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Food Safety
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Service

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HACCP-3

Generic HACCP Model for Raw, Ground Meat and Poultry Products

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INTRODUCTION

The Hazard Analysis Critical Control Points (HACCP) concept is a systematic, scientific approach to process control. The Food Safety Inspection Service (FSIS) views HACCP as a means of preventing the occurrence of health and safety hazards in plants producing meat and poultry 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 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 plant-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 Points. 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 to be unsafe for human consumption.

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 on Microbiological Criteria for Foods (NACMCF) has defined 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.

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

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NACMCF, HACCP, 1992

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. Pathogenic microorganisms of public health significance should be identified in the Hazard Analysis under the appropriate process step as a biological hazard with preventive measures to preclude their growth and proliferation.

Remember that in your hazard analysis there are three categories of hazards to consider: chemical, biological, and physical. Appendix 3 includes a table of hazards that are controlled in a HACCP system. 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 significance of identified hazards and 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 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 and the information and data you recorded on the Hazard Analysis/Preventive Measures form will be required 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 specified 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 or an equivalent process proven to render the product unadulterated.

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 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 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 an individual trained to meet the requirements in 9CFR 417.7.

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 CCP's. There are two HACCP 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 2). 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 Meat and Poultry Products" 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 "Generic HACCP Model for Meat and Poultry Procucts with Secondary Inhibitors, Not Shelf- Stable" 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 HACCP Model Heat Treated Not Fully Cooked, Not Shelf Stable Meat and Poultry Products" will be most useful.

If a product is not shelf stable and is raw, the "Generic HACCP Model for Raw, Ground Meat and Poultry Products" or "Generic HACCP Model for Raw, Not Ground Meat and Poultry Products" models will be most useful. Products in the "Generic HACCP Model for Raw, Not Ground Meat and Poultry Products" 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 "Generic HACCP Model for Raw, Ground Meat and Poultry Products" process category are subjected to the grinding process and may include products such as fresh sausage.

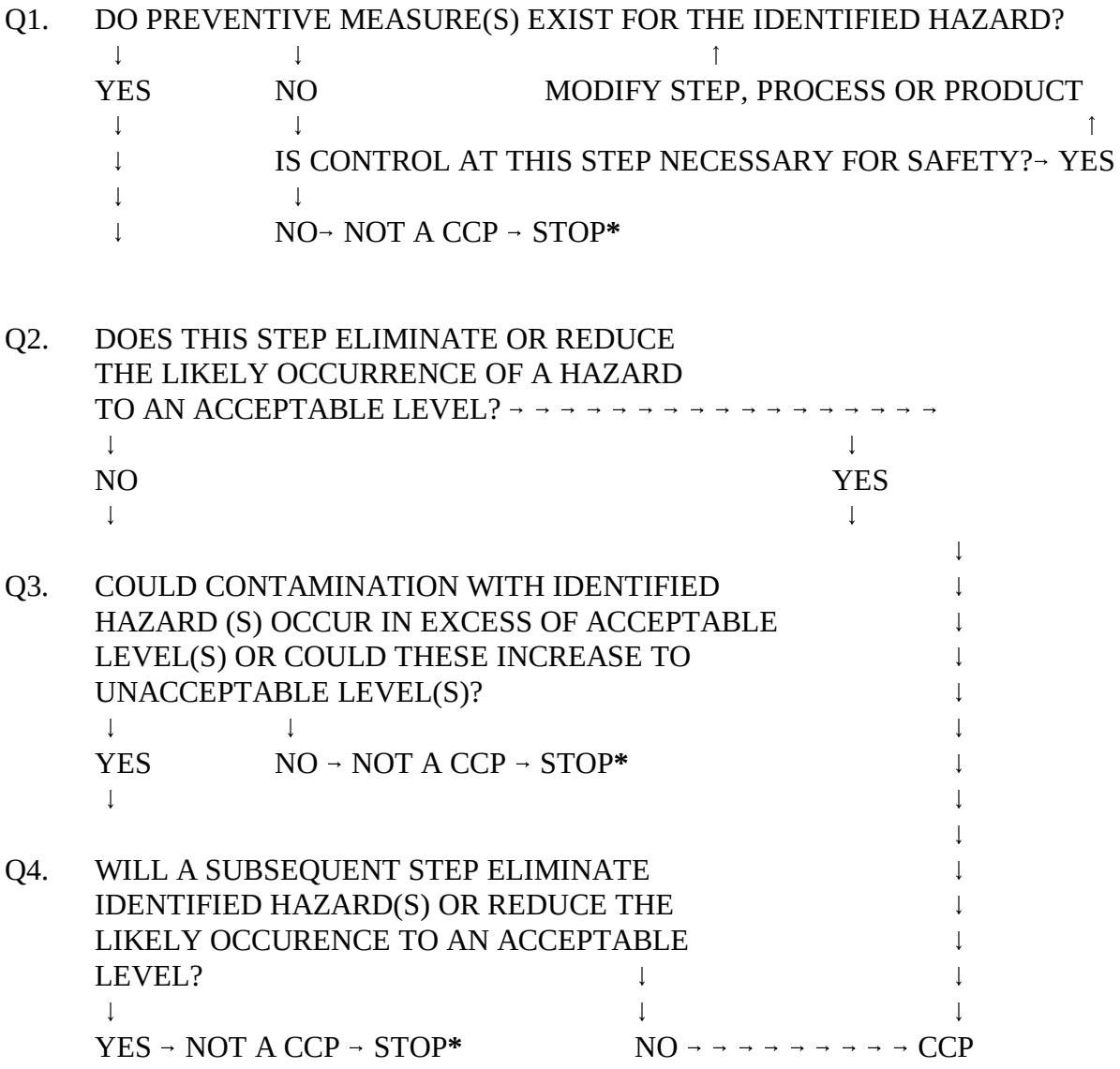
After the correct generic model has been selected, you should proceed through the steps outlined in the model. The same generic process model may include diverse products, so it is important that you identify and group all products covered by the process model in order to correctly identify the hazards, 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.)



***** Proceed to the next step in the described process

Model Plan for Process: Raw Ground

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 for the Preparation of HACCP Plans and 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 as possible relevant to the public health hazards associated with your process, 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 inplemented. Each establishment should maintain records documenting the establishments 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 biological, 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, broken 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 occuring 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.

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. eds. 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, DC .

4. Microorganisms in Foods. Vol 5. ICMSF. Blackwell Scientific Publications, Oxford.

All the 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 is 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) (Note: 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, safe food handling); 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 : GROUND BEEF

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

1.	COMMON NAME?	GROUND BEEF
2.	HOW IS IT TO BE USED?	COOKED AND CONSUMED
3.	TYPE OF PACKAGE?	BULK-PACKED (E.G., PLASTIC BAG, VACUUM PACKED); LAYER OR STACK PACKED, PATTIE 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? CONSUMERS? INTENDED USE?	RETAIL AND HRI, WHOLESALE GENERAL PUBLIC; MAY INCLUDE HOSPITALS
6.	LABELING INSTRUCTIONS?	KEEP FROZEN; COOKING INSTRUCTIONS (MINIMUM INTERNAL TEMPERATURE FOR COOKING); THAWING INSTRUCTIONS; KEEP REFRIGERATED; SAFE FOOD HANDLING LABEL
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(S) AND INGREDIENTS

PROCESS CATEGORY: RAW, GROUND

PRODUCT EXAMPLE : GROUND BEEF

MEAT

BEEF

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 their HACCP plan and will also serve as a future guide for regulatory officials who must understand the process for their verification activities.

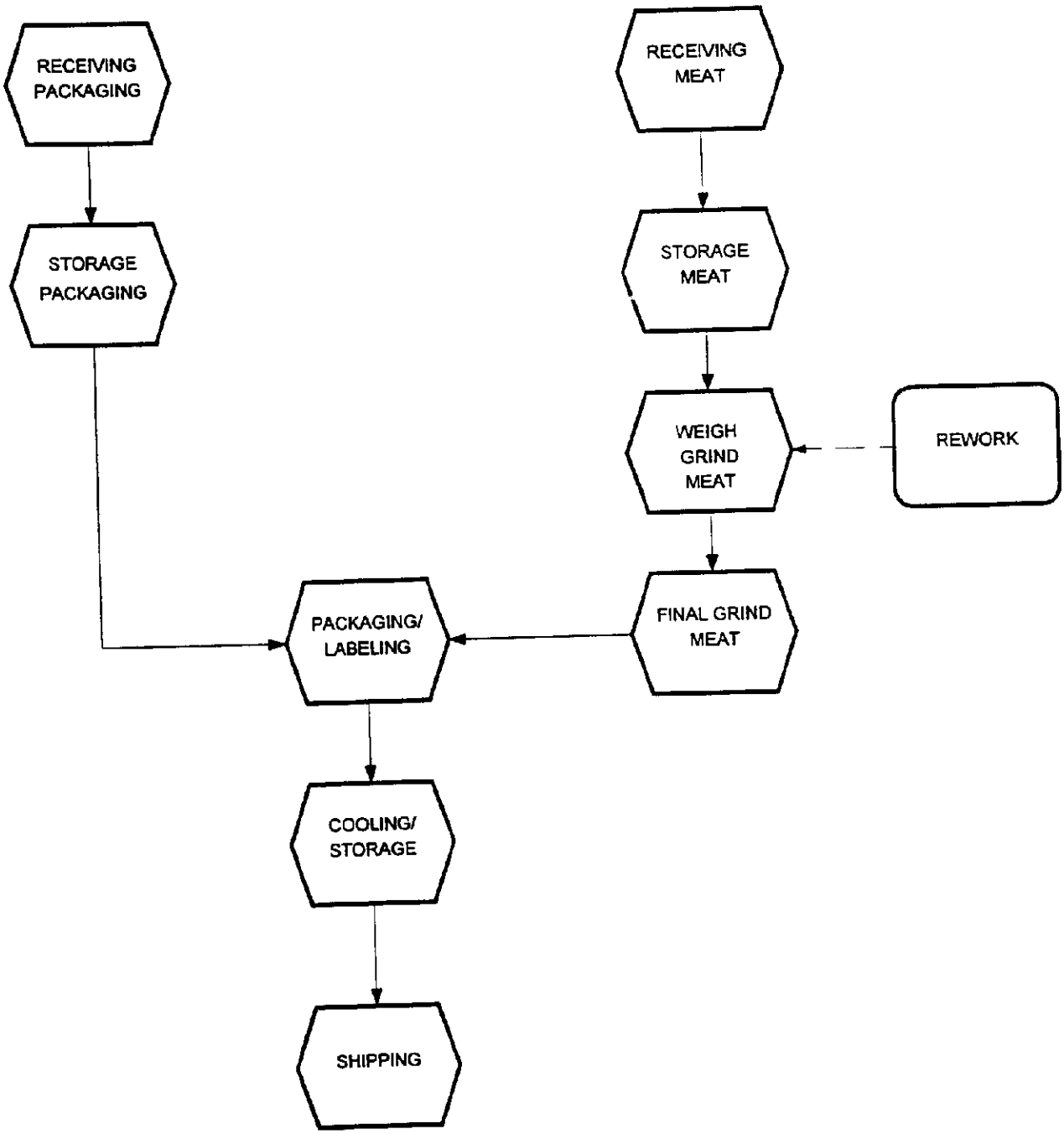
The flow diagram must cover all the steps in the process which are directly under the control of the establishment. It can also include steps in the food chain which are before and after the processing that occurs. For the sake of simplicity, the flow diagram should consist solely of words, not engineering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

Member(s) of the HACCP Team should use the drafted 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: RAW, GROUND

PRODUCT: GROUND BEEF



Hazard Analysis/Preventive Measures Form

The Hazard Analysis/Preventive Measures Form is used to review 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/or 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. The analysis 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. This should be a consideration since it affects public health.

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

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

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

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

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

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

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 Sanitation Standard 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-Meat	B - Microbial Growth.	YES	YES			CCP 1B
	C - N/A (Not Applicable)					
	P - Foreign Material	YES	YES			CCP 1P
Receiving-Non-Meat	B - N/A low risk					
	C - Deleterious Chemicals.	YES	YES			CCP 1C
	P - Foreign Material.	YES	YES			CCP 2P
Storage-Meat	B - Microbial Growth.	YES	YES			CCP 2B
	C - N/A					
	P - N/A low risk					
Storage-Non-Meat	B - N/A					
	C - N/A					
	P - Foreign Material/Adulteration.	YES	YES		This may be controlled using GMP's if a plant incorporates CCP 4P into their HACCP plan.	CCP 3P
Assemble:Weigh/ Pre-Grind/Re-Work/ Final Grind-Meat	B - Microbial Growth.	YES	YES			CCP 3B
	C - N/A					
	P - Foreign Material.	YES	NO	YES	NO	CCP 4P

CCP DETERMINATION

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

PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY 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
Packaging	B - N/A Low Risk	Controlled at assembly & storage & by use of safe food handling label				
	C - N/A (Not Applicable)					
	P - Foreign Material	YES	NO	YES	NO	CCP 5P
Cooling and Storage of Product	B - Microbial Growth.	YES	YES			CCP 4B
	C - N/A					
	P - N/A					
Shipping	B - Microbial Growth.	YES	YES			CCP 5B
	C - N/A					
	P - N/A					

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 the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. 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 initialled, dated, and the time recorded 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; and 4) assure that no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce. 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, dated, and the time of action recorded 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 a processing 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, date and record the time all records are 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.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

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

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

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

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

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

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

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

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

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

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

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

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

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

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : GROUND BEEF

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

Process Category Description Form

The Process Category Description Form is used to describe each food product for 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, safe food handling); 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 : FRESH PORK SAUSAGE

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

1.	COMMON NAME?	FRESH PORK SAUSAGE
2.	HOW IS IT TO BE USED?	COOKED AND CONSUMED
3.	TYPE OF PACKAGE?	BULK-PACKED (E.G., PLASTIC BAG, VACUUM PACKED); LAYER OR STACK PACKED, LINK 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? CONSUMERS? INTENDED USE?	RETAIL AND HRI, WHOLESALE GENERAL PUBLIC, NO DISTRIBUTION TO SCHOOLS OR HOSPITALS
6.	LABELING INSTRUCTIONS?	KEEP FROZEN; COOKING INSTRUCTIONS (MINIMUM INTERNAL TEMPERATURE FOR COOKING); THAWING INSTRUCTIONS; KEEP REFRIGERATED; SAFE FOOD HANDLING LABEL
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(S) AND INGREDIENTS

PROCESS CATEGORY: RAW, GROUND

PRODUCT EXAMPLE : FRESH PORK SAUSAGE

MEAT

PORK
EDIBLE CASING

INGREDIENTS

WATER
SPICE MIX
SUGAR

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 their HACCP plan and will also serve as a future guide for regulatory officials who must understand the process for their verification activities.

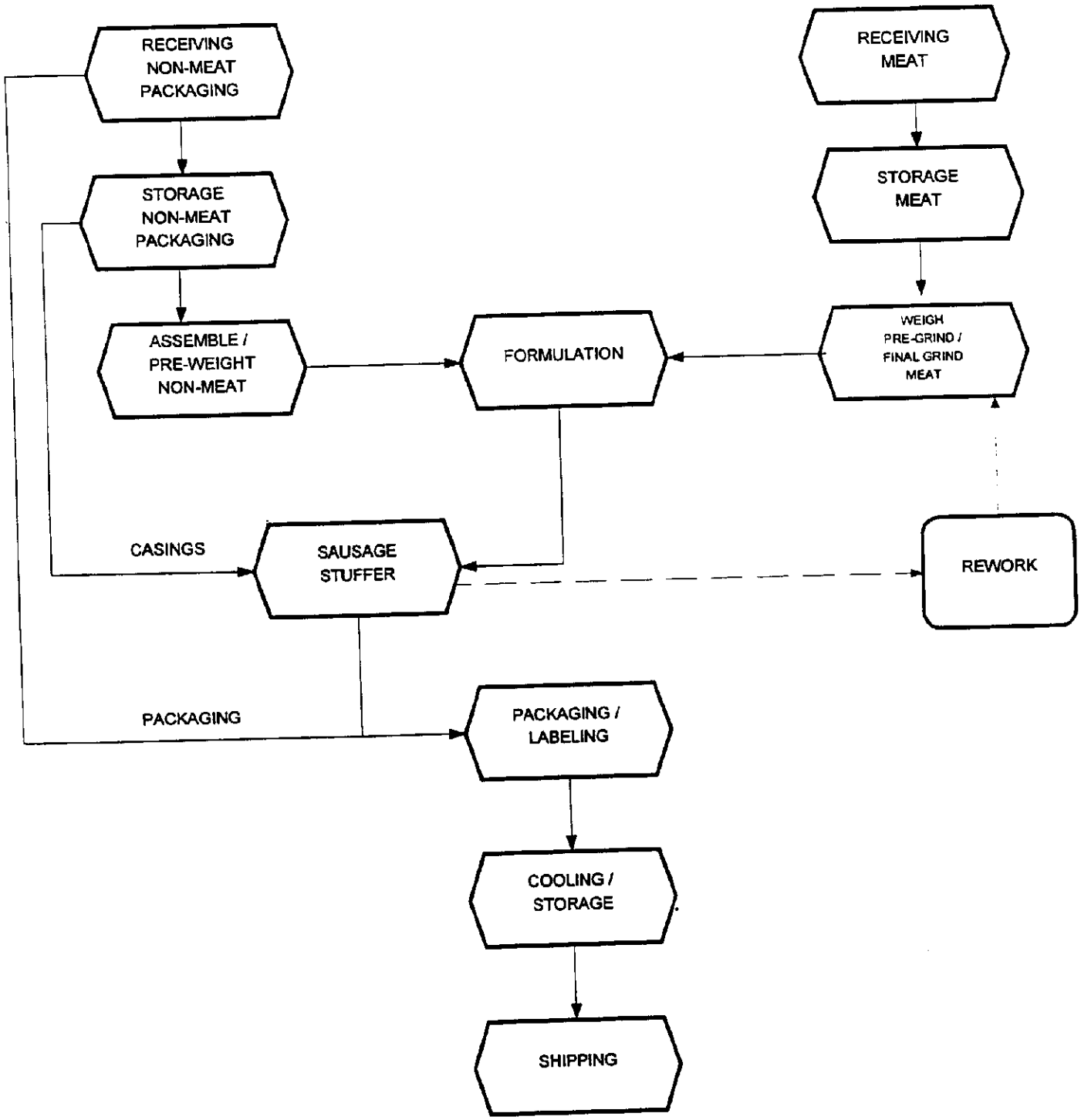
The flow diagram must cover all the steps in the process which are directly under the control of the establishment. It can also include steps in the food chain which are before and after the processing that occurs. For the sake of simplicity, the flow diagram should consist solely of words, not engineering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

Member(s) of the HACCP Team should use the drafted 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: RAW, GROUND

PRODUCT: FRESH PORK SAUSAGE



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 means which can be used to control an identified food safety hazard.

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

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY: RAW, GROUND
PRODUCT EXAMPLE: FRESH PORK SAUSAGE

Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures (This may be controlled using GMP's. Not to be included in a plant specific HACCP plan)	Examples of How Hazard Is Introduced (This column is for illustrative purpose only and not to be included in a plant specific HACCP plan)
RECEIVING-MEAT	B (Microbial Growth) - Insufficient temperature control will result in unacceptable microbial proliferation. Ayres, J.C. 1979, Duitschaver, C.L. and C.I. Buteau. 1979. B Trichinae cysts B (Mishandling) - The integrity of the immediate container is compromised such that microbial contamination could occur. P (Foreign Material) - Visible foreign material that could compromise product safety. Meat and Poultry Products Hazards and Control Guide.	Maintain product temperature at or below a level sufficient to preclude microbial growth. Visual inspection to ensure no foreign material.* Visual inspection to ensure that immediate container is not compromised.* Analysis of supplier history to determine occurrence of contamination.	B-Transport refrigeration unit is not functioning properly (out of freon). B-The shipping container (cardboard combo bin) was pierced by a bloody forklift and the immediate container (the film wrapped around the individual trays) was torn and punctured introducing harmful microbes into the product. P-Pieces of glass found in product from a broken light bulb; metal clips, knives, etc.
RECEIVING - NON-MEAT	C (Deleterious Chemicals) - Chemicals/non-meat ingredients/ packaging materials, are not acceptable for intended use. Food grade material should be approved for intended use. Bean, N.H. and P.M. Griffin, 1990. P (Foreign Material) - Visible foreign material that could compromise product safety; metal, plastic, wood, etc. Meat and Poulty Hazards and Control Guide	Verify that the letter of guarantee is on file and appropriate for product use. Third party audit of supplier* Visual inspection to ensure no visible foreign material is present.* Analysis of past history of incidence of contamination from each supplier.	C-The new tray pack "diapers" ordered came in and the letter of guarantee is present with the shipment, however the letter states that the diapers are acceptable for industrial use and not food grade. P-Pieces of metal are found in the spice mix.

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY: RAW, GROUND
PRODUCT EXAMPLE: FRESH PORK SAUSAGE

Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures (This may be controlled using GMP's. Not to be included in a plant specific HACCP plan)	Examples of How Hazard Is Introduced (This column is for illustrative purpose only and not to be included in a plant specific HACCP plan)
STORAGE - MEAT	B (Microbial Growth) - Insufficient cooling could result in unacceptable microbial growth. Internal product temperature and environmental temperature must be monitored. Ayres, J.C. 1979, Johnston, R.W. et.al. 1982.	Monitor the internal product temperature to ensure temperature is at or below a level sufficient to preclude microbial growth and environmental temperature does not exceed 50 °F for more than 2 hours (e.g. cooler or freezer) to ensure product safety.	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 permitting excessive bacterial growth.
STORAGE - NON-MEAT	P (Foreign Material/Adulteration) - All non-meat ingredients, packaging materials, etc. must be stored to prevent contamination due to foreign material.	Visual inspection of storage area to ensure that materials are maintained in a proper manner(off the floor and away from walls).	P-The product is stored directly against the walls which have visible debris on them. The debris falls onto the packaging materials that contact product.**

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY: RAW, GROUND
PRODUCT EXAMPLE: FRESH PORK SAUSAGE

Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures (This may be controlled using GMP's. Not to be included in a plant specific HACCP plan)	Examples of How Hazard Is Introduced (This column is for illustrative purpose only and not to be included in a plant specific HACCP plan)
ASSEMBLE/ PRE-WEIGH/ PRE-GRIND/ RE-WORK FINAL GRIND MEAT	B (Microbial Growth) - Insufficient control of internal product temperature and environmental temperature could result in unacceptable microbial growth. Ayres, J.C. 1979, Comi, G. et. al., 1992. P (Foreign Materials) - Visible foreign material that could compromise product safety; metal and plastic shavings, rubber gloves, bone, etc. Meat and Poultry Products Hazards and Control Guide. Surkiewics, B.F.,et al. 1972.	Monitor ambient room temperature and product temperature to ensure temperature of product does not exceed a level sufficient to preclude microbial growth for more than 2 hours, and the room temperature does not exceed 50 °F for more than 4 hours. Visual or mechanical inspection to ensure no hazardous foreign material is present. Equipment maintenance on a routine basis. **This may be controlled using the SSOP.	B-As a result of a mechanical breakdown, the product movement into the cooling cycle was delayed 6 hours and the product temperature increases above 55°F due to exposure to ambient room temperature. P-Moving parts of the grinder are not set properly or are worn and grind together leaving pieces of metal in the product.
ASSEMBLE/ PRE-WEIGH NON-MEAT	NONE		
FORMULATION	P (Foreign Materials) - Visible foreign material that could compromise product safety; metal and plastic shavings, bone, etc.	Visual or mechanical inspection to ensure no foreign material is present. Each plant should review their history of physical contamination incidence to determine the level of risk and the appropriate point for addressing the physical hazard.	P-The product was not properly ground and large sharp pieces of bone are still present in the product.

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY: RAW, GROUND
PRODUCT EXAMPLE: FRESH PORK SAUSAGE

Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures (This may be controlled using GMP's. Not to be included in a plant specific HACCP plan)	Examples of How Hazard Is Introduced (This column is for illustrative purpose only and not to be included in a plant specific HACCP plan)
SAUSAGE STUFFER	C: N/A P:(Foreign Materials) - Visible foreign material that could compromise product safety; metal and plastic shavings, bone, etc.	Each plant should review their history of physical contamination incidence to determine the level of risk and the appropriate point for addressing the physical hazard.	P- The stuffer was not routinely maintained and worn metal pieces from the stuffing horn contaminated the product.
PACKAGING/ LABELING	B: Trichinosis due to undercooking by consumer. C: None identified P: None identified	B-Apply safe food handling label.	
COOLING AND STORAGE OF PRODUCT	B (Microbial Growth) - Product temperature if not maintained at an acceptable level would result in an increase in microbial growth. Cooling rates must be sufficient to limit the growth of enteric pathogens and bacteria of human health significance. Ayres, J.C. 1979 Buchanan, R.L. and L.A. Klawilter. 1992.	Maintain product at temperature adequate to limit microbial growth. Assure that the temperature and recording device used are appropriately calibrated. Product is arranged to assure adequate airflow to maintain acceptable temperature ($\leq$ 40 $^{\circ}$F) throughout all parts of product. Monitoring the ambient cooler room temperature to assure product temperature is adequate to limit microbial growth.	B-Continuous temperature recording device has not been calibrated for weeks and is not recording actual ambient room temperatures. The actual ambient room temperature is 27 degrees higher than it should be, increasing product temperature to the point where bacteria can proliferate and/or spoilage can occur.
SHIPPING	B (Microbial Growth) - Potential for an increase in bacterial flora and other enteric pathogens that will proliferate on the product if the temperature significantly increases over time during transport. Ayres, J.C. 1979	Product temperature must be $\leq$40°F prior to leaving the establishment. Refrigerated transport.	Product was not $\leq$40°F before it left the dock and microbial proliferation resulted during transport.

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 Attachment 2). 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 Sanitation Standard 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-Meat	B - Microbial Growth.	NO *Establishment's only supplier has an operating HACCP system for production and transportation of meat products.				
	P - Foreign Material. This is controlled by supplier specification procedures	NO				
Receiving-Non-Meat	B - N/A					
	C - Deleterious Chemicals.	YES	YES			CCP 1C
	P - Foreign Material.	YES	YES			CCP 1P
Storage-Meat	B - Microbial Growth.	YES	YES			CCP 1B
	C - N/A - in-plant chemical contamination - low incidence - controlled by SSOP's					
	P - N/A - no significant hazards identified					
Storage-Non-Meat	B - N/A - no significant hazards identified					
	C - N/A - low likehood of occurrence					
	P - Foreign Material/Adulteration.	YES	YES		This may be controlled through plant GMPs if CCP 3P is part of the HACCP plan.	CCP 2P*
Assemble/Pre-Weigh/ Pre-Grind/Re-work/ Final Grind - Meat	B - Microbial Growth.	YES	YES			CCP 2B
	C - N/A					
	P - Foreign Material.	YES	NO	YES	YES	

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
Formulation	B - N/A	Controlled at meat formulation and storage				
	C - N/A					
	P - Foreign Material.	YES	NO	YES	NO	CCP 3P
Cooling and Storage of Product	B - Microbial Growth.	YES	YES			CCP 3B
	C - N/A					
	P - N/A					
Shipping	B - Microbial Growth.	YES	YES			CCP 4B
	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 the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. 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, dated, and the time recorded 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; 3) maintain records of the corrective actions that have been taken where there has been a deviation from critical limits; and, 4) assure that no product that is injurious to health or otherwise aduterated as a result of the deviation enters commerce. Because of the variations in CCP's for different processes and the diversity of possible deviations, 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 against the establishment. In accordance with the HACCP principles, HACCP records must include: records associated with establishing 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, date and record the time all records are reviewed. The approved HACCP plan and associated records must be on file at the meat 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 each particular CCP.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : FRESH PORK SAUSAGE

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING - MEAT	B - Microbial Growth. B - Mishandling P - Foreign Material.	1 B 1 P	Temperature within plant specifications.* Immediate container is clean and intact. No visible hazardous foreign material.** * Carcasses or red meat must be received at 40° F or below. * Note: Insufficient scientific data exist regarding the growth of pathogens during chilling parameters provided above will control quality and limit the growth rates of even psychrotrophic spoilage organisms. Therefore, these parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens. ** Condemn product or remove particles 1/32" or larger.	Internal temperature monitored as product is received by qualified personnel. Visual inspection of immediate container at the time each shipment is received by receiving personnel. Record all findings in HACCP receiving log, sign, and date record.	If product temperature exceeds 40 °F, immediate container is compromised or foreign material is noted in/on the meat product: identify and control affected product for disposition or return to supplier; take corrective action to prevent reoccurrence. Plant designee documents actions taken in HACCP receiving log, signs, and dates record.	Record all results and corrective action(s) in a plant specific log/record and/or corrective action log and sign record.	Bi-weekly visual observation of product and receiving procedures, done by receiving manager. Audit to verify sampling techniques and accuracy of records; verify accuracy of temperature devices; determine if the Critical Limit corresponds to the plant records; check to see if Critical Limit is adequate for hazard; assure corrective actions are adequate; document findings. Weekly calibration of thermometers.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : FRESH PORK SAUSAGE

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING- NON-MEAT	C - Deleterious Chemicals. P - Foreign Material.	1 C 2 P	Letters of guarantee are on file for all packaging materials/ non-meat supplies used by the establishment that specify food grade material must be used. No visible foreign material.	Supervisory review of letters of guarantee for each new packaging material/non-meat supply brought onto establishment premises. Check incoming material/ supplies to see if material identification matches the accompanying letter of guarantee. Check letters of guarantee at appropriate times for materials/supplies used on a continuous basis to assure compliance. Visual inspection of product at appropriate times by qualified personnel. Record all findings in HACCP records log and sign record.	Establish program through purchasing dept. to assure that letters of guarantee for each ingredient and packaging material are on file prior to delivery. 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. Notify plant designee.	Record all results and corrective action(s) in a plant specific log/record and/or corrective action log. Sign record and date.	Twice weekly inspection of product and observation of receiving procedures, done by qualified personnel Yearly audit of suppliers by third party. 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 : FRESH PORK SAUSAGE

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
STORAGE - MEAT	B - Microbial Growth.	1 B	Environmental and internal temperature within plant specifications. Carcasses or meat must be stored at 40° F or below. A maximum of 50° F maintained in product handling areas.* *Note: Insufficient scientific data exist regarding the growth of pathogens during chilling parameters provided above will control quality and limit the growth rates of even psychrotrophic spoilage organisms. Therefore, these parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.	Environmental and internal temperature monitored at appropriate times by qualified personnel. Monitor refrigeration parameters daily by maintenence personnel. Record all findings in HACCP records log and sign record, date, and record time of observation.	If process does not demonstrate control within written HACCP plan procedures, control affected product, rechill product;repair and/or readjust refrigeration device, cooler, 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. Notify plant designee.	Record all results and corrective action(s) in a plant specific log/record and/or corrective action log. Sign record and record time of observation.	Twice weekly visual inspection and temperature check of product done by a individual who did not produce the records and who 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 calibrations of thermometers.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : FRESH PORK SAUSAGE

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
STORAGE-NON-MEAT	P - Foreign Material/ Adulteration	2 P	No visible foreign material.	Visual inspection of storage room and representative sample inspection for foreign material of non-meat supplies/ packaging materials at appropriate times by qualified personnel. Record all findings in HACCP records log and sign record.	If process does not demonstrate control within written HACCP plan procedures, control affected product, rechill product; correct or adjust procedures; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP records log and signs record.	Record all results and corrective action(s) in a plant specific log/record and/or corrective action log. Sign record and record time of observation.	Weekly visual inspection of product and room by an individual who did not produce the records and who 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 : FRESH PORK SAUSAGE

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
ASSEMBLE/ PRE-WEIGH/ PRE-GRIND/ RE-WORK FINAL GRIND MEAT	B - Microbial Growth.	2 B	Product temperature maintained at or below 40° F during handling.* A maximum of 50° F maintained in product handling areas. *Note: Insufficient scientific data exist regarding the growth of pathogens during chilling parameters provided above will control quality and limit the growth rates of even psychrotrophic spoilage organisms. Therefore, these parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.	Product temperature monitored at appropriate times by qualified personnel. Refrigeration controls and operations routinely monitored by personnel responsible for the function. Record all findings in HACCP records log and sign record.	If process does not demonstrate control within written HACCP Plan procedures, identify and control affected product; correct or adjust procedures; recondition/rework product; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP records log and signs record. Notify plant designee.	Record all results and corrective action(s) in a plant specific log/record and/or corrective action log, sign record, date and record time of observation.	Periodic measurement of product temperatures by designated personnel. Audit to verify sampling techniques and accuracy of records; verify accuracy of temperature devices; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings. Weekly calibration of thermometers.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : FRESH PORK SAUSAGE

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
FORMULATION	P - Foreign material.	3 P	No visible foreign materials. Condemn product or remove particles 1/32" or larger. No bone particles ≥ 0.8 inch (20 mm).	Visual inspection of product at appropriate times by qualified personnel. Record all findings in HACCP records log and sign record.	If process does not demonstrate control within written HACCP Plan procedures, identify and control affected product; correct or adjust procedures; recondition/rework product; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP records log and signs record. Notify plant designee.	Record all results and corrective action(s) in a plant specific log/record and/or corrective action log, sign record, date and record time of observation.	Daily visual observation of procedures and/or visual inspection of product, done by designated personnel. 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 : FRESH PORK SAUSAGE

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
COOLING AND STORAGE OF PRODUCT	B - Microbial Growth.	3 B	Product temperature maintained at or below 40° F.* A maximum of 50°F maintained in product storage area. *Note: Insufficient scientific data exist regarding the growth of pathogens during chilling parameters provided above will control quality and limit the growth rates of even psychrotrophic spoilage organisms. Therefore, these parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.	Product temperatures, environmental temperatures monitored every four hours by personnel responsible for the function. Refrigeration controls and operation routinely monitored by personnel responsible for the function. Record all findings in HACCP records log and sign record.	If process does not demonstrate control within written HACCP plan procedures, control affected product, rechill product; correct or adjust procedures; evaluate operation for cause of deficiency; take corrective action to prevent reoccurrence; plant designee documents actions taken in HACCP records log and signs record. Notify plant designee.	Record all results and corrective action(s) in a plant cooler log/record and/or corrective action log, and sign record, date and record time of observation.	Daily measurement of product temperatures, of environmental temperatures done by designated personnel. Audit to verify sampling techniques and accuracy of records; verify accuracy of temperature devices; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings. Weekly calibration of thermometers.

HACCP PLAN

PROCESS CATEGORY : RAW, GROUND
PRODUCT EXAMPLE : FRESH PORK SAUSAGE

PROCESS STEP	BIOLOGICAL CHEMICAL PHYSICAL HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
SHIPPING	B - Microbial Growth.	4 B	Product must reach 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 parameters provided above will control quality and limit the growth rates of even psychrotrophic spoilage organisms. Therefore, these parameters are more than sufficient to prevent growth of mesophilic enteric bacterial pathogens.	Product temperatures, truck temperatures, and/or environmental temperatures, monitored at appropriate times by qualified personnel. If plant owned truck, routine maintenance and monitoring of refrigeration unit operation and controls. Record all findings in HACCP records log and sign record.	If process does not demonstrate control within written HACCP plan procedures, control affected product, rechill 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. Notify plant designee.	Record all results and corrective action(s) in a plant specific log/record and/or corrective action log, sign record, date and record time of observation.	Daily measurement of product temperatures, of environmental temperatures, and/or truck temperatures, done by designated personnel. 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

Generic HACCP Model for Beef Slaughter

Generic HACCP Model for Poultry Slaughter

Generic HACCP Model for Pork Slaughter

Generic HACCP Model for Raw, Not Ground Meat and Poultry Products

Generic HACCP Model for Raw, Ground Meat and Poultry Products

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

Generic HACCP Model for Heat Treated Not Fully Cooked, Not Shelf Stable Meat and Poultry Products

Generic HACCP Model for Meat and Poultry Products with Secondary Inhibitors, Not Shelf-Stable

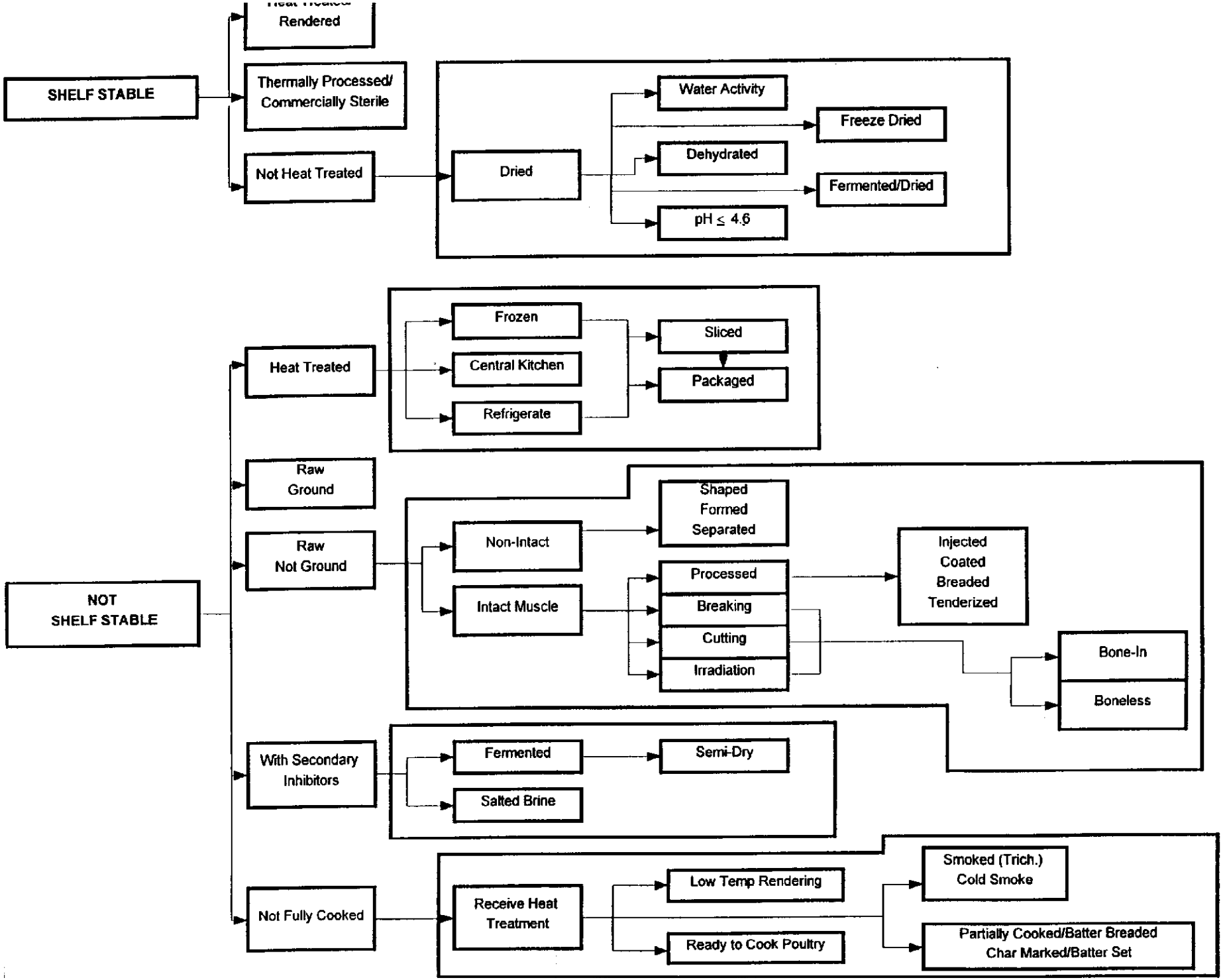
Generic HACCP Model for Not Heat Treated, Shelf-Stable Meat and Poultry Products

Generic HACCP Model for Fully Cooked, Not Shelf-Stable Meat and Poultry Products

Generic HACCP Model for Heat Treated, Shelf-Stable Meat and Poultry Products

Generic HACCP Model for Thermally Processed Commercial Sterile Meat and Poultry Products

Generic HACCP Model for Irradiation


Rendered
SHELF STABLE
Thermally Processed/
Commercially Sterile
Not Heat Treated
Dried
Water Activity
Freeze Dried
Dehydrated
Fermented/Dried
pH ≤ 4.6
Heat Treated
Frozen
Central Kitchen
Refrigerate
Sliced
Packaged
Raw
Ground
Raw
Not Ground
NOT
SHELF STABLE
Non-Intact
Intact Muscle
Shaped
Formed
Separated
Processed
Breaking
Cutting
Irradiation
Injected
Coated
Breaded
Tenderized
Bone-In
Boneless
With Secondary
Inhibitors
Fermented
Salted Brine
Semi-Dry
Not Fully Cooked
Receive Heat
Treatment
Low Temp Rendering
Ready to Cook Poultry
Smoked (Trich.)
Cold Smoke
Partially Cooked/Batter Breaded
Char Marked/Batter Set

Appendix 3

EXAMPLES OF
FOOD SAFETY HAZARDS BEING CONTROLLED IN HACCP PROGRAMS

PHYSICAL	**CHEMICAL**	**BIOLOGICAL**
Glass	Allergens	Cross-Contamination
Metal	Animal Drug Residues	- Post Cooked
Other Foreign Materials	Cleaning Compound Residues	Pathogens
		- Raw Ingredients
		- Raw Storage
	Illegal Residues/Pesticides	Zoonotic Disease
	- Packaging Materials	Parasites
	- Raw Ingredients	Decomposition
	- Shipping Containers	
	Natural Toxins	
	Unapproved direct or indirect food or color additives	

Appendix 4

Literature Review for Hazard Identification - Ground Beef/Pork Sausage

Appendix 4, a source review of the literature was prepared for two product examples of the Raw, Ground Meat and Poultry Products process. The literature search focused on ground beef and fresh pork sausage products. The sources listed in this review were gathered primarily from a search of databases (e.g., Food Science and Technology Abstracts, Agricola, and Medline) on CD-ROM. Bound abstracts, such as the Food Safety and Technology Abstracts and the Bibliography of Agriculture, also could be used. References cited in scientific journal articles are another source of material.

The source review is divided into three parts: foodborne illnesses; the prevalence of pathogens found in ground beef and fresh pork sausage; and the effect of processing procedures, such as the application of heat, on the growth of pathogens in these products.

The first section lists articles on foodborne illnesses associated with meat products in general, or ground beef and pork sausage in particular. The initial search used "foodborne illnesses" as a keyword. This search was narrowed to include only foodborne illnesses caused by meat products, ground beef, or pork sausage. Another search of the articles on foodborne illness was conducted to determine the pathogens involved in the various outbreaks or incidents of foodborne illness related to raw, ground meat. From this search, the pathogens of interest were found to include, but not be limited to, E. coli O157:H7, Shiga-like toxin producers, Salmonella, Clostridium perfringens, Clostridium botulinum, Listeria monocytogenes, Yersinia, and Trichinella spiralis. These sources listed in this section indicate whether a problem exists; the extent of that problem (percentage of population affected and associated costs); and the risk associated with eating undercooked meat products. This section underscores the importance of establishing a HACCP program for the products in question. These references may indicate the level of microorganisms that can cause illness in a susceptible individual. In addition, the pathogens to test for in a microbiological monitoring program would be indicated from these references.

While the first section identifies the various foodborne pathogens, the second section lists references for the prevalence of those pathogens in raw, ground meat products i.e., how often the pathogens in question are found in raw, ground product. The number of organisms usually found in this type of product also may be reported in some of the references. The review was not limited to those products of U.S. origin since outbreaks could involve imported product. These references can assist in identifying the hazards associated with raw, ground meat products -the first HACCP principle. In addition, the microbiological testing of the raw, ground product for pathogens will be based on the information contained in the scientific literature. For example, since E. coli O157:H7 is a pathogen of concern in ground beef, this product may be examined for this organism when an establishment submits samples

for microbiological testing.

References to factors that control, limit, or influence the growth or survival of the pathogens cited above were the primary focus for Appendix 4. The various pathogens served as the keywords in this search. This search was further defined by the factors that affect growth of any microorganism, such as a salt concentration or thermal process. This information will be used to determine the preventive measures when initially organizing the HACCP plan. It is also necessary for establishing the critical limits and monitoring procedures of the HACCP plan.

Part I - Factors Affecting the 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).

Part II - Prevalence of Pathogens Found in Ground Beef and Fresh Pork Sausage

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* 0157 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 serotyope 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 _Salmonella_; 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 vertoxigenic (*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* 0157: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* 0157:H7 are described. Aspects considered include: the food poisoning outbreak; details of *E. coli* 0157: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. Supernants 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 *Salmonella* 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 *Salmonella* 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. entercolitica*, 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. entercolitica*, 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.

Part III - Effects of Processing Procedures on the Growth of Pathogens

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 $\geq$ 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. 10-7 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(time)=17.3 -0.0302(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 vertoxin 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.

On the basis of studies on meat deboning using various types of deboning machines, a proposal for guidelines for the production and processing of mechanically deboned meat were worked out. The draft proposal covers qualitative and hygienic characteristics, as well as methods for determination of the ratio of bone marrow and bone chips in the mechanically deboned meat; it is recommended that the proportion of marrow and bone chips should be less than 10% in selected meat products.

Schoeni, J. L., K. Brunner, and M. P. Doyle. 1991. Rates of thermal inactivation of

Listeria monocytogenes **in beef and fermented beaker sausage. J. Food Prot. 54(5):334-337.**

Rates of thermal inactivation of a 5-strain mixture of Listeria monocytogenes [Scott A, V7, LM-101M, LM-102M, LM-103M] were determined in ground beef roast and fermented beaker sausage. Ground beef contaminated with *L. monocytogenes* Scott A from an experimentally infected cow was also examined. D-values for the 5-strain mixture at 54.4, 57.2, 60.0 and 62.8 degree C were 22.4, 15.7, 4.47, and 2.56 min, resp., for ground beef roast. D-values for fermented beaker sausage at 48.9, 51.7, 54.4, and 60.0 degree C were 98.6, 44.4, 20.1, 11.2, and 9.13 min, resp. D-values for the single strain of *L. monocytogenes* mixture in ground beef from the infected cow were about 2-4x less at equivalent temp. than those of the 5-strain *L. monocytogenes* mixture in ground beef roast. Results from the 5-strain mixture indicate that *L. monocytogenes* is about 4x more heat resistant that *Salmonella* in ground beef roast.

Todd, E., et al. 1991. "Thermal resistance of verotoxigenic *Escherichia coli* in ground beef -Initial work" in *Escherichia coli O157:H7* and other verotoxigenic *E. coli* in foods. E. C. C. Todd and J. M. MacKenzie (Ed.) pp. 93-109.

Because *E. coli* O157:H7 and possibly other verotoxigenic *E. coli* have been responsible for human infections arising from consumption of undercooked hamburger, it was important to establish the heat resistance of these organisms in ground beef, and ultimately to determine the minimum heat processes that substantially reduce the risk of illness. Eighteen strains (10 *E. coli* O157:H7 or non-motile and 8 other verotoxigenic *E. coli* representing 7 serotypes) were screened for high, medium or low heat resistance in phosphate buffer. Stationary phase (17 h) cells were used for the heat resistance studies, because they were at their maximum resistance at this time. Washed cells were added to phosphate buffer and heated at 52 °C for various times. Surviving cells were recovered on tryptic soy agar containing 0.25 g of fast green/L to enable automated counting. D-values ranged from 7.0 to 37.4 (mean 19 min) for O157 and 4.6 to 20.1 min (mean 13 min) for the other *E. coli* strains. The most resistant strains for both groups (one O157 and one O26) were then tested in irradiated regular ground beef (24% fat) packed in flexible pouches. Heating times between 55 and 60 °C for 0 to 90 min were used to calculate three D-values for each of the strains. For O157 these ranged from 31.4 min (at 55 °C) to 1.7 min (at 60 °C) and for O26 from 16.9 min (at 55 °C) to 1.2 min (at 60 °C). From these data z-values for O157 and O26 were calculated to be 3.5C° and 4.3 C°, respectively. These values are about the same as those reported by Doyle and Schoeni and by Line et al. More resistant clones were then selected for subsequent heat resistance studies; with these clones D-values were found to be higher in medium ground beef.

Restaurant and home cooking methods will be evaluated later for their ability to eliminate these pathogens in rare, medium and well-done hamburger patties.

Sources for Epidemiology of Foodborne Illness

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Factors Influencing/Controlling Microbial Growth

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Attachment 1

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 in 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 infirmed, immunocompromised individuals)?**

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