GENERIC HACCP MODEL FOR

IRRADIATION

Developed:
June 5-7, 1996
College Station, TX

Submitted to

USDA, Food Safety and Inspection Service

by the

International Meat and Poultry HACCP Alliance

on

September 9, 1996

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Introduction:

Hazard Analysis Critical Control Point (HACCP) is a systematic, scientific approach to process control. It is designed to prevent the occurrence of problems by ensuring that controls are applied at any point in a food production system where hazardous or critical situations could occur. Hazards can include biological, chemical or physical contamination 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 industry.

In May 1996, the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) awarded Contract Number 53-3A94-6-04 to the International Meat and Poultry HACCP Alliance for the development of ten generic HACCP models. The ten models developed were:

1. Not Heat Treated, Shelf-Stable (dried products, those controlled by water activity, pH, freeze dried, dehydrated, etc.)
2. Heat Treated, Shelf-Stable (rendered products, lard, etc.)
3. Heat Treated Not Fully Cooked, Not Shelf-Stable (ready to cook poultry, cold smoked and products smoked for trichinae, partially cooked battered, breaded, char-marked, batter set, and low temperature rendered products, etc.)
4. Products with Secondary Inhibitors, Not Shelf-Stable (products that are fermented, dried, salted, brine treated, etc., but are not shelf-stable)
5. Irradiation (includes all forms of approved irradiation procedures for poultry and pork)
6. Fully Cooked, Not Shelf Stable (products which have received a lethal kill step through a heating process, but must be kept refrigerated. This includes products such as fully cooked hams, cooked beef, roast beef, etc.).
7. Beef Slaughter
8. Pork Slaughter
9. Poultry Slaughter
10. Raw Products - not ground (all raw products which are not ground in their final form. This includes beef trimmings, tenderized cuts, steaks, roasts, chops, poultry parts, etc.)

USDA developed three additional models:

1. Raw, Ground
2. Thermally Processed/Commercially Sterile
3. Mechanically Separated Species/Deboned Poultry

This document contains the generic HACCP model for the process category titled: **IRRADIATION.**

In order to develop this model, a literature review and an epidemiological assessment of the products selected were performed to present an overview of the microbiological characteristics and profile of the product. This information then was reviewed by a team of industry, academic, public health officials, and consumer representatives. The team met in a workshop in College Station, TX on June 5-7, 1996.

Subsequent to the workshop, this generic HACCP model was reviewed by small business establishments for clarity and usability, and it was submitted to an expert peer review panel for technical review.

Generic HACCP plans serve as useful guidelines; however, it is impossible for a generic model for to be developed without it being too general. Therefore, it is incumbent on each plant's HACCP Team to tailor this model to fit products in each plant, based on the knowledge about the process. Several points should be considered when using this model to develop specific HACCP plans.

All plants shall have Sanitation Standard Operating Procedures (SSOPs). Good Manufacturing Practices (GMPs) (FDA, 21 CFR 110; Appendix 1) and Standard Operating Procedures (SOPs) may be in place as the foundation of the HACCP program. Good Manufacturing Practices are minimum sanitary and processing requirements applicable to all companies processing food. Standard Operating Procedures (SOPs) are step-by-step directions for completing important plant procedures. SOPs should specifically describe the method for conducting and controlling the procedure. SOPs should be evaluated regularly (i.e., daily) to confirm proper and consistent application, and modified as necessary to ensure control.

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 for use in developing a plant-specific HACCP plan are defined according to process category. 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, 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 assist in developing your plant-specific plans.

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, over-lapping critical control points (CCPs) can be combined as long as all significant hazards are addressed.

Seven Principles of HACCP:

The following seven principles of HACCP were adopted by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF, 1992):

1. Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.
   Three types of hazards:
   Biological (B)— primarily concerned with pathogenic bacteria, such as *Salmonella*, *Staphylococcus aureus*, *Campylobacter jejuni*, *Clostridium perfringens*, *Clostridium botulinum*, *Listeria monocytogenes*, and *Escherichia coli* O157:H7; also should consider *Trichinella sprialis*, and other parasites, as well as potential pathological concerns.
   Chemical (C)— toxic substances or compounds that may be unsafe for consumption; i.e., cleaners, sanitizers, pesticides, insecticides, rodenticides, paint, lubricants, etc.

Physical (P)— foreign objects which may injure the consumer; i.e., rocks, stones, wood, metal, glass, nuts, bolts, screws, plastic, knife blades, etc.

2. Identify the critical control points (CCPs) 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.

3. Establish critical limits for preventive measures associated with each identified CCP. A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to assure prevention, elimination or reduction of hazards to acceptable levels. Each preventive measure has associated with it critical limits that serve as boundaries of safety for each CCP.

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

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

6. Establish effective record-keeping procedures that document the HACCP system.

7. Establish procedures for verification that the HACCP system is working correctly.

Specifics about this Generic Model:

1. Products Included In This Model. This model deals only with the **PROCESS CATEGORY**, **IRRADIATION.** This product examples are poultry parts and ground pork.

2. Items Addressed. This model does not address certain aspects of product safety, such as Sanitation Standard Operating Procedures (SSOPs). Good Manufacturing Practices (GMPs) and Standard Operating Procedures (SOPs) may be in place as the foundation of HACCP.

3. Critical Control Points. The Critical Control Points in this model were established by the team members of the workshop. Some products or processes may require fewer or more CCPs depending on the individual operation.

4. Product Flow. In the product flow, the general processes were included; however, order of flow varies. The product flow of every HACCP plan should be specific and accurately reflect the processes involved at each plant.

5. Safety vs. Quality. Several parameters have been discussed to ensure a safe product. Only parameters relating to product safety were discussed. Quality issues were not addressed in this model.

6. Critical Limits. Critical limits selected must be based on the best information available to provide a safe product and yet be realistic and attainable. Processors must keep in mind that any product which does not meet a critical limit must have a Corrective Action taken on the product before being released from the plant.

7. Process Authority. Reference may have been made about a "Process Authority" in this model. A Process Authority may be an in-plant employee who has had specialized training, an outside consultant, or other professional.

8. Record-keeping. Record-keeping is an important part of the HACCP plan. Lack of accurate, current records may be cause for withholding or suspending inspection from a plant.

9. Chain of Custody. Chain of custody refers to the point at which a plant gains control of the meat. This is particularly important to know the history of incoming meat products. Requiring a HACCP plan from the supplier will in effect, extend the chain of custody to the supplier.

10. Sampling Procedures. Each plant must establish a sampling plan to verify critical control points (biological, chemical and physical) in the operation. The procedures will be based on prior knowledge about the problem areas and not necessarily on random testing. A Process Authority may help establish these sampling procedures which are most likely to identify a problem if it exists.

USING THIS GENERIC MODEL TO DEVELOP AND IMPLEMENT A HACCP PROGRAM

Getting Started: The plant should establish a HACCP team which includes at least one HACCP trained individual, and then develop a flow chart for each product (or process category). In addition, a training program should be completed for all employees. It is important for all employees to have ownership in the HACCP plan and to participate in its development as appropriate. It also is important that the employees be given the authority to stop production if the process becomes out of control. This empowerment is critical to make the HACCP program a successful one. Once HACCP is established, it must be continually evaluated, upgraded, and modified. Experience in working a HACCP plan will be helpful in continual improvement in the plan. In effect, the HACCP program is a long-term commitment to improving the safety of the product by controlling the process.

The NACMCF has 12 steps (five preliminary steps listed below and the seven principles previously listed) in developing a HACCP 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 beginning with conducting a hazard analysis.

The following steps should be considered when developing an effective HACCP system.

Before developing the HACCP system it is important to ensure that an adequate sanitation system (sanitation standard operating procedures - SSOPs) is in place for compliance with FSIS regulation. GMPs and SOPs are also important because they establish basic operational parameters for the production of safe food.

Assembling the HACCP Team: An important step in developing a plan is to gain management commitment and assemble a HACCP team. Top management must be fully committed to product safety through HACCP to make the program effective. After commitment is obtained, the HACCP team should be assembled. The team should consist of individual(s) from all aspects of production and should include at least one HACCP trained individual.

Product Description. The description should include the products within the process, their distribution, intended use, and potential consumers. This step will help ensure that all areas of concern are addressed. If a particular area on the example form is not applicable to your process, then eliminate it from your description. The description for the **IRRADIATION** is included in this model.

Flow Diagram. The HACCP team should develop and verify a flow diagram for production of the product(s). A simple flow diagram which includes every step of production is necessary. The flow diagram should be verified for accuracy and completeness by physically walking through each step in the diagram on the plant floor. The purpose of the flow diagram is to provide a clear, simple description of the steps in the process which are directly under the control of the facility. This model contains a generic flow diagram for **IRRADIATION.**

Hazard Analysis. A hazard has been defined as any biological (B), chemical (C) or physical (P) property that may cause a food to be unsafe for human consumption. The hazard analysis is one of the most critical steps in the development of a HACCP plan. The HACCP team must conduct a hazard

analysis and identify steps in the process where significant hazards can occur. The significant hazards must be "of such a nature that their prevention, elimination, reduction or control to acceptable levels is essential to the production of safe food." (NACMCF, 1992) The team should focus on risk and severity as criteria for determining whether a hazard is significant or not. Risk, as defined by the National Advisory Committee, is "likelihood of occurrence." "The estimate of risk is usually based on a combination of experience, epidemiological data, and information in the technical literature." (NACMCF, 1992). Severity is the potential magnitude of the consequences to the consumer if the hazard is not adequately controlled. Hazards that are not significant or not likely to occur will not require further consideration in the HACCP plan.

Appendix 3 provides a list of example food safety hazards as identified in the Pathogen Reduction; Hazard Analysis Critical Control Point (HACCP) Systems regulation (USDA, 1996).

The hazard analysis and identification of associated preventive measures accomplishes the following:

Identifies hazards of significance and associated preventive measures.
The analysis can be used to modify a process or product to further assure or improve food safety.
The analysis provides a basis for determining CCPs, principle 2.

Critical Control Point (CCP): A CCP is any point, step, or procedure at which control can be applied so that a food safety hazard can be prevented, eliminated, reduced, or controlled to acceptable levels. Information developed during the hazard analysis should enable the HACCP team to identify which steps in the process are CCPs. A decision tree, such as the NACMCF Decision Tree (Appendix 4) may be useful in determining if a particular step is a CCP for an identified hazard.

The CCPs discussed in this generic model should be considered as examples. Different facilities preparing the same product can differ in the risk of hazards and the points, steps, or procedures which are considered CCPs. This can be due to differences in each facility layout, equipment, selection of ingredients, or the production process that is being used. Plant-specific HACCP plans may include additional or fewer CCPs than this model based on their individual process.

Critical Limit: A critical limit is a criterion that must be met for each preventive measure associated with a CCP. Therefore, there is a direct relationship between the CCP and its critical limits that serve as boundaries of safety. Critical limits may be derived from sources such as regulatory standards and guidelines, scientific literature, experimental studies, and advice from experts. The HACCP worksheet provided in this model summarizes the critical limits for each CCP. Critical limits must be based on the best information available at the time to provide a safe product and yet must be realistic and attainable. Establishments must keep in mind that any product which does not meet the critical limit must have a Corrective Action taken. Corrective actions may be as simple as re-processing or re-packaging or may require destroying the product.

Monitoring: Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and produces an accurate record for future use in verification. Monitoring serves three purposes:

1) Monitoring is essential to food safety management in that it tracks the systems operation.
2) Monitoring is used to determine when there is a loss of control and a deviation occurs at a CCP, exceeding the critical limit. Corrective action must then be taken.
3) Monitoring provides written documentation for use in verifying the HACCP plan.

Because of the potential serious consequences of a critical defect, monitoring procedures must be effective. Continuous monitoring is possible with many types of equipment, and it should be used when possible.

Individuals monitoring CCPs must:

1) Be trained in the technique used to monitor each preventive measure;
2) Fully understand the purpose and importance of monitoring;
3) Have ready access to the monitoring activity;
4) Be unbiased in monitoring and reporting; and
5) Accurately report the monitoring activity.

All records associated with monitoring must be signed or initialed, dated, and the time recorded by the person conducting the monitoring activity.

Corrective Actions: Corrective actions are procedures to be followed when a deviation occurs. Because of variations in CCPs for different products and the diversity of possible deviations, specific corrective action plans must be developed for each CCP. The actions must demonstrate that the CCP has been brought under control and that the product is handled appropriately.

Record-Keeping: Record keeping is a critical aspect of the HACCP system. Records must be accurate and reflect the process, the deviations, the corrective actions, etc. Lack of accurate, current records may be cause for withholding or suspension of inspection from the plant.

It is also important that all HACCP records dealing with CCPs and corrective actions taken, be reviewed on a daily basis by an individual who did not produce the records and who has completed a course in HACCP, or the responsible establishment official who must sign or initial, date and record the time all records are reviewed. The HACCP plan and associated records must be on file at the meat and/or poultry establishment.

Example forms have been included in this model. It may be beneficial to combine forms as possible to reduce the amount of paperwork.

Verification: Verification consists of the use of methods, procedures or tests in addition to those used in monitoring to determine that the HACCP system is in compliance with the HACCP plan and whether the HACCP plan needs modification. There are three processes involved.

1) The scientific or technical process to verify that critical limits at CCPs are satisfactory — review of critical limits to verify that the limits are adequate to control hazards that are likely to occur.
2) Process verification to ensure that the facility's HACCP plan is functioning effectively.
3) Documented periodic reassessment, independent of quality audits or other verification procedures, that must be performed to ensure the accuracy of the HACCP plan.

Sanitation SOPs: According to USDA's Pathogen Reduction/HACCP regulation (USDA, 1996), effective establishment sanitation is essential for food safety and to successfully implement HACCP. There are direct and substantial links between inadequate sanitation and the contamination of meat and poultry products by pathogenic bacteria. Sanitation SOPs are necessary because they clearly define each establishment's responsibility to consistently follow effective sanitation procedures and substantially minimize the risk of direct product contamination and adulteration.

Microbial testing for indicator organisms can be used to validate CCP effectiveness, and to establish in-plant trend analysis. Microbial testing should be part of a sanitation program in order to validate effectiveness. Microbial testing does not indicate that the product is safe, but it is used to verify that the process was in control.

PROCESS CATEGORY DESCRIPTION

WORKSHOP LOCATION: College Station, Texas

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

COMMON NAME: Poultry Parts, Raw, Fresh or Frozen

HOW IS IT TO BE USED? Ready to Cook or further process

TYPE OF PACKAGE?

Poultry Parts: Bulk pack/resealable pouch or Retail Package (with air permeable and approved packaging material for irradiation.)

LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?

Shelf-life will vary depending on holding temperature. The following are estimates only.

Poultry Parts: Frozen, for approximately 3 -6 months
Refrigerated, for approximately 1-3 weeks

WHERE WILL IT BE SOLD?

Retail
Food Service

LABELING INSTRUCTIONS:

Fresh: Must have Safe Handling Label, Irradiation label in compliance with regulations, "Keep refrigerated"

Frozen: Must have Safe Handling Label, Irradiation label in compliance with regulations, "Keep frozen".

IS SPECIAL DISTRIBUTION CONTROL NEEDED?

Safe food handling instructions should be evident. Poultry Irradiation regulation requires transportation under refrigerated conditions. Identify if product is "Fresh" or "Frozen."

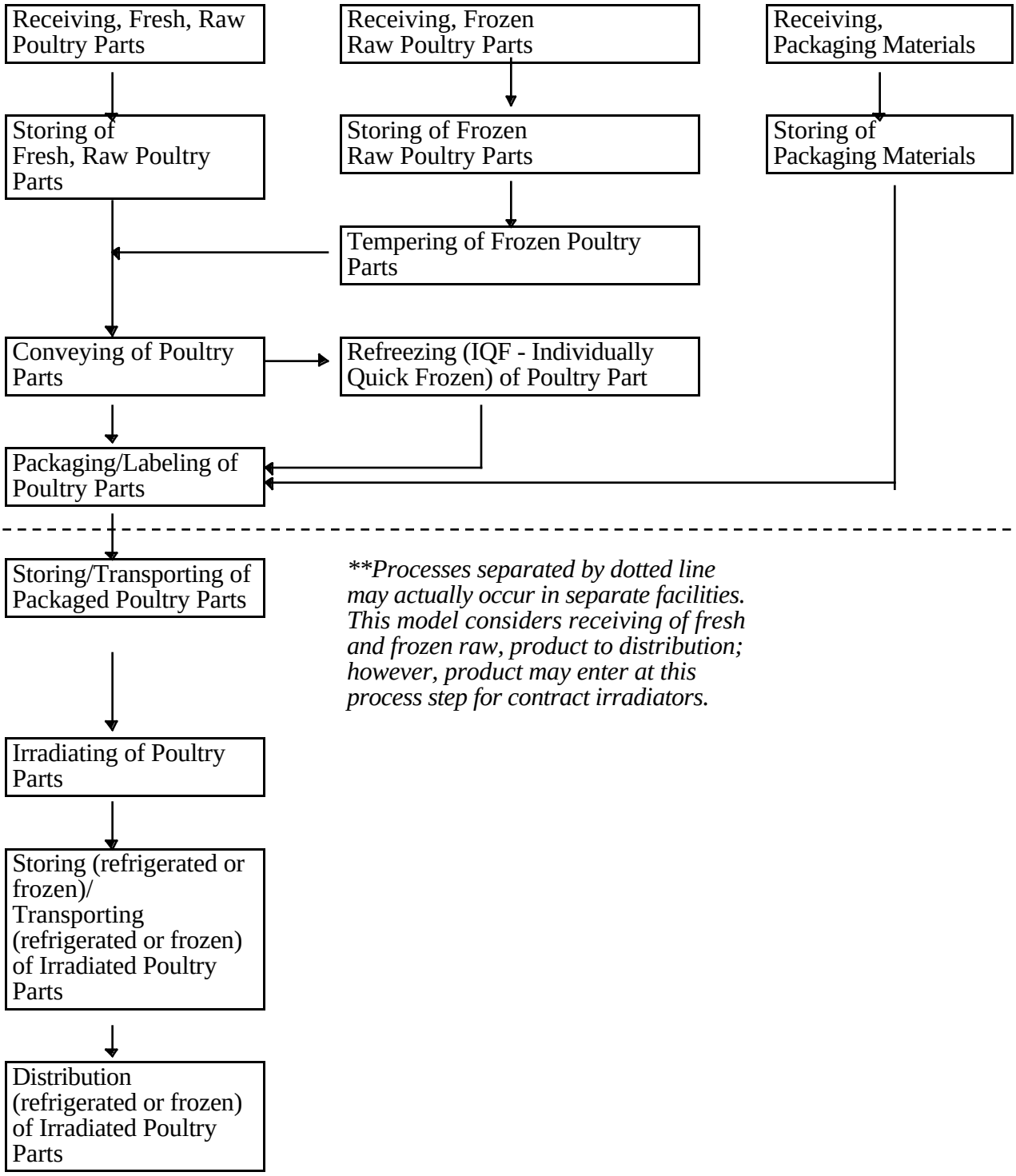
LIST PRODUCT CATEGORIES AND INGREDIENTS

PRODUCT CATEGORY: Irradiation: Product Examples — Poultry Parts

WORKSHOP LOCATION: College Station, Texas

MEAT AND MEAT BYPRODUCTS	NONMEAT FOOD INGREDIENTS	BINDERS/EXTENDERS
Raw Poultry	None allowed.	None allowed.
SPICES/FLAVORINGS	RESTRICTED INGREDIENTS	PRESERVATIVES/ ACIDIFIERS
None allowed.	None allowed.	None allowed.
OTHER		
Approved packaging material (i.e., nitrocellulose coated or vinylidene chloride copolymer coated cellophane, and polyolefin film) for irradiation. (Listed in 21CFR 179.45) Irradiation Label.		

IRRADIATION FLOW CHART
PRODUCTS: POULTRY PARTS



***Processes separated by dotted line may actually occur in separate facilities. This model considers receiving of fresh and frozen raw, product to distribution; however, product may enter at this process step for contract irradiators.*

PROCESS CATEGORY DESCRIPTION

WORKSHOP LOCATION: College Station, Texas

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

COMMON NAME: Ground Pork, Raw, Fresh or Frozen

HOW IS IT TO BE USED? Ready to Cook or further process

TYPE OF PACKAGE?
Ground Pork: Chub Package or Retail Package (with air permeable and approved packaging material for irradiation.)

LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?
Shelf-life will vary depending on holding temperature. The following are estimates only.

Ground Pork: Frozen, for approximately 3 -6 months
Refrigerated, for approximately 1-3 weeks

WHERE WILL IT BE SOLD?
Retail
Food Service

LABELING INSTRUCTIONS:
Fresh: Must have Safe Handling Label, Irradiation label in compliance with regulations, "Keep refrigerated"

Frozen: Must have Safe Handling Label, Irradiation label in compliance with regulations, "Keep frozen".

IS SPECIAL DISTRIBUTION CONTROL NEEDED?
Safe food handling instructions should be evident. Transport under refrigerated/frozen conditions. Identify if product is "Fresh" or "Frozen."

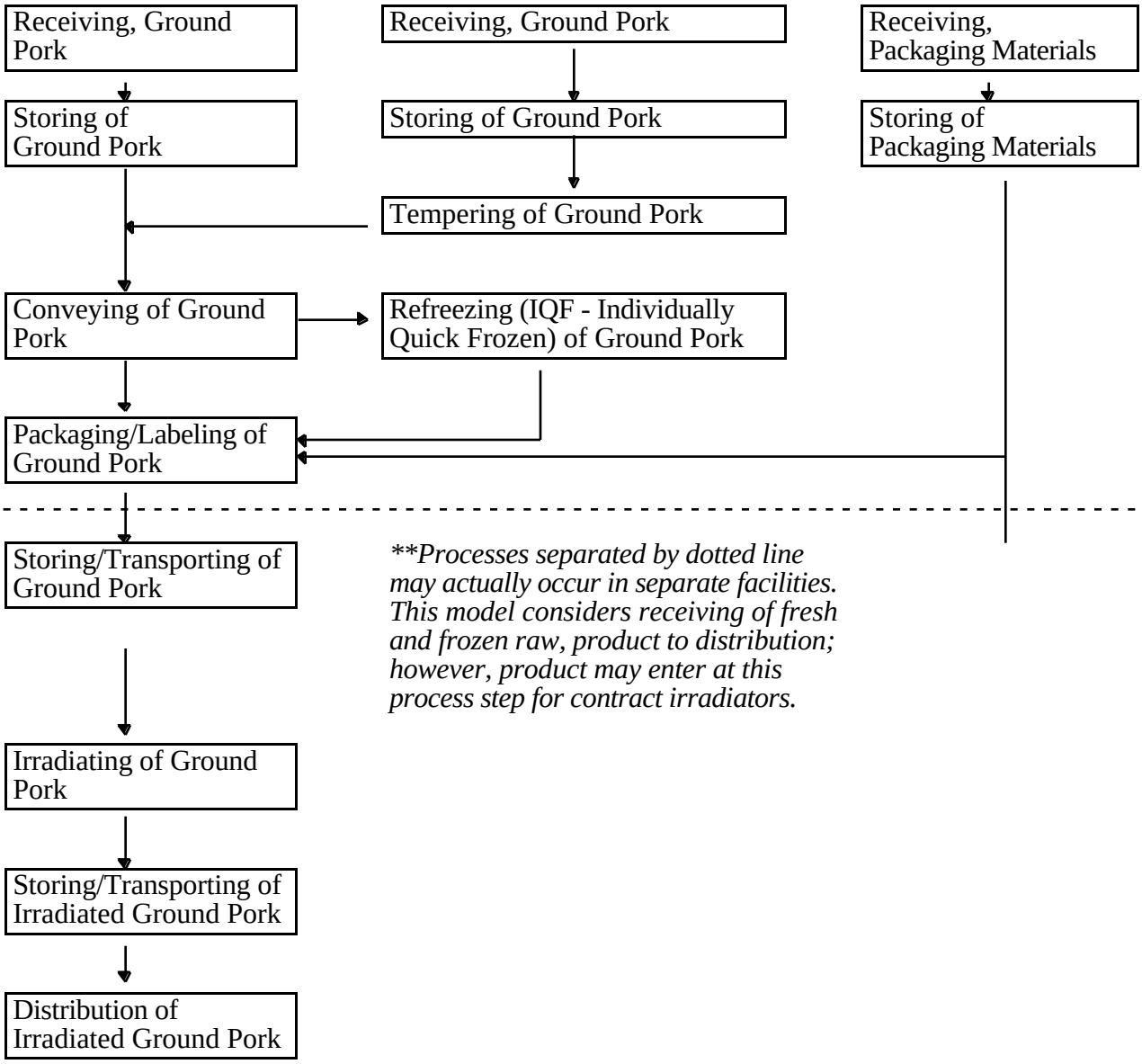
LIST PRODUCT CATEGORIES AND INGREDIENTS

PRODUCT CATEGORY: Irradiation: Product Examples — Ground Pork Parts

WORKSHOP LOCATION: College Station, Texas

MEAT AND MEAT BYPRODUCTS	NONMEAT FOOD INGREDIENTS	BINDERS/EXTENDERS
Raw Ground Pork	None allowed.	None allowed.
SPICES/FLAVORINGS	RESTRICTED INGREDIENTS	PRESERVATIVES/ ACIDIFIERS
None allowed.	None allowed.	None allowed.
OTHER		
Approved packaging material (i.e., nitrocellulose coated or vinylidene chloride copolymer coated cellophane, and polyolefin film) for irradiation. (Listed in 21CFR 179.45) Irradiation Label.		

IRRADIATION FLOW CHART
PRODUCTS: GROUND PORK



***Processes separated by dotted line may actually occur in separate facilities. This model considers receiving of fresh and frozen raw, product to distribution; however, product may enter at this process step for contract irradiators.*

Background and Reasoning for Model Development Methodology

To better understand irradiation, it is often useful to use an analogy of a process with which we are all familiar, such as pasteurization by heat. In such a process, the product configuration, viscosity, etc. must be taken into account in order to ascertain the correct parameters of temperature and time of pasteurization required to process the product correctly. This would be akin to the dose-mapping that is done when a particular product is to be irradiated. In addition, processors take care that nay product to be pasteurized does not remain without refrigeration for long periods before processing. Similar care should be taken before irradiation. In pasteurization by heat, the temperature that the product was subjected to and the time during which it was subjected to this temperature, are monitored. In irradiation, dosimetry is carried out to determine the dose that the product received.

Before considering how HACCP fits into this example, it is important to note the step in which the parameters for pasteurization are determined, and the steps that are followed to ensure that the product is not abused during this operation, from part of the pasteurization operation. These preliminary steps, if you will, should not be considered Critical Control Points in themselves, rather they are carried out as part of the step of pasteurizing food, which itself is the CCP. Critical limits are set on the processing parameters for this step, which are then monitored and verified. Similarly, in canning, it is the canning process itself that is the CCP. The steps that one has to follow in order to determine the right time and temperature combination for the particular product to be processed are merely part of that step.

Following the same logic, one would not assign as a CCP the step in which dose-mapping is done for irradiation, since this is simply part of the irradiation process. Regarding dosimetry, one would not make this a CCP, just as one would not make the act of measuring temperature or time of pasteurization a CCP. These are monitoring steps within the CCP in which the processing of the product is carried out. As such, there would be standard operating procedures on how to do these operations, which would be part of the HACCP plan.

The following generic model reflects these considerations.

The following references may also be useful in conducting a hazard analysis.

Federal Register: Vol. 51 #10, 1-15-86 - pork
Vol. 50 #26, 2-7-85 - pork
Vol. 57 #88, 183, 9/2/92, 5/6/92 -poultry

Hazard Analysis Worksheet:

The Hazard Analysis Worksheet format used in this model is an example format. Alternative forms can be used for the hazard analysis.

This worksheet should be used in two steps.

The first step, is to review each process step listed in the Process Flow Diagram and identify all potential hazards that can be introduced or enhanced at this step. Chemical, physical, and biological hazards should all be addressed. It is recommended that you list all potential hazards for each process step before moving to column two.

The second step, is to determine if the potential hazard is significant. The significant hazards must be "of such a nature that their prevention, elimination, reduction, or control to acceptable levels is essential to the production of safe food." (NACMCF, 1992) The team should focus on risk and severity as criteria for determining whether a hazard is significant or not. Risk, as defined by the National Advisory Committee, is "likelihood of occurrence." "The estimate of risk is usually based on a combination of experience, epidemiological data, and information in the technical literature." (NACMCF, 1992). Severity is the potential magnitude of the consequences to the consumer if the hazard is not adequately controlled. Hazards that are not significant or not likely to occur will not require further consideration in the HACCP plan.

It is important that you justify your decision for determining if a hazard is or is not significant. This will help you document your rationale for making decisions and is a useful tool when you re-validate or revise your HACCP plan.

The fifth column, addresses preventive measures. For each significant hazard, identify preventive measures, if they exist. A preventive measure is a physical, chemical, or other means which can be used to control an identified food safety hazard.

It is recommended that you complete columns 1 through 5, before starting on column 6. Column six asks, "Is this step a critical control point (CCP)?" A CCP is any point, step, or procedure at which control can be applied so that a food safety hazard can be prevented, eliminated, reduced, or controlled to acceptable levels. Information developed during the hazard analysis should enable the HACCP team to identify which steps in the process are CCPs. A decision tree, such as the NACMCF Decision Tree (Appendix 4) may be useful in determining if a particular step is a CCP for an identified hazard. The hazards identified during the development of this model were subjected to a decision tree by the team members. CCPs must be carefully developed and documented and must be for product safety only. Different facilities preparing the same product can differ in the risk of hazards and the points, steps, or procedures which are CCPs.

The CCPs identified in this model are for illustrative purposes only. Individual plant process will determine the CCPs identified for plant-specific plans. Remember that Sanitation Standard Operating Procedures are essential prerequisites to HACCP.

HAZARD ANALYSIS

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Purchasing/ Receiving of Fresh Poultry Parts or Ground Pork	B: Pathogens C: Pesticides, antibiotics, hormones, residues P: Foreign material	B: Yes C: No P: No	B: Raw meat and poultry products are a known source of pathogens. C: Unlikely to occur, raw product suppliers must follow established regulatory guidelines for HACCP and Sanitation SOPs; letters of guarantee from supplier. P : Unlikely to occur; low risk.	B: Temperature and organoleptic evaluation of raw product.	Yes CCP1 (B)
Purchasing/ Receiving of Frozen Poultry Parts or Ground Pork	B: Pathogens C: Pesticides, antibiotics, hormones, residues P: Foreign material	B: Yes C: No P: No	B: Raw meat and poultry products are a known source of pathogens. C: Unlikely to occur, raw product suppliers must follow established regulatory guidelines for HACCP and Sanitation SOPs; letters of guarantee from supplier. P : Unlikely to occur; low risk.	B: Temperature and organoleptic evaluation of raw product by using a coring method. **Note: If not taking cores for evaluations, this may be deferred to the tempering process step.*	Yes CCP 2(B)
Receiving of Packaging Material	B: None C: Residues, pesticides P: Foreign Material	C: No P: No	C: Letters of guarantee. Packaging material specifically approved for irradiation and for direct food contact must be used to prevent a chemical hazard from occurring. P: Letters of guarantee. Supplier audits and history.		No

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Storing of Fresh Poultry Parts and Ground Pork	B: Pathogens C: Disinfectants, insecticides, Sanitizers, cleaners P: Foreign Material	B: Yes C: No P: No	B: Potential for growth of psychotrophic pathogens. C: Unlikely to occur, low risk. Sanitation SOPs should address potential contamination. P: Unlikely to occur, low risk; Procedure for removal of foreign material, if present, should be developed by the establishment.	B: Temperature control and product rotation to minimize storage time (e.g., first in/first out) according to Storing Fresh Product SOPs.	No
Storing of Frozen Poultry Parts and Ground Pork	B: Pathogens C: Disinfectants, insecticides, Sanitizers, cleaners P: Foreign Material	B: No C: No P: No	B: No significant growth of pathogens at storage temperatures. C: Unlikely to occur, low risk. Sanitation SOPs should address potential contamination. P: Unlikely to occur, low risk. Procedure for removal of foreign material, if present, should be developed by the establishment.		No
Storing of Packaging Materials	B: Pathogens C: Disinfectants, insecticides, sanitizers, cleaners P: Foreign Material	B: No C: No P: No	In-plant GMPs and SOPs for storing packaging materials and utilizing disinfectants, insecticides, sanitizers, cleaners.		No
Tempering of Frozen Poultry Parts and Ground Pork	B: Pathogens C: Disinfectants, insecticides, sanitizers, cleaners P: Foreign Material	B: Yes C: No P: No	B: Potential for growth C: Unlikely to occur; Sanitation SOPs should address potential contamination. P: Unlikely to occur; Supplier audits and history.	Time and Temperature controls are needed to reduce potential growth of pathogens.	Yes CCP 3(B)

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Conveying of Product	B: Potential for pathogen growth C: Disinfectants, insecticides, sanitizers, cleaners P: Foreign Material	B: No C: No P: No	B: Low risk since this is a rapid process and should not allow sufficient time for pathogen growth. Product temperature should be maintained to reduce the potential for pathogen growth (i.e., poultry irradiation regulation states it must be 40°F). C: Unlikely to occur; Sanitation SOPs should address potential contamination. P: Establishment procedures should allow for on-going visual inspection of product to remove foreign material, if present.		No
Refreezing of Poultry Parts for Individually Quick Frozen (IQF) product	B: Potential pathogen growth C: Pesticides, antibiotics, hormones, residues P: Foreign materials	B: No C: No P: No	B: Follow establishment procedure for rapid refreezing product. C: Unlikely to occur; Sanitation SOPs should address potential contamination. P: Procedure for removal of foreign material, if present, should be developed by the establishment.		No

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Packaging/Labeling of Fresh and Frozen Raw Poultry Parts and Ground Pork	B: Pathogens C: Disinfectants, insecticides, sanitizers, cleaners. Since irradiation is consider a food additive, failure to label the package with the irradiation logo could result in exceeding upper limit of absorbed dose if product was re-irradiated. P: Foreign materials	B: No C: No P: No	B: Sanitation SOPs should address potential contamination of product during packaging. C: Unlikely to occur; Sanitation SOPs should address potential contamination. Plant should have a written procedure in place as part of the Good Manufacturing Practices or Irradiation Processing to prevent mislabeling and re-irradiation of product. P: Procedure for removal of foreign material, if present, should be developed by the establishment.	P: Establishment may want to consider including a metal detector for use on packaged product.	No
Storing and/or Transporting of Packaged Fresh, Raw Poultry Parts and Ground Pork	B: Pathogens C: Disinfectants, insecticides, sanitizers, cleaners P: Foreign materials	B: Yes C: No P: No	B: Potential for growth of pathogens. C & P: Unlikely to occur; packaged product reduces risk of chemical and physical hazards.	B: Temperature control and product rotation to minimize storage time (e.g., first in/first out) according to Storing Fresh Product SOPs.	No

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Storing and/or Transporting of Packaged Frozen, Raw Poultry Parts and Ground Pork	B: Pathogens C: Disinfectants, insecticides, Sanitizers, cleaners P: Foreign Material	B: No C: No P: No	B: No significant growth of pathogens at proper storage temperatures (40°F or less). C: Unlikely to occur, Sanitation SOPs should address potential contamination. P: Unlikely to occur; Procedure for removal of foreign material, if present, should be developed by the establishment.		No
Irradiating Fresh or Frozen, Raw Poultry Parts or Ground Pork	B: Pathogens C: Disinfectants, insecticides, Sanitizers, cleaners P: Foreign Material	B: Yes C: No P: No	B: Bacterial and/or parasite reduction. *Note Irradiation regulation for pork is currently only for *Trichinae* control. C: Unlikely to occur, Sanitation SOPs should address potential contamination. P: Unlikely to occur; Procedure for removal of foreign material, if present, should be developed by the establishment.	Allowed dose range as per FDA/USDA regulation according to approved treatment protocol described in 9 CFR. (Pork 9 CFR 318.7 and poultry 9 CFR 381.147 and 381.149.)	Yes CCP 4(B)

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Storing, Transporting and Distributing of Irradiated, Frozen, Raw Poultry Parts or Ground Pork	B: Pathogens C: Disinfectants, insecticides, Sanitizers, cleaners P: Foreign Material	B: No C: No P: No	B: Proper temperature during storage, transportation and distribution to reduce potential pathogen growth (frozen) and Maintain Package Integrity. C: Unlikely to occur, Sanitation SOPs should address potential contamination. P: Unlikely to occur; Procedure for removal of foreign material, if present, should be developed by the establishment.		No

Ingredient/Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Storing, Transporting and Distributing of Irradiated, Fresh, Raw Poultry Parts or Ground Pork	B: Pathogens C: Disinfectants, insecticides, Sanitizers, cleaners P: Foreign Material	B: No C: No P: No	B: Proper temperature during storage, transportation and distribution to reduce potential pathogen growth (40°F or less) and Maintain Package Integrity. Follow Good Irradiation Practices 9 CFR 381.149 to prevent co-mingling of non-irradiated and irradiated products. Aerobic competitors will cause spoilage and reduce the risk of C. botulinum. C: Unlikely to occur, Sanitation SOPs should address potential contamination. P: Unlikely to occur; Procedure for removal of foreign material, if present, should be developed by the establishment.		No

HACCP Worksheet:

The HACCP Worksheet format used in this model is an example format. Alternative forms can be used for the HACCP plan.

The first three columns of the form, identify the process step associated with the CCP, allows for CCP identification (number and type of hazard), and provides a description of the CCP. Columns four through eight are used to indicate the establishment's critical limits, monitoring procedures, corrective actions, recordkeeping methods, and verification procedures for each CCP.

A critical limit is a criterion that must be met for each preventive measure associated with a CCP. Critical limits may be derived from sources such as regulatory standards and guidelines, scientific literature, experimental studies, and advice from experts. Critical limits must be based on the best information available at the time to provide a safe product and yet must be realistic and attainable. Establishments must keep in mind that any product which does not meet the critical limit must have a Corrective Action taken. Corrective actions may be as simple as re-processing or re-packaging or may require destroying the product.

Monitoring procedures should include a planned sequence of observations or measurements to assess whether a CCP is under control and produce an accurate record for future use in verification. Monitoring serves three purposes:

1) Monitoring is essential to food safety management by tracking the systems operation.
2) Monitoring is used to determine when there is a loss of control and a deviation occurs at a CCP, exceeding the critical limit. Corrective action must then be taken.
3) Monitoring provides written documentation for use in verifying the HACCP plan.

All records associated with monitoring must be signed or initialed, dated, and the time recorded by the person conducting the monitoring activity.

Corrective actions are procedures to be followed when a deviation occurs. Because of variations in CCPs for different products and the diversity of possible deviations, specific corrective action plans must be developed for each CCP. The actions must demonstrate that the CCP has been brought under control and that the product is handled appropriately. Corrective action records must be signed, dated, and the time of action recorded by the individual responsible for taking the action.

Record keeping is a critical aspect of the HACCP system. Records must be accurate and reflect the process, the deviations, the corrective actions, etc. Lack of accurate, current records may be cause for withholding or suspension of inspection from the plant. It is also important that all HACCP records dealing with CCPs and corrective actions taken, be reviewed on a daily basis by an individual, who did not produce the records and who has completed a course in HACCP, or the responsible establishment official who must sign or initial, date, and record the time all records are reviewed. The HACCP plan and associated records must be on file at the meat and/or poultry establishment.

Example recordkeeping forms have been included in this model. It may be beneficial to combine forms as practical to reduce the amount of paperwork.

Verification consists of the use of methods, procedures, or tests in addition to those used in monitoring to determine that the HACCP system is in compliance with the HACCP plan and whether the HACCP plan needs modification. Verification involves:

1) The scientific or technical process to verify that critical limits at CCPs are satisfactory — review of critical limits to verify that the limits are adequate to control the hazards and that are likely to occur.
2) Process verification to ensure that the facility's HACCP plan is functioning effectively.
3) Documented periodic revalidation, independent of quality audits or other verification procedures, that must be performed to ensure the accuracy of the HACCP plan.

INDUSTRY WORKSHOP HACCP MODEL
PROCESS CATEGORY: Irradiation — Product Examples: Poultry Parts and Ground Pork
WORKSHOP LOCATION: College Station, TX

Process Step	CCP/ Hazard Number	CCP Description	Critical Limits	Establishment Monitoring	Corrective Action	HACCP Records	HACCP System Verification
Purchasing/ Receiving of Fresh or Frozen, Raw Poultry Parts and Ground Pork	CCP 1: B	Temperature Organoleptic evaluation Supplier Records	Internal product temperature to meet in-plant requirements (i.e., 40°F) as established by Process Authority unless superseded by USDA regulations (e.g., poultry $\leq$ 40°F) and meets in plant specifications for visual and organoleptic properties. **Individual plants may want to consider establishing APC or other microbial criteria to be met by supplier*.	Temperature monitoring, visual and organoleptic evaluation according establishment receiving protocol for each lot received. Monitoring to be completed by responsible plant employee	Hold; responsible plant employee must evaluate level of significance of deviation, then reject, divert or accept product. Evaluate cause of deviation and take action to prevent reoccurrence.	Receiving log, completed by designated person, recorded at CCP site on a real time basis. Thermometer calibration log, completed by designated person. Employee performance/ measurement review log completed by designated person. Hold log, completed by responsible plant employee, recorded at CCP site on a real time basis. Microbial data log. completed by designated person. Deviation and corrective action log, completed by designated person.	Calibrate thermometer according to SOPs. Monthly (or as deemed appropriate according to volume and other factors) microbial testing. Monthly (or as deemed appropriate according to volume and other factors) observation and/or temperature checks. Cross reference receiving log with supplier documents. Review of relevant HACCP records. Perform ongoing review of HACCP plan in response to deviations and/or system and product modifications

Process Step	CCP/ Hazard Number	CCP Description	Critical Limits	Establishment Monitoring	Corrective Action	HACCP Records	HACCP System Verification
Tempering of Frozen, Raw Poultry Parts and Ground Pork	CCP 2: B	Time and Temperature	Establish and validated time and temperature requirements in procedure in order to attain tempering while precluding the growth of microorganisms. For example, place product in 40°F cooler for 4 days, monitor product temperature. *Recommend using a processing authority if assistance is needed to determine appropriate time/temperature requirements.*	Tempering time and Temperature (of appropriate reference points: product, tempering cooler, tempering water, etc.) for each lot of product. Monitoring completed by responsible plant employee	Reject from raw product irradiation process category (may be able to utilize product by diverting it to a different processing operation such as canning, if appropriate). Evaluate cause of deviation and take action to prevent reoccurrence.	Time/ Temperature log, completed responsible plant employee, recorded at CCP site on a real time basis. Thermometer calibration log, completed by designated person. Employee performance/ measurement review log completed by responsible plant employee. Hold log, completed by designated person, recorded at CCP site on a real time basis. Micro data sheet. Deviation and corrective action log, completed by designated person.	Calibrate thermometer/ thermocouple and timer periodically, (i.e., daily). Monthly (or as deemed appropriate according to volume and other factors) microbial testing to validate the established time/ temperature requirements. Monthly (or as deemed appropriate according to volume and other factors) employee observation and/or time/temperature checks. Daily review of relevant HACCP records prior to shipping product. Perform ongoing review of HACCP plan in response to deviations and/or system and product modifications

Process Step	CCP/ Hazard Number	CCP Description	Critical Limits	Establishment Monitoring	Corrective Action	HACCP Records	HACCP System Verification
Irradiating Fresh or Frozen, Raw Poultry Parts and Ground Pork	CCP 3 - B	Ionizing Radiation Processing (includes dose-mapping and irradiation, with standard operating procedures to be written in compliance with Good Irradiation Practices as stated in 9 CFR 381).	D_{min} and D_{max} according to FDA, USDA/FSIS approved protocols, which includes time of process and dose mapping for each product configuration. (i.e., 1.5 to 3.0 kGy for poultry and 0.3 - 1.0 kGy for pork)	Dosimetry, to measure actual absorbed dose, according to American Society of Testing Material (ASTM E1204-93 and E1431-91), to be carried out during dose-mapping as well as after processing of product.	If exceed D_{max} then Reject product. If do not achieve D_{min} then evaluate and further irradiate at appropriate dose increments to meet compliance or Reject product. Evaluate cause of deviation to prevent reoccurrence.	Records of irradiation processing as required by 9 CFR 381.149. Facility/ source preventative maintenance records. Inoculated Pack study log. Deviation and corrective action log, completed by designated person.	Dosimetry calibration according to NIST (National Institute of Science and Technology) standards. Monthly (or as deemed appropriate according to volume and other factors) microbial testing by contract irradiator or client (may be one in the same). Inoculated Pack Studies. Daily review of relevant HACCP records prior to shipping product. Perform ongoing review of HACCP plan in response to deviations and/or system and product modifications. Review of Customer Complaints by contract irradiator or client (may be one in the same).

Example Records

Example: HOLD SUMMARY LOG

Hold Number	Date/ Time of Hold	Product/ Code	Reason for Hold	Number Units Held	"Held by" Operator Initials	Date of Disposition	Final Disposition	Number Released	Number Destroyed	Total Number	Released by Initials/ Date/Time

_____
Reviewed by:

_____
Date:

Example: CALIBRATION LOG*

Date/Time	ID for Equipment Calibrated	Comments	Operator Initials

*Calibration logs can be used for thermometers, thermocouples, timers, or other equipment.
Instructions: Record equipment calibrations and comments according to individual equipment calibration SOPs.

_____
Reviewed by:

_____
Date:

Example: RECEIVING LOG

Date Rec'd	Ingredient	Supplier	Supplier Code	Lot ID/ Code	Quantity Received	Temper-ature on Receipt	Organoleptic Evaluation:	Accept/ Reject	Micro Sent	Operator Initials/ Date/ Time

_____
Reviewed by:

_____
Date:

Example: EMPLOYEE PERFORMANCE/MEASUREMENT VERIFICATION LOG*

DATE/TIME	CCP NUMBER/ID	NAME OF EMPLOYEE OBSERVED	OBSERVATION/MEASUREMENT	COMMENTS	INITIALS

*****This log can be used for verifying observations of employees and measurement checks taken for individual CCPs.

_____
Reviewed by:

_____
Date:

Example: MICROBIAL DATA LOG

Date Received	Lot ID/ Code	Sample Description	Date of Analysis	Date Reported	Micro Analysis:		Operator Initials/ Time
					Organism	Result	

_____

Reviewed by:

_____

Date:

Example: DEVIATION and CORRECTIVE ACTION LOG

Date	Deviation Number	CCP Number/ID	Description of Deviation	Corrective Actions For:		Initials/ Time
				Product	System to Prevent Reoccurrence	

_____
Reviewed by:

_____
Date:

Example: TIME / TEMPERATURE LOG

Date	Lot ID/Code	Product Description	Product ID/ Code	Time In	Time Out	Temperature	Operator Initials

_____
Reviewed by:

_____
Date:

APPENDIX 1

This is not an FSIS requirement. The following Good Manufacturing Practices (21 CFR Part 110) codified by the Food and Drug Administration are being provided for reference material to help assist you in developing your plant's manufacturing procedures. The document provides information which may also be useful as part of your Sanitation Standard Operating Procedures.

FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR PART 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

SUBPART A - GENERAL PROVISIONS

110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) “Acid foods or acidified foods” means foods that have an equilibrium pH of 4.6 or below.

(b) “Adequate” means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) “Batter” means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) “Blanching,” except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) “Critical control point” means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) “Food” means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) “Food-contact surfaces” are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. 'Food-contact surfaces' includes utensils and food-contact surfaces of equipment.

(h) “Lot” means the food produced during a period of time indicated by a specific code.

(i) “Microorganisms” means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term 'undesirable microorganisms' includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective 'microbial' instead of using an adjectival phrase containing the word microorganism.

(j) “Pest” refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) “Plant” means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) “Quality control operation” means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) “Rework” means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) “Safe-moisture level” is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a (INFERIOR w)). An a (INFERIOR w) will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a (INFERIOR w) will not support the growth of undesirable microorganisms.

(o) “Sanitize” means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) “Shall” is used to state mandatory requirements.

(q) “Should” is used to state recommended or advisory procedures or identify recommended equipment.

(r) “Water activity” (a (INFERIOR w)) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control*. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more 'raw agricultural commodities,' as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

SUBPART B - BUILDING AND FACILITIES

110.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a

condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

110.35 Sanitary operations.

(a*) General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials*. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) *Pest control.* No pests shall be allowed in any area of a food

plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces*. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e*) Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply*. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing*. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal*. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities*. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) *Hand-washing facilities.* Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each

absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

SUBPART C - EQUIPMENT

110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

SUBPART D - [RESERVED]

SUBPART E - PRODUCTION AND PROCESS CONTROLS

110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) *Raw materials and other ingredients.* (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain

levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) *Manufacturing operations.* (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a (INFERIOR w), pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 (degree)F (7.2 (degree)C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 (degree)F (60 (degree)C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a (INFERIOR w) that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the

meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a (INFERIOR w) for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the a (INFERIOR w) of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a (INFERIOR w) of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

SUBPART F - [RESERVED]

SUBPART G - DEFECT ACTION LEVELS

110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current

good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204**.**

APPENDIX 2

PROCESS CATEGORIES

(Pathogen Reduction/HACCP Regulation, 1996)

1. Not Heat Treated, Shelf-Stable (dried products, those controlled by water activity, pH, freeze dried, dehydrated, etc.)

2. Heat Treated, Shelf-Stable (rendered products, lard, etc.)

3. Heat Treated Not Fully Cooked, Not Shelf-Stable (ready to cook poultry, cold smoked and products smoked for trichinae, partially cooked battered, breaded, char-marked, batter set, and low temperature rendered products, etc.)

4. Products with Secondary Inhibitors, Not Shelf-Stable (products that are fermented, dried, salted, brine treated, etc., but are not shelf-stable)

5. Irradiation (includes all forms of approved irradiation procedures for poultry and pork)

6. Fully Cooked, Not Shelf Stable (products which have received a lethal kill step through a heating process, but must be kept refrigerated. This includes products such as fully cooked hams, cooked beef, roast beef, etc.).

7. Beef Slaughter

8. Pork Slaughter

9. Poultry Slaughter

10. Raw Products - not ground (all raw products which are not ground in their final form. This includes beef trimmings, tenderized cuts, steaks, roasts, chops, poultry parts, etc.)

11. Raw, Ground

12. Thermally Processed/Commercially Sterile

13. Mechanically Separated Species

APPENDIX 3

Overview of Biological, Chemical and Physical Hazards (Pathogen Reduction/HACCP Regulation, USDA, 1996)

(Hazards are not limited to the following information.)

Biological Hazards: The following biological hazards should be considered:

Pathogenic microorganisms:
Bacillus cereus
Campylobacter jejuni
Clostridium botulinum
Clostridum perfringens
Escherichia coli O157:H7
Listeria monocytogenes
Salmonella spp
Staphylococcus aureus
Yersinia enterocolitica

Zoonotic agents:
Trichinella spiralis
Taenia saginata
Taenia solium
Toxoplasma gondii
Balantidium coli
Cryptosporidium spp.

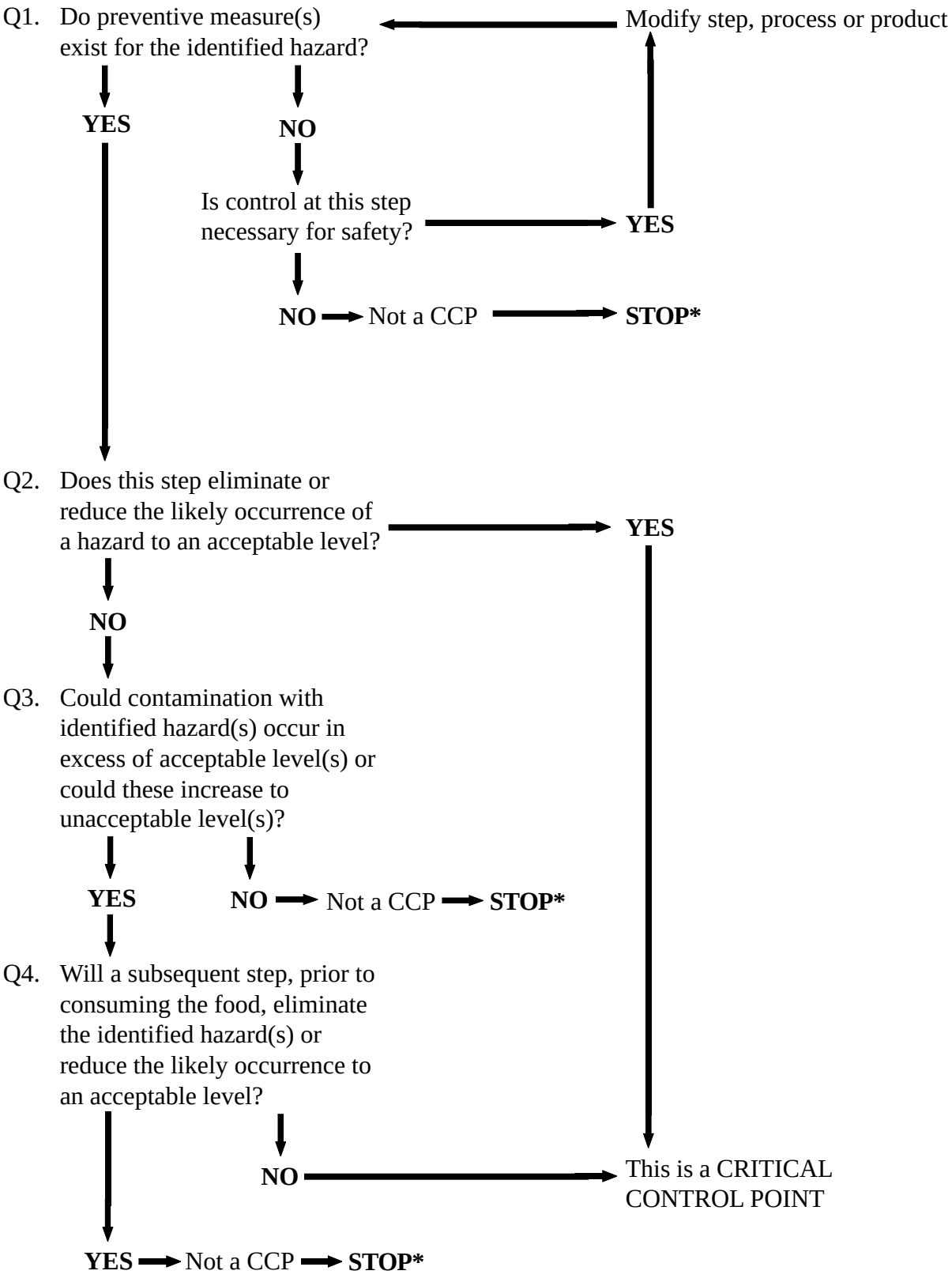
Chemical Hazards: The following sources were identified.

1) Agriculture chemicals: pesticides, herbicides, animal drugs, fertilizers, etc.
2) Plant chemicals: cleaners, sanitizers, oils, lubricants, paints, pesticides, etc.
3) Naturally-occurring toxicants: products of plant, animal or microbial metabolism such as aflatoxins, etc.
4) Food chemcals: preservatives, acids, food additives, sulfiting agents, processing aids, etc.
5) Environmental contaminants: lead, cadmium, mercury, arsenic, PCBs.

Physical Hazards:
Glass, metal, stones, plastics, bone, bullet/BB shots/needles, jewelry, etc.

APPENDIX 4

The NACMCF (1992) CCP Decision Tree
(Apply at each point where an identified hazard can be controlled.)



*Proceed to the next step in the selected process

APPENDIX 5

Below are listed the references used in the development of the USDA Model HACCP Plans. The first category includes generic HACCP references that were used as a basis for all ten model plans. The remaining references are divided by product category.

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References for all HACCP Model Teams

1. Pearson and Dutson, editors, 1995. HACCP in Meat, Poultry, and Fish Processing. Blakie Academic & Professional, Glasgow.

Useful sections in particular are:

Chapter 4 - meat and poultry slaughter, pp. 58 -71
Chapter 5 - processed meats, pp. 72 - 107
Chapter 7 - risk analysis, pp. 134 - 154
Chapter 13 - predictive modeling, pp. 330 - 354

2. Stevenson and Bernard, editors, 1995. HACCP Establishing Hazard Analysis Critical Control Point Programs, A Workshop Manual. The Food Processors Institute, Washington, D.C.

Useful sections in particular are:

Chapter 11 - forms for hazard analysis, CCP, limits, HACCP master sheet, example HACCP for breaded chicken

3. Baker, D. A., 1995. Application of modeling in HACCP plan development. Int. J. Food Microbiol. 25: 251 - 261.

4. AMI, 1994. HACCP: The Hazard Analysis and Critical Control Point System in the Meat and Poultry Industry. American Meat Institute Foundation, Washington, D.C.

Useful sections in particular are:
Chapter 3 - microbiological hazards, pp. 15 - 26
Chapter 4 - chemical hazards, pp. 27 - 32
Chapter 5 - physical hazards, pp. 33 - 35
Appendix A - NACMCF HACCP
Appendix C - Model HACCP plans (beef slaughter, roast beef, ham, chicken slaughter, etc.)

5. Easter, M. C., et al. 1994. The role of HACCP in the management of food safety and quality. J. Soc. Dairy Technol. 47: 42 - 43.

6. Notermans, S., et al. 1994. The HACCP concept: Identification of potentially hazardous micro-organisms. Food Microbiol. 11: 203 - 214.

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Useful sections in particular are:
Chapter 10 - raw meat and poultry, pp. 176 - 193
Chapter 11 - roast beef, pp. 234 - 238
Chapter 11 - canned ham, pp. 238 - 242

8. National Research Council, 1985. An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients. National Academy Press, Washington, D.C.

Useful sections in particular are:
Chapter 4 - microbiological hazards, pp. 72 - 103
Chapter 9 - raw meat, pp. 193 - 199
Chapter 9 - processed meats, pp. 199 - 216

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References for Shelf-stable, Not-heat Treated (**Salami & Pepperoni**)

1. Hinkens, J. C., et al. 1996. Validation of Pepperoni Processes for Control of *Escherichia coli* O157:H7. J. Food Prot. In Press.

2. Nickelson, R., et al. 1996. Dry fermented sausage and *E. coli* O157:H7. National Cattlemen's Beef Association, Research Report No. 11-316, Chicago, IL.

3. AMI, 1995. Interim Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products. American Meat Institute, Washington, D.C.

4. Papa, F., et al. 1995. Production of Milano style salami of good quality and safety. Food Microbiol. 12: 9 - 12.

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6. Raccach, M. 1992. Some aspects of meat fermentation. Food Microbiol. 9: 55 - 65.

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8. Glass, K. A. and M. P. Doyle. 1989. Fate and thermal inactivation of *Listeria monocytogenes* in beaker sausage and pepperoni. J. Food Prot. 52: 226 - 231.

9. Smith, H. J., et al. 1989. Destruction of *Trichinella spiralis* during the preparation of 'dry cured' pork products procuitto, procuittini and Genoa salami. Can. J. Vet. Res. 53: 80 - 83.

10. Johnson, J. L., et al. 1988. Fate of *Listeria monocytogenes* in tissues of experimentally infected cattle and in hard salami. Appl. Environ. Microbiol. 54: 497 - 501.

11. Martinez, E. J., et al. 1986. Combined effect of water activity, pH and additives on growth of *Staphylococcus aureus* in model salami systems. Food Microbiol. 3: 321 -329.

12. Collins-Thompson, D. L., et al. 1984. The Effect of Nitrite on the Growth of Pathogens during Manufacture of Dry and Semi-dry Sausage. Can. Inst. Food Sci. Technol. J. 17: 102 - 106.

References for Shelf-Stable, Heat Treated Product (**Snack Sticks & Jerky**)

1. AMSA, 1995. Flow Chart for Beef Jerky. American Meat Science Association.

2. CDC, 1995. Outbreak of Salmonellosis Associated with Beef Jerky - New Mexico, 1995. Morbidity and Mortality Weekly Report. 44: 785 - 787.

3. Bunic, Sava, et al. 1991. The Fate of *Listeria monocytogenes* in Fermented Sausages and in Vacuum-Packaged Frankfurters. J. Food Prot. 54: 413 - 417.

4. Dykes, Gary A., et al. 1991. Quantification of microbial populations associated with the manufacture of vacuum-packaged, smoked Vienna sausages. Int. J. Food Microbiol. 13: 239 - 248.

References for Not Shelf Stable, Heat Treated, Not Fully Cooked Product (**Chicken Patties & Smoked Sausage**)

1. FPI, 1995. Process Flow Description for Battered and Breaded Chicken Pieces. Chapter 11 - 14. In HACCP, Establishing Hazard Analysis Critical Control Point Programs. Food Processors Institute, Washington D.C.

2. AMSA, 1995. Flow Chard for Uncooked, Cured Summer Sausage. American Meat Science Association. Chicago, IL.

3. Yen, Lynn C., et al. Effect of Meat Curing Ingredients on Thermal Destruction of *Listeria monocytogenes* in Ground Pork. J. Food Prot. 54: 408 - 412.

4. Marcy, J. A., et al. 1988. Effect of Acid and Neutral Pyrophosphates on the Natural Bacterial Flora of a Cooked Meat System. J. Food Science. 53: 28 - 30.

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References for Not Shelf Stable with Secondary Inhibitors (**Country Hams & Semi-dry Fermented Sausage**)

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References for Irradiation (**Ground Pork & Poultry Parts**)

1. Tarte R. R., et al. 1996. Survival and injury of *Listeria monocytogenes, Listeria innocua* and *Listeria ivanovii* in ground pork following electron beam irradiation. J. Food Prot. 59: 596 - 600.

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