 1979. *Salmonella* in meat products. Proceedings of the 31st Annual Reciprocal Meat Conference. pp. 148-155.

Occurrence of *Salmonella* in meat and meat products is discussed with reference to literature data. Aspects considered include: sources of contamination; cross-contamination of pigs held for prolonged periods at the abattoir before slaughter; incidence of *Salmonella* in meat trimmings and comminuted meat products; vacuum packaging of meat, and its inhibitory effect on growth of *Salmonella*; effects of temp. on growth or survival of *Salmonella* in packaged ground beef; incidence of *Salmonella* in retail samples of meat and meat products; and need for hygienic handling and constant refrigeration of meat to minimize danger of growth of *Salmonella* or contamination of other foods.

Buchanan, R. L. and L. A. Klawitter. 1992. The effect of incubation temperature, initial pH, and sodium chloride on the growth kinetics of *Escherichia coli* O157:H7. *Food Microbiol.* 9:185-196.

The effects of initial pH, sodium chloride content, and incubation temperature on the aerobic and anaerobic growth kinetics of a three strain mixture of *Escherichia coli* O157:H7 were evaluated using brain heart infusion broth. The three variables interacted to affect growth, with the primary effects being noted in relation to

generation times (GTs) and lag phase durations (LPDs). The maximum population densities (MPDs) achieved by the cultures were largely independent of the three variables; however, there was a general depression of MPDs by 0.5-1.0 log cycles when the cultures were incubated anaerobically. Under the otherwise optimal conditions, GTs and LPDs were largely unaffected by initial pH at values ≥ 5.5 . Initial pH had a greater effect when the NaCl content was elevated. Increasing NaCl levels decreased the growth rate of the organism, with the effect being greater if the other variables were also non-optimal. In general, the effect of temperature could be adequately described by the Ratkowsky square root function; however, there was a general depression of optimal growth temperatures and an increase in the differential between T_{\min} and actual temperature that did not support growth as other variables became non-optimal. Comparison of the current data with previous reports suggest that the growth kinetics of *E. coli* O157:H7 are similar to those for non-pathogenic strains.

Conner, D. E., et al. 1993. Heat Resistance of *Escherichia coli* O157:H7 in low-fat meat and poultry products. *Highlights of Agricultural Research* 40:11.

This research targeted the influence of fat-reduction formulations on the survival of the *E. coli* O157:H7 when heating ground beef, pork sausage, ground turkey, and ground chicken at various temperatures and fat concentrations.

Crespo, F. L. and H. W. Ockerman. 1977. Thermal destruction of microorganisms in meat by microwave and conventional cooking. *J. Food Prot.* 40(7):442-444.

When heating ground beef to internal temp. of 34 degree , 61 degree , and 75 degree C, high temp. (232 plus/minus 6 degree C) oven cooking was more effective for bacterial destruction than low temp. (149 plus/minus 6 degree C) oven cooking. Low temp. oven cooking was more effective than microwave cooking. These differences in microbial destruction rates became significant (P less than 0.05) when the meat reached the 75 degree C internal temp. level.

Doyle, M. P. and J. L. Schoeni. 1987. Isolation of *Escherichia coli* O157:H7 from retail fresh meats and poultry. *Appl. Environ. Microbiol.* 53(10):2394-2396.

A total of 896 samples of retail fresh meats and poultry was assayed for *Escherichia coli* serogroup O157:H7 by a hydrophobic grid membrane filter-immunoblot procedure developed specifically to isolate the organism from foods. The procedure involves several steps, including selective enrichment, filtration of enrichment culture through hydrophobic grid membrane filters, incubation of each filter on nitrocellulose paper on selective agar, preparation of an immunoblot (by using antiserum to *E. coli* O157:H7 culture filtrate) of each nitrocellulose paper, selection from the filters of colonies which corresponded to immunopositive sites on blots, screening of isolates by a Biken test for precipitin lines from metabolites and antiserum to *E. coli* O157:H7 culture filtrate, and

confirmation of isolates as Vero cell cytotoxic *E. coli* O157:H7 by biochemical, serological, and Vero cell cytotoxicity tests. *E. coli* O157:H7 was isolated from 6 (3.7%) of 164 beef, 4 (1.5%) of 264 pork, 4 (1.5%) of 263 poultry, and 4 (2.0%) of 205 lamb samples. One of the 14 pork samples and 5 of 17 beef samples contaminated with the organism were from Calgary, Alberta, Canada, grocery stores, whereas all other contaminated samples were from Madison, Wis., retail outlets. This is the first report of the isolation of *E. coli* O157:H7 from food other than ground beef, and the results indicate that the organism is not a rare contaminant of fresh meats and poultry.

Doyle, M. P. and J. L. Schoeni. 1984. Survival and growth characteristics of *Escherichia coli* associated with hemorrhagic colitis. *Appl. Environ. Microbiol.* 48(4):855-856.

Escherichia coli O157:H7 in ground beef was more sensitive to heat than *Salmonella*, but survived for 9 months at -20° C with little change in number. The organisms grew well in Trypticase soy broth (BBL Microbiology Systems) between 30 and 42° C, with 37° C being optimal for growth. *E. coli* O157:H7 grew poorly in the temperature range (44 to 45.5° C) generally used for recovery of *E. coli* from foods.

El-Kest, S., et al. 1991. Fate of *Listeria monocytogenes* during freezing and frozen storage. *J Food Science* 56(4): 1068-1071

[Lethal and sublethal effects on *Listeria monocytogenes* Scott A caused by freezing and storage or a combination of both, single and multiple freeze-thaw cycles, and presence or absence of nutrients in the medium in which the pathogen was suspended, were investigated.] A cell suspension of *L. monocytogenes* was frozen for 30 min at -18 degree C, or 10 min in liquid nitrogen (LN) at -198 degree C. Solidification required 15 min at -18 degree C and approx. 1 min at -198 degree C. Freezing and storage for 1 month in phosphate buffer (PB) at -18 degree C caused 87% death and 79% injury. These were 54 and 45%, resp., for cells in Tryptose Broth (TB) at -18 degree C. Freezing and storage 1 month in LN caused no death or injury of cells suspended in PB, whereas some injury and death occurred in TB. Freezing at -198 degree C followed by storage 1 month at -18 degree C resulted in 60% death and 36% injury in PB, and 61 and 44.2%, in TB. Repeated freezing and thawing caused more death/injury than did a single freeze-thaw cycle.

Fain, A. R., et al. 1991. Lethality of heat to *Listeria monocytogenes* Scott A: D-value and z-value determinations in ground beef and turkey. *J. Food Prot.* 54(10)756-761.

D-Values and z-values for *Listeria monocytogenes* strain Scott A were determined in lean (2.0% fat) and fatty (30.5%) ground beef inoculated with approx. 10⁷ cells/g. Inoculated ground meat was sealed in glass thermal death time tubes which were completely immersed in a circulating water bath and held at prescribed temp. for predetermined times. Survival was determined by enumeration on Columbia CNA agar

base containing 1% sodium pyruvate with a CNA + 4% horse blood overlay (CBNA) and on *Listeria* Plating Medium (LPM). D-values for *L. monocytogenes* in lean and fatty ground beef at 125 degree F were 81.3 and 71.1 min, resp., as enumerated on CBNA plus pyruvate. D-values at 135 degree F were 2.6 and 5.8 min in lean and fatty beef. At 145 degree F, D-values were determined to be 0.6 and 1.2 min. D-values calculated from LPM recovery data from fatty ground beef at 125 degree F were 56.1 and 34.5 min, resp. D-values at 135 degree F were 2.4 and 4.6 min in lean and fatty beef. At 145 degree F a D-value of 0.5 min was calculated in lean beef and a D-value of 1.1 min was determined in fatty beef. The z-values determined in lean beef and fatty beef using CBNA recovery data were 9.3 and 11.4 degree F, resp. The z-value in lean beef using LPM recovery data was 9.8 degree F. The z-value in fatty beef using LPM recovery data was 13.2 degree F. A D-value for ground turkey meat at 160 degree F could not be determined under the conditions of this study. Problems encountered are discussed.

Goepfert, J. M. and H. U. Kim. 1975. Behavior of selected food-borne pathogens in raw ground beef. *J. Milk Food Technol.* 38(8):449-452.

Raw ground beef was inoculated with five strains each of *Escherichia coli*, enterococci, *Salmonellae*, *Staphylococci*, *Bacillus cereus*, and *Clostridium perfringens*. Changes in population levels of these organisms, psychrotrophs, and total aerobic flora as these were influenced by temperature and packaging film were recorded. Among the organisms inoculated, only *E. coli*, *Salmonellae*, and the enterococci were able to grow and then only at the highest test temperature (12.5 C). As expected, the packaging film did not influence the behavior of any of the test organisms. These results and the fact that a cooking step is involved demonstrate why ground beef is very rarely involved as a vehicle in bacterial food poisoning. This study indicates that there is no reason to expect protection of public health to evolve from bacteriologic standards which limit numbers of non-pathogenic organisms.

Harris, L. J. and M. E. Stiles. 1992. Reliability of *Escherichia coli* counts for vacuum-packaged ground beef. *J. Food Prot.* 55(4):266-270.

Test strains of *Escherichia coli* were inoculated into fresh ground beef that been irradiated or carefully excised and aseptically ground. Samples were vacuum-packaged and stored at 4°C. Plate counts on selective media incubated at 35 or 45°C were highly consistent during the 7- to 20-d storage periods. The standard most probable number (MPN) technique (lauryl tryptose broth at 35°C, followed by EC broth at 45°C) was also reliable. In contrast, direct inoculation into broths incubated at 45°C gave unreliable and highly variable results. The cause of the variability of the MPN counts 45°C could not be determined. It was not due to lactic acid bacteria growing in the ground beef. *E. coli* in refrigerated, vacuum-packaged ground beef can be reliably

detected by direct inoculation of several plating media incubated at 45°C. Direct inoculation of selective broth media for the MPN technique at 45°C is not recommended.

Kotula, A. W., et al. 1983. *Trichinella spiralis*: Effect of high temperature on infectivity of pork. *Experimental Parasitol.* 56:15-19.

Twenty gram samples of homogenized Boston shoulder from swine experimentally infected with *Trichinella spiralis* were sealed in plastic pouches, pressed to a uniform thickness of 2mm, and subjected to water bath temperatures of 49, 52, 55, 60, and 63±0.5C for intervals of 2 min to 6 hr, especially within the interval of 0 to 15 min. These times included a period of about 1 min at the start and a period of about 1 min at the end for temperature equilibration. Treated samples were rapidly chilled to 25C and then digested in a 1% pepsin-HCl solution at 37 C for 18 hr to recover *T. spiralis* larvae. The recovered larvae were suspended in 2 ml saline; 1 ml of this suspension was introduced into the stomach of each of two rats. The linear equation, $\log(\text{time})=17.3 - 0.0302(\text{temperature})$, was calculated from the time required at each temperature for the inactivation of *T. spiralis* larvae. The correlation coefficient for that relationship was $r = -0.994$. Larvae heated in the meat to 55C for 4 min retained their infectivity, but were rendered noninfective after 6 min at 55C. At 60C, larvae were not infective after only 2 min (zero dwell time); whereas at 52C, 47 min were required to render the larvae noninfective. Larvae in meat heated to 49C were infective after 5 hr but not after 6 hr. These data demonstrate that the destruction of infectivity of *T. spiralis* is time-temperature related.

Kotula, A. W., et al. 1983. Destruction of *Trichinella spiralis* during cooking. *J. Food Science* 48:765-768.

Center cut chops (longissimus dorsi) 2.5 cm in thickness, from 31 pigs experimentally infected with *Trichinella spiralis* larvae and containing 37±5 larvae per gram were cooked to a final internal temperature of 66, 71, 77 or 82°C by one of eight methods to determine their efficacy in killing encysted larvae. The results indicate that with the time and temperatures used in this study, some rapid methods of cooking pork chops that involved the use of a microwave oven did not completely destroy *T. spiralis* larvae at 77 and 82°C. The data also showed that cooking pork chops to an internal temperature of 77°C in the conventional oven, convection oven, flat grill, charbroiler or deep fat fryer did inactivate encysted *T. spiralis* larvae in pork chops.

Line, J. E., et al. 1991. Lethality of heat to *Escherichia coli* 0157:H7: D-value and z-value determinations in ground beef. *J. Food Prot.* 54(10):762-766.

D-values and z-values were determined for lean (2.0% fat) and fatty (30.5% fat) ground beef inoculated with approx. 10⁻⁷ *Escherichia coli* 0157:H7 cells per g. Inoculated

ground meat was sealed in glass thermal death time tubes which were completely immersed in a circulating water bath and held at prescribed temp. for predetermined times. Survival was determined by enumeration on plate count agar (PCA) containing 1% sodium pyruvate and by the 2-h indole test. D-values for fatty ground beef exceeded those for lean ground beef at the temp. tested. D-values for lean and fatty ground beef at 125 degree F were 78.2 and 115.5 min, resp., as enumerated on PCA plus pyruvate. D-values at 135 degree F were 4.1 and 5.3 min for lean and fatty beef. At 145 degree F D-values were determined to be 0.3 and 0.5 min. D-values calculated from 2-h indole test data for lean and fatty ground beef at 125 degree F were 80.1 and 121.0 min, resp. D-values at 135 degree F were 4.0 and 7.4 min for lean and fatty beef and at 145 degree F a D-value of 0.2 min was calculated for lean beef only, due to insufficient survival of *E. coli* 0157:H7 in fatty beef at this temp. The z-values determined for lean beef and fatty beef using PCA were 8.3 and 8.4 degree F, resp. The z-value for lean beef using the 2-h indole data was 7.8 degree F. No z-value for fatty beef using 2-h indole data could be determined.

Linton, R. H., M. D. Pierson, and J. R. Bishop. 1990. Increase in heat resistance of *Listeria monocytogenes* Scott A by sublethal heat shock. *J. Food Prot.* 53(11):924-927.

Log phase cells of *Listeria monocytogenes* Scott A were heat shocked in trypticase soy + 0.6% yeast extract broth at 40, 44 and 48 degree C for 3, 10 and 20 min, followed by heating at 55 degree C for 50 min in order to determine an optimum heat shock response. Most heat shocking temp. significantly increased thermal resistance (P less than 0.05). Increasing heat shock temp. and time allowed the organism to survive much longer than nonheat shocked cells at 50-65 degree C. Optimal heat shock condition was 48 degree C for 20 min where D-values at 55 degree C increased 2.3-fold in nonselective agar and 1.6-fold in selective agar. Cells heat shocked at 48 degree C for 10 min gave more consistent results; these cells were heat processed at 50, 55, 60 and 65 degree C

to determine a z-value. Although D-values notably increased due to heat shocking, z-values remained constant. Heat shocking at 48 degree C significantly increased D-value ratios for cells enumerated on nonselective vs. selective media. Heat shocking conditions may be created in pasteurization or minimal thermal processing of food allowing increased heat resistance of pathogenic and spoilage microorganisms.

Palumbo, S. A., et al. 1994. Influence of temperature on hemorrhagic *Escherichia coli*: Verotoxin production and minimum temperature of growth. (81st Annual Meeting of IAMFES) Dairy, Food Environ. Sanitation p.612.

Hemorrhagic *Escherichia coli* has emerged as a major foodborne pathogen. In general, its culture characteristics are similar to nonpathogenic strains. Refrigeration of fresh foods, particularly red meats, represents one means of controlling the growth of pathogens in these foods. However, there are no data on the effect of temperature on the growth of hemorrhagic *E. coli* and on verotoxin production. Using BHI broth in a temperature gradient incubator set at 5 to 50°C, we determined time to visible turbidity for 15 O157:H7, O26:H11, and O111:NM strains. At this point, samples were removed for verotoxin assay. The minimum temperature of growth ranged from 6.9 to 13 °C, with 10 strains growing at 9.0-9.5 °C. Except for the two O111:NM strains, verotoxin was produced at all temperatures. Production was a time-temperature relationship, with more verotoxin produced at higher temperatures. Holding foods at 5 °C should prevent hazards from this organism.

Sources for Epidemiology of Foodborne Illness

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Examples of Questions to be Considered in a Hazard Analysis

The Hazard Analysis consists of asking a series of questions which are appropriate to each step in a HACCP plan. It is not possible in these recommendations to provide a list of all the questions which may be pertinent to a specific food or process. The Hazard Analysis should question the effect of a variety of factors upon the safety of the food.

A. Ingredients

1. Does the food contain any sensitive ingredients that may present biological hazards (e.g., *Salmonella*, *Staphylococcus aureus*); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
2. Is potable water used in formulating or in handling the food?

B. Intrinsic factors

Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing

1. Which intrinsic factors of the food must be controlled in order to assure food safety?
2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
4. Are there other similar products in the market place? What has been the safety record for these products?

C. Procedures used for processing

1. Does the process include a controllable processing step that destroys pathogens? Consider both vegetative cells and spores.

2. Is the product subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging?

D. Microbial content of the food

1. Is the food commercially sterile (e.g., low acid canned food)?
2. Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?
3. What is the normal microbial content of the food?
4. Does the microbial population change during the normal time the food is stored prior to consumption?
5. Does the subsequent change in microbial population alter the safety of the food pro or con?

E. Facility design

1. Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods if this is important to food safety?
2. Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
3. Is the traffic pattern for people and moving equipment a significant source of contamination?

F. Equipment design

1. Will the equipment provide the time-temperature control that is necessary for safe food?
2. Is the equipment properly sized for the volume of food that will be processed?
3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
4. Is the equipment reliable or is it prone to frequent breakdowns?

5. Is the equipment designed so that it can be cleaned and sanitized?
6. Is there a chance for product contamination with hazardous substances (e.g., glass)?
7. What product safety devices are used to enhance consumer safety?
 - metal detectors
 - magnets
 - sifters
 - filters
 - screens
 - thermometers
 - deboners
 - dud detectors

G. Packaging

1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
2. Is the package clearly labeled "keep refrigerated" if this is required for safety?
3. Does the package include instructions for the safe handling and preparation of the food by the end user?
4. Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?
5. Are tamper-evident packaging features used?
6. Is each package and case legibly and accurately coded?
7. Does each package contain the proper label?

H. Sanitation

1. Can sanitation impact upon the safety of the food that is being processed?
2. Can the facility and equipment be cleaned and sanitized to permit the

safe handling of food?

- 3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?**

I. Employee health, hygiene, and education

- 1. Can employee health or personal hygiene practices impact upon the safety of the food being processed?**
- 2. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?**
- 3. Will the employees inform management of a problem which could impact upon safety of the food?**

J. Conditions of storage between packaging and the end user

- 1. What is the likelihood that the food will be improperly stored at the wrong temperature?**
- 2. Would an error in improper storage lead to a microbiologically unsafe food?**

K. Intended use

- 1. Will the food be heated by the consumer?**
- 2. Will there likely be leftovers?**

L. Intended consumer

- 1. Is the food intended for the general public?**
- 2. Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirm, immunocompromised individuals)?**