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

Additional copies of the Guidebook for the Preparation of HACCP Plans and the Generic HACCP Models are available from:

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TO THE USERS OF THESE VOLUMES

When the Pathogen Reduction; Hazard Analysis and Critical Control Point Systems (PR/HACCP); Final Rule was published on July 25, 1996, the Guidebook for the Preparation of HACCP Plans was included as an appendix. The Generic Models for different meat and poultry processes, developed for FSIS under contract, were available shortly thereafter in April 1997. There were significant differences between the final regulatory language of Title 9 Code of Federal Regulations (9 CFR) Part 417 and the DRAFT Generic Models because they were developed independently. FSIS developed the final regulatory language of 9 CFR 417. The contractor based the Generic Models on HACCP documents from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). FSIS accepted the Generic Models with full knowledge that significant revisions would be necessary.

The Generic HACCP Models are the Agency's major technical assistance documents on developing HACCP plans, but they did not clearly inform the regulated industry of Agency expectations regarding regulatory compliance. Because the intended audience for these technical assistance materials was primarily the small and very small establishments that have the least HACCP-experience, the Agency began the systematic revision of the documents.

The Generic Models contain a description of the steps in preparing a HACCP plan and the thinking process used by a HACCP team in developing their plan. Two appendices are included. Appendix A contains one reference list on HACCP systems and regulatory requirements and a second reference list on microbiological principles and processing procedures for specific meat and poultry product(s) described in the generic model. Appendix B contains the process flow diagram, product description, hazard analysis, HACCP plan, and monitoring logs of the model.

The generic models are designed to provide establishments with guidance in meeting the regulatory requirements in 9 CFR 417. The generic models are not intended to be used "as is." Because HACCP plans are specific to an individual establishment's processing procedures and products, each establishment must determine their own critical control points (CCPs) and critical limits based on their hazard analysis of their processing procedures. The Generic Models provide the basics; they are not designed to be the ultimate teaching and training materials. The Generic Models do not interpret existing regulations; rather, they are designed to send the user back to the regulations so he/she can become familiar with the requirements as well as the flexibility they permit. The generic models are not intended to present new or alternative methods of producing and processing meat and poultry products.

As an establishment's team members begin their work, and as they proceed, some questions arise as to whether what they have developed is appropriate. This is the point when FSIS expects the team to pick up the appropriate generic model and get a sense of whether they are on the right track. They should be able to determine whether the forms that they have developed, while different from the various ones in the generic models and not the same as what other companies use, are acceptable because they include the required information. They will also be able to identify the food safety hazards that are reasonably likely to occur in their establishment, as explicitly in 9 CFR 417.2, and how to think through the problems that these hazards represent for their own products. They can see how critical limits might arise from existing regulatory requirements, such as the ones for rapid chilling of poultry products. Resources are identified for sources of scientific expertise. The HACCP team can choose to make a conservative decision to provide a good margin of safety. They can find out the essential differences between monitoring and verification and have a basis for making their choices about verification activities and their frequencies. FSIS believes that these are useful, beneficial and worthwhile functions for which its generic models can be used.

FSIS is updating the generic models to include new technical information and to revise those parts that are out of date. Although water activity replaces moisture protein ratio (MPR) as a measure of dryness for food safety assurance in this model, an MPR of 0.75:1 or less remains part of the standard of identity for jerky. As noted above, this model, and the other FSIS generic HACCP models, is intended as guidance material to which industry can refer.

We hope that these documents are helpful.

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GENERIC HACCP MODEL

FOR

HEAT TREATED, SHELF STABLE MEAT AND POULTRY PRODUCTS

Introduction

The Hazard Analysis Critical Control Point (HACCP) system is a scientific approach to process control. It is designed to prevent the occurrence of problems by assuring that controls are applied at any point in a food production system where hazardous or critical situations could occur. Hazards include biological, chemical, or physical contamination of food products. There are two basic kinds of bacteriological hazards: (1) infectious bacteria (e.g. *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, and *Clostridium perfringens*) that must be inactivated by an effective lethal treatment and prevented from contaminating the treated product, and (2) toxigenic bacteria (e.g. *Clostridium botulinum* and enterotoxigenic staphylococci) that must be inhibited from growing and producing their toxin during processing and in the finished product. For heat treated, shelf stable products, the control of infectious bacteria is ordinarily a validated heat treatment but in some cases a combination of curing, heat, and drying has been validated. The toxigenic bacteria and mold can pose a hazard if the drying process is too slow or insufficient. The hazard from these microorganisms is controlled by controlling the time and temperature of drying or curing, water activity, and packaging of the final product.

The Food Safety and Inspection Service (FSIS) published a final rule in July 1996 mandating that HACCP be implemented as the system of process control in all inspected meat and poultry plants. As part of its efforts to assist establishments in the preparation of plant-specific HACCP plans, FSIS determined that a generic model for each process defined in the regulation would be made available for use on a voluntary basis by inspected establishments.

The generic models have been revised since their initial publication and distribution as DRAFTS. The most important change in the revised versions is to make certain that these models are fully consistent with the features of the final regulation. Also, other technical and editorial improvements have been made.

Throughout this generic model, FSIS discusses a HACCP team with members from different departments. In many very small establishments, there will not be separate departments with different employees. But, there will be employees who perform these different functions – often several of them. For purposes of explaining concepts, it is easier to speak as if these were different people, even though in many cases, they may be the same person carrying out more than one responsibility.

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Each generic model can be used as a starting point for the development of plant-specific plan(s) reflecting actual plant environments and the processes conducted. The generic model is not intended to be used “as is” for plant specific HACCP plans.

The generic models are designed for use in conjunction with the list of process categories found in the HACCP regulations in section 417.2(b)(1).

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter--all species.

(ii) Raw product--ground.

(iii) Raw product--not ground.

(iv) Thermally processed--commercially sterile.

(v) Not heat treated--shelf stable.

(vi) Heat treated--shelf stable.

(vii) Fully cooked--not shelf stable.

(viii) Heat treated but not fully cooked--not shelf stable.

(ix) Product with secondary inhibitors--not shelf stable.

This generic model is designed for use with the process category: Heat treated--shelf stable.

The purpose of the process category listing in 417.2 is to set out the circumstances under which a HACCP team may develop a single HACCP plan for multiple products. This may be done when products are in the same process category, and food safety hazards, critical control points, and other features are essentially the same. There is a generic model for each process category, plus two for subcategories which present special issues: irradiated products and mechanically separated products.

In order to select the model or models that will be most useful for the activities performed in any specific plant, the following steps should be taken:

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- 1) For slaughtering operations, select the model for the appropriate species.
- 2) For processed products, make a list of all products produced in the plant.
- 3) Examine the list and group like products, considering common processing steps and equipment used.
- 4) Compare the grouped products with the list of processes in the regulations; this step should reveal how many and which of the generic models might be useful.

Deciding on a generic model and which products can be covered by a single plan is an important achievement. If the team does it well, it can save a lot of unnecessary effort and paperwork.

Selecting an inappropriate generic model reduces its potential benefits. However, often the HACCP team will discover they have made this error when they develop their process flow diagram or during their hazard analysis. These are early stages in the process when it is relatively easy to make changes.

In any case, establishments must meet all regulatory requirements for their products.

Using This Generic Model

This generic model is designed to be used by establishments that produce heat treated, shelf stable product(s), the sixth process category listed above. The model can be used for all heat treated, shelf stable products: either meat or poultry. The generic model is not suitable for products that fall into any of the other process categories.

The model will be most useful to a HACCP team that includes access to one trained individual, as specified in 417.7(b).

(b)The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

It would be beneficial for other team members to have reviewed any of the various guidance materials available on how to develop a HACCP plan for your company, including several useful videos, handbooks, or computer programs. References 12 and 13 in the “References for General HACCP and Regulatory Issues” in Appendix A of this model provide a detailed description of the seven principles. Once the HACCP team has prepared itself as thoroughly as possible in general HACCP principles and how to use them, this model should be helpful.

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Note: This generic model includes a number of forms that can be used to record various types of required information. The forms themselves are examples; a company HACCP team can develop whatever forms it finds most useful. All the forms mentioned in this document are included in Appendix B; they appear in the order in which they appear in the HACCP plan. All of the forms in the previous generic model have been modified or replaced. The Form Letter Confirming *Salmonella* Compliance with Performance Standards was removed since the performance standard for *Salmonella* in raw product is not a critical control point (CCP) for heat treated, shelf stable meat and poultry products. The Oven Temperature/Humidity Log is a modification of the Room Temperature Log. The Water Activity (a_w) Log replaces the Shrink Log as water activity is a better measure of proper drying for shelf stability or safety. Each form now contains a section for record review.

All FSIS generic models are designed to assist establishments in applying the seven HACCP principles to their meat and poultry processing operations **AND** to meet the regulatory requirements of Part 417. Therefore, the definitions used in this and all other FSIS generic models are those found in 417.1:

§ 417.1 Definitions.

For purposes of this part, the following shall apply:

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

Critical control point. *A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.*

Critical limit. *The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.*

Food safety hazard. *Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.*

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

Hazard. *See Food Safety Hazard.*

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

Process-monitoring instrument. *An instrument or device used to indicate conditions during processing at a critical control point.*

Responsible establishment official. *The individual with overall authority on-site or a higher level official of the establishment.*

Process Flow Diagram and Product Description

To begin using this model, the company's HACCP team should first describe the product(s) which are part of this process category and covered by this HACCP plan. The product(s) should be described in two ways:

- (1) by a simple diagram which shows each of the steps the company uses when it produces the product, and
- (2) in a brief written product description which provides key facts about the product and its use.

In this generic model, there are two examples for heat treated, shelf stable products – snack sticks and jerky. Other examples of these types of products include summer sausage sticks and pickled sausages. FSIS has developed certain forms as part of the examples in the generic models; **company HACCP teams are not required to use these forms.**

Figure 1 is an example of a **PROCESS FLOW DIAGRAM** for the production snack sticks and jerky in generic establishment X. Figure 2 is an example of a **PRODUCT DESCRIPTION** for the snack sticks and jerky produced in generic establishment X.

Once the company HACCP team in your establishment has prepared your Process Flow Diagram, they should verify it by walking through the establishment following the flow of product and making sure that **all** the steps of the process are included in the flow diagram. The team should also review the information provided on the Product Description to make sure all the key facts are included, such as identifying consumers, especially those with particular health problems or known to be at risk.

Note: If the establishment's process includes steps not included in this example, those steps should be added. Also, if that process does not include all the steps identified in this example, those steps would be omitted when conducting the hazard analysis. That is generally how the HACCP team should use these generic model examples--just omit the features which do not apply to their operation or add those features of their operation not included in this example.

By completing a Process Flow Diagram and a Product Description, the HACCP team meets the requirements of 417.2(a)(2). The team can use the Process Flow Diagram to help you complete the rest of the hazard analysis. They use the flow diagram to systematically review each step in the process and ask the question, "Is there a food safety hazard which is reasonably likely to occur which may be introduced, increased, or controlled at this step?" In answering the question, the HACCP team needs to consider biological (including microbiological), chemical, and physical hazards.

Hazard Analysis

Once the establishment's product(s) are accurately described through the flow diagram and product description, the HACCP team should begin work on the **HAZARD ANALYSIS**. The hazard analysis is fundamental to developing a good HACCP plan that meets regulatory requirements. The regulatory requirements for a hazard analysis are found at 417.2(a).

§ 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

Generic establishment X, which we are using for our example, is capturing these regulatory requirements on a 6-column **Hazard Analysis Form (See Figure 3)**. The first column contains each step listed in the process flow chart. The second column lists the hazards that can be introduced, increased, or controlled at each step in the first column. A good way to use a form like this is to create the first column by using the Process Flow Diagram and the second by answering the question. Once the HACCP team has considered all the steps in the flow diagram and determined if a food safety hazard could be introduced, increased, or controlled, it needs to consider whether the hazard is "reasonably likely to occur", using the meaning of this phrase included in 417.2(a). On the 6-column form used by generic establishment X, the third and fourth columns address this issue. If the establishment's HACCP team has decided that the hazard is not reasonably likely to occur, they enter "No" in column three, explain the basis for their determination in column four, and do not need to further consider activity at this point in the process.

If, however, the team has determined there is a "food safety hazard reasonably likely to occur" introduced at a certain point in the process, column five is used to describe a measure which could be applied to "prevent, eliminate, or reduce to acceptable levels" the food safety hazard identified in column three. Column six is used when a critical control point (CCP) is identified

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based upon the decision made in the hazard analysis. Each CCP has a number – the order corresponds to steps in the process. For example, 1 is the first identified CCP in the process flow, 2 the next, etc. The letter indicates whether the hazard is biological – B; chemical – C; or physical – P.

Look at the entries for “Drying” on the six-column Hazard Analysis form for heat treated, shelf stable: the HACCP team has determined that *Staphylococcus aureus* may be present, so it has put a “Yes” in the third column. Column four explains the basis for the team’s determination. In the fifth column, the HACCP team has described the preventive measures it will use to make sure that each hazard has been prevented, eliminated, or reduced to an acceptable level. For this hazard, the HACCP team decided that the water activity (a_w) will be checked to ensure that growth and toxigenesis will not occur. FSIS does not consider safe handling labels alone to be an adequate CCP for any pathogenic microorganisms such as bacteria and viruses.

IMPORTANT: Manufacturers should not use the moisture protein ratio (MPR) as a measure of proper drying for shelf-stability or safety. This is because MPR is a product standard and because the water activity can vary greatly at any given MPR (as a result of the different kinds and quantity of solutes such as sugar and salt). It is product water activity that is best correlated to inhibition of each pathogen's growth.

Note: Look at the entries for “Storage – (Cold – Frozen/Refrigerated) – Raw Meat/Poultry” on the six-column Hazard Analysis form: the HACCP team has determined that a food safety hazard is not reasonably likely to occur at this step in the process. Column four contains the reason for their thinking: pathogenic organisms are not likely to grow if the product is maintained at the proper temperature. Column five contains their description of a measure that will prevent the growth of these organisms: prerequisite program is in place to prevent pathogen growth from being likely to occur.

In this generic hazard analysis for snack sticks and jerky, there are five food safety hazards likely to occur (metal contamination is listed as a hazard in two process steps) . The HACCP team has identified a point in the process to control each hazard.

When the HACCP team has completed their hazard analysis (whether they use this format or not), it is a good idea to review the flow diagram, the product description and the hazard analysis itself to make sure they are complete. Part 417.2(a)(3) includes a list of sources from which food safety hazards might be expected to arise. Reviewing that list could help the HACCP team check for completeness.

Note: If the team is using this generic model to produce a different heat treated, shelf stable product or if the establishment uses a different process flow, different hazards which are reasonably likely to occur may be identified. For these different hazards, there may be different measures that could be used for control purposes.

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This generic model, and all other FSIS generic models, contains a list of references which can help the HACCP team in making sure the hazard analysis is complete. These references are found in Appendix A. A member of the HACCP team might want to review at least some of the references to make sure hazards have not been omitted from the hazard analysis.

Completing the hazard analysis is a very significant and important element in developing the HACCP system. The HACCP team should feel a real sense of accomplishment when they get this far; this is like completing the foundation of a house.

Developing Your HACCP Plan

The company HACCP team can now take the materials developed while doing the hazard analysis and use them to build the **HACCP plan**. Remember that one of the important objectives of the FSIS generic models is to provide examples which illustrate **how to meet the regulatory requirements of Part 417**, as well as to correctly apply the principles of HACCP. Part 417.2 (c) and (d) are the regulatory requirements:

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with §417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

Generic establishment X has prepared its HACCP plan for snack sticks and jerky on a six column form (See **Figure 4**). You do not need to use this form, although some kind of a form is probably the easiest way to present your HACCP plan.

Identifying CCPs

The first column on the HACCP plan is used to enter information previously developed and contained on the Hazard Analysis Form. Part 417.2(c)(1) and (2) require that the food safety hazards identified in the hazard analysis be listed on the HACCP plan and that there be a CCP for each identified hazard. You will notice that there were five points on the Hazard Analysis form for snack sticks and jerky where food safety hazards reasonably likely to occur were identified: 1) pathogens on incoming raw product, 2) metal contamination during mechanical processing, 3) *S. aureus* proliferation at fermentation (snack sticks); 4) pathogen (including *L. monocytogenes*) survival and subsequent growth if inadequate heat and humidity is not used, and 5) *S. aureus* proliferation at drying. The establishment HACCP team has chosen to have four CCPs to address these five hazards: 1) time for product to reach a pH of ≤ 5.3 at the end of the fermentation step in order to meet the relative good manufacturing practice (GMP) degree-hour* limits for control of *S. aureus*, 2) proper time/temperature/humidity is reached during heat treatment, 3) proper drying to preclude growth of *S. aureus* and *L. monocytogenes*, and 4) a metal detector prior to packaging and labeling.

* Degree-hours is the time, in hours, for the product to reach a pH ≤ 5.3 multiplied by the number of degrees the fermentation chamber is over 60°F (minimum growth temperature for *S. aureus*). The degree-hours is calculated for each temperature used during fermentation, but

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a constant chamber temperature may be used (as in the examples provided in 1B of the HACCP plan and on the Fermentation Log). The number of degree-hours is limited by the highest temperature in the fermentation process prior to reaching a pH of 5.3 or less. For example, if the highest chamber temperature is less than 90°F, the process is limited to fewer than 1200 degree-hours; fewer than 1000 degree-hours if the chamber temperature is between 90 and 100°F; or fewer than 900 degree-hours if the chamber temperature is greater than 100°F. (A more detailed explanation of degree-hours can be found in the American Meat Institute Foundation document “Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products at www.amif.org/FactsandFigures/SAUSAGE.pdf).

- Process passing the guideline (Limit: 1200 degree-hours)

Degrees: $80 - 60 = 20$

Hours: 55

Degree-hours: $20 \times 55 = 1100$ degree-hours

- Process failing the guideline (Limit: 1200 degree-hours)

Degrees: $80 - 60 = 20$

Hours: 65

Degree-hours: $20 \times 65 = 1300$ degree-hours

Look at the entries for “Heat Treatment (jerky)” six column HACCP plan form for heat treated, shelf stable; the HACCP team determined that humidity must be applied during heating in order to eliminate the pathogens of concern (e.g., *Salmonella*, *E. coli* O157:H7, *L. monocytogenes* and *Staphylococcus aureus*). Bacterial resistance to heat has been shown to increase with a decrease in the moisture level. If humidity is not applied during heating, the bacteria may survive the heat process and remain viable.

After identifying its CCPs, the HACCP team proceeded to consider critical limits, monitoring procedures and their frequencies, and verification procedures and their frequencies, and HACCP records.

In deciding what would be the critical limits, the HACCP team first considered whether there were any regulatory requirements which had to be met and would function as critical limits. They did find FSIS regulatory requirements for shelf stability (water activity of 0.85 or below). They also found guidelines for MPR as a product identity standard for jerky and lethality compliance guidelines in Appendix A of the final rule, “Performance Standards for the Production of Certain Meat and Poultry Products.” MPR is not a safety consideration and is not included in a hazard analysis or HACCP plan.

Once they had decided on their critical limits, they needed to identify how the monitoring procedures would be carried out and at what frequency.

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For their drying step, the establishment had a production employee perform water activity (a_w) checks on each lot and the drying time/temperature will be monitored using room recorder charts.

These decisions by the HACCP team regarding critical limits, plus monitoring procedures and their frequencies, are written up in columns two and three of the HACCP plan.

The team then went on to consider appropriate verification procedures; the team knew that there were different types of verification and that Part 417.4(a)(2) included specific regulatory requirements for each. The regulatory requirements for ongoing verification are:

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with §417.5(a)(3) of this part.

The HACCP team decided they could verify through the following procedures and frequency:

1. QA supervisor or designee will review the Fermentation Log, Corrective Actions Log, Smokehouse/Product Temperature Log, Thermometer Calibration Log, Oven Temperature/Humidity Log, Water Activity Log and Metal Detector Performance Log once per shift.
2. Maintenance supervisor or designee will check the calibration and functioning of the metal detector before the start of operations and after lunch; verify that the wet bulb wick well contains appropriate amount of water prior to startup and during operation if necessary.
3. QA technician or designee will check all thermometers used for monitoring and verification activities daily and calibrate to within 1 °F accuracy as necessary.
4. QA technician or designee will check all pH meters used for monitoring and verification activities for accuracy daily and calibrate to within 0.1 pH unit as necessary.
5. QA technician or designee will check all water activity meters used for monitoring and verification activities for accuracy daily to within 0.003 units as necessary.
6. The QA supervisor or designee will observe the QA technician or designee perform each monitoring activity once per shift.

The HACCP team described the verification procedures and their frequencies in the fifth column of their HACCP plan.

The HACCP team for generic establishment X knew that their HACCP plan needed to provide for a recordkeeping system. They wanted their records to be easy to create and understand. They wanted to be sure their records met regulatory requirements, so they reviewed part 417.5(a) and (b):

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decision making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

The HACCP team decided that their records would be kept on some simple forms, some of which the team itself devised. The forms for monitoring and verification records are listed under the HACCP Records column of the HACCP plan. They are: Fermentation Log, Corrective Actions Log, Smokehouse/Product Temperature Log, Thermometer Calibration Log, Oven Temperature/Humidity Log, Water Activity Log, and Metal Detector Performance Log.

Column four (HACCP Records) in the HACCP plan references the Corrective Actions Log. This is used to create the records of any corrective actions taken because of deviations from critical limits at CCPs. Column six in the HACCP plan describes the planned corrective actions for each CCP. The HACCP team carefully reviewed the regulatory requirements for planned corrective actions found at 417.3(a):

§ 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

The HACCP team has developed a corrective action plan that meets the four regulatory requirements of 417.3(a). Whenever a deviation from a critical limit occurs, company employees follow the corrective action plan and use the Corrective Actions Log to create a record of their actions. The Corrective Actions Log forms are available at CCP locations, so they can be used immediately when an employee performing a monitoring check discovers and records a deviation. All Corrective Actions Logs, which have been used during the day, are turned in to the HACCP coordinator.

There is one final verification/recordkeeping requirement which the company must perform; it is found at 417.5(c):

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

In generic establishment X product is shipped out, often in small lots, throughout the day. This means that pre-shipment verification checks must be as complete as possible when finished product is in storage, so that a shipment can be made up quickly and moved into distribution channels.

The establishment uses a half day lotting system and a midshift cleanup. While the midshift cleanup is being performed, QA personnel or the HACCP coordinator review results of monitoring and verification checks applied to that lot; if there were deviations from critical limits, they review the Corrective Actions Logs to make sure all appropriate planned responses

Heat Treated, Shelf Stable Model

were carried out. If everything is in order and there are complete records showing that the establishment has controlled production of this product through its HACCP system, the HACCP coordinator will sign the pre-shipment review form which the HACCP team devised for this purpose.

Note: It is not a regulatory requirement that a separate form be used for pre-shipment review; in addition, FSIS has indicated that it will be very flexible in accepting a variety of arrangements for accomplishing pre-shipment review to reflect the variety of commercial practices in the industry. It is, however, important to remember that pre-shipment review is a regulatory requirement that must be met, as it indicates that the establishment is taking full responsibility for the product having been produced under a well-functioning HACCP system.

The HACCP team believes it has now completed preparation of the documents which are necessary to meet regulatory requirements for a hazard analysis and a HACCP plan for their heat treated, shelf stable production process. They obtained a copy of FSIS Directive 5000.1, Rev. 1, Verifying an Establishment's Food Safety System. The Basic Compliance Checklist will be used by inspection program personnel. The HACCP team has modified the inspection form to make the statements into positives, and now has a checklist for its own use to make sure they have not omitted anything in their plan development and preparation. When they are confident that they have done what is necessary, they will turn their hazard analysis and HACCP plan over to the establishment owner for decisions about implementation.

APPENDIX A

References for General HACCP and Regulatory Issues

1. Agriculture Canada. 1996. Food Safety Enhancement Program – HACCP Implementation Manual. Camelot Drive, Nepean, Ontario, Canada..
2. American Meat Institute Foundation. 1994. *HACCP: The Hazard Analysis and Critical Control Point System in the Meat and Poultry Industry*. 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

3. Baker, D.A. 1995. Application of modeling in HACCP plan development. *Int. J. Food Microbiol.* 25:251-261.
4. Corlett, D.A., Jr. and Stier, R.F. 1991. Risk assessment within the HACCP system. *Food Control* 2:71-72.
5. Council for Agriculture Science and Technology. 1993. *Risks Associated with Foodborne Pathogens*. February.
6. 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.
7. Environmental Protection Agency. 1998. Tolerances for Pesticides in Foods. Title 40, Code of Federal Regulations, Part 185. U.S. Government Printing Office, Washington, D.C.
8. Food and Drug Administration. 1998. The Food Defect Action Levels. FDA/CFSAN. Washington, D.C.
9. Food and Drug Administration. Fish and Fishery Products Hazards and Control Guide --Get Hooked on Seafood Safety. Office of Seafood. Washington, D.C., 1994.
10. International Commission on Microbiological Specification for Foods. 1988. HACCP in Microbiological Safety and Quality. Blackwell Scientific Publications, Oxford.

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

11. International Commission on Microbiological Specification for Foods. 1989. Microorganisms in Foods 4. Application of Hazard Analysis and Critical Control Point (HACCP) Systems to Ensure Microbiological Safety and Quality. Blackwell Scientific Publications, Boston.
12. National Advisory Committee on Microbiological Criteria for Foods. –1993. Hazard analysis and critical control point system. *Int. J. Food Microbiol.* 16: 1-23.
13. National Advisory Committee on Microbiological Criteria for Foods. 1998. Hazard analysis and critical control point principles and application guidelines. *J. Food Protect.* 61(9): 1246-1259.

Heat Treated, Shelf Stable Model

14. National Advisory Committee on Microbiological Criteria for Foods. August 1999. DRAFT document - FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants. 1-22.
15. National Advisory Committee on Microbiological Criteria for Foods. 1994. Report on generic HACCP for raw beef. *Food Microbiol.* 10: 449-488.
16. 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

17. Notermans, S., M. H. Zwietering and G. C. Mead. 1994. The HACCP concept: Identification of potentially hazardous microorganisms. *Food Microbiol.* 11:203-214.
18. Pierson M.D. and Dutson, T. Editors. 1995. HACCP in Meat, Poultry, and Fish Processing. Blackie 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

19. Pierson, M.D. and Corlett, D.A., Jr. Editors. 1992. HACCP Principles and Applications. Van Nostrand Reinhold, New York.
20. Stevenson, K.E. and Bernard, D.T. 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, CCPs, critical limits, HACCP master sheet, example HACCP for breaded chicken

21. Stevenson, K.E. and Bernard, D.T. Editors. 1999. HACCP: A Systematic Approach to Food Safety. 3rd Edition. The Food Processors Institute, Washington, D.C.
22. Tompkin, R.B. 1990. The use of HACCP in the production of meat and poultry products. *J. Food Protect.* 53(9): 795-803.
23. Tompkin, R.B. 1995. The Use of HACCP for Producing and Distributing Processed Meat and Poultry Products. In *Advances in Meat Research. Volume 10. Hazard Analysis Critical Control Point in Meat, Poultry and Seafoods.* Chapman & Hall.

References for Heat Treated, Shelf Stable Meat and Poultry Products

1. Albright, S.N., P. A. Kendall, J. A. Avens and J.N. Sofos. 2002. Effect of marinade and drying temperature on inactivation of *Escherichia coli* O157:H7 on inoculated home dried beef jerky. *J. Food Safety*. 22:155-167.
2. Albright, S.N., P. A. Kendall, J. A. Avens and J.N. Sofos. 2003. Pretreatment effect on inactivation of *Escherichia coli* O157:H7 inoculated beef jerky. *Food Science and Technology/LWT*. 36:381-389.
3. American Meat Institute Foundation. 1997. Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products.
4. American Meat Science Association. 1995. Flowchart for beef jerky. AMSA, Chicago, IL.
5. Bunic, S., L. Paunovic and D. Radisic. 1991. The fate of *Listeria monocytogenes* in fermented sausages and in vacuum-packaged frankfurters. *J. Food Prot.* 54: 413-417.
6. Calicioglu, M., J.N. Sofos, J. Samelis, P. A. Kendall and C. G. Smith. 2002. Destruction of acid- and non-adapted *Listeria monocytogenes* during drying and storage of beef jerky. *Food Microbiol.* 19:545-559.
7. Calicioglu, M., J.N. Sofos, J. Samelis, P.A, Kendall and G.C. Smith. 2002. Inactivation of acid-adapted and nonadapted *Escherichia coli* O157:H7 during drying and storage of beef jerky treated with different marinades. *J. Food Prot.* 65:1394-1405.
8. Calicioglu, M., J.N. Sofos and P.A. Kendall. 2003. Influence of marinades on survival during storage of acid-adapted and nonadapted *Listeria monocytogenes* inoculated post-drying on beef jerky. *Intl. J. Food Microbiol.* 86:283-292
9. Calicioglu, M., J.N. Sofos, J. Samelis, P.A. Kendall and G.C. Smith. 2003. Effect of acid-adaptation on inactivation of *Salmonella* during drying and storage of beef jerky treated with marinades. *Intl. J. Food Microbiol.* 89:51-65.
10. Calicioglu, M., J.N. Sofos, P.A. Kendall and G.C. Smith. 2003. Effects of aid-adaptation and modified marinades on survival of post-drying *Salmonella* contamination on beef jerky during storage. *J. Food Prot.* 66:396-401.
11. Calicioglu, M., J.N. Sofos, J. Samelis, P.A. Kendall and G.C. Smith. 2003. Fate of Acid-Adapted and Nonadapted *Escherichia coli* O157:H7 Inoculated Post-drying on Beef Jerky Treated with Marinades Before Drying. *Food Microbiol.* 20:169-177.
12. Centers for Disease Control and Prevention. 1995. Outbreak of salmonellosis associated with beef jerky – New Mexico, 1995. *Morbidity and Mortality Weekly Report*. 44: 785-787.
13. United States Department of Agriculture. Food Safety and Inspection Service. 1999. Performance standards for the production of certain meat and poultry products. *Federal Register* 64(3):732-49.
14. Dykes, G., T. E. Cloete and A. von Holy. 1991. Quantification of microbial populations associated with the manufacture of vacuum-packaged, smoked Vienna sausages. *Int. J. Food Microbiol.* 13:239-248.

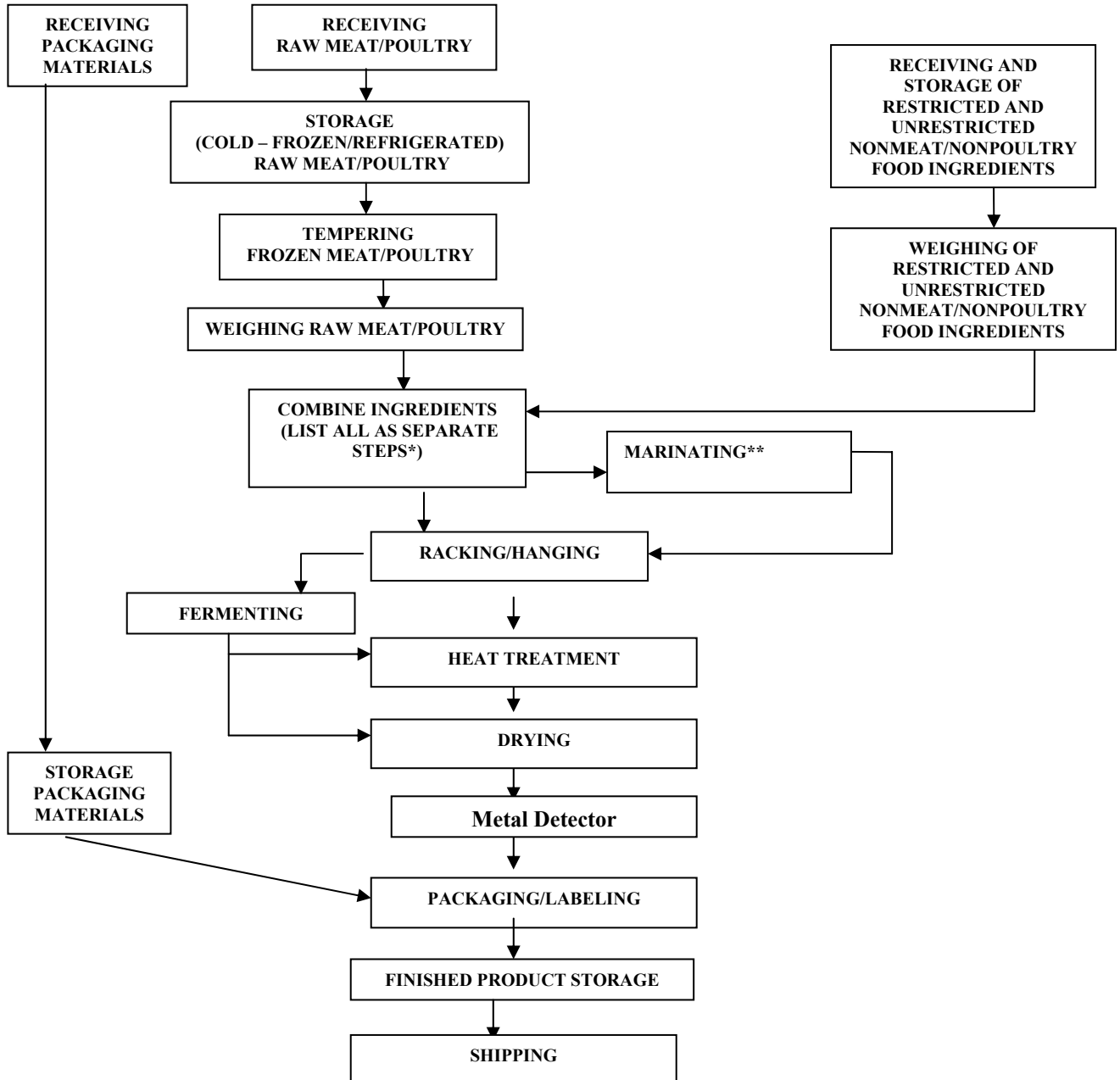
Heat Treated, Shelf Stable Model

15. Genigeorgis, C. and S. Lindroth. 1984. The safety of basturma, an Armenian-type dried beef product with regard to *Salmonella*. Proceedings of the 30th European Meeting of Meat Research Workers. 30:217-224.
16. Goepfert, J. M., I. K. Iskander and C.H. Amundson. 1970. Relation of the heat resistance of salmonellae to the water activity of the environment. Appl. Microbiol. 19(3):429-33.
17. Harrison, J. A. and M. A. Harrison. 1996. Fate of *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella typhimurium* during preparation and storage of beef jerky. J. Food Prot. 59(12):1336-8.
18. Harrison, J. A., M. A. Harrison, R. A. Rose-Morrow and R. L. Shewfelt. 2001. Home-style beef jerky: effect of four preparation methods on consumer acceptability and pathogen inactivation. J. Food Prot. 64(8):1194-98.
19. Holley, R. 1984. Beef jerky: viability of food-poisoning microorganisms on jerky during its manufacture and storage. J. Food Prot. 48(2):100-106.
20. Levine, P., B. Rose, S. Green, G. Ransom and W. Hill. 2001. Pathogen testing of ready-to-eat meat and poultry products collected at federally inspected establishments in the United States, 1990 to 1999. J. Food Prot. 64(8):1188-1193.
21. Smith, S.E., J. L. Mauer, A. Orta-Ramirez, E. T. Ryser and D. M. Smith. 2001. Thermal inactivation of *Salmonella* spp., *Salmonella typhimurium* DT104, and *Escherichia coli* O157:H7 in ground beef. J. Food Prot. 66(8):1164-68.

APPENDIX B

PROCESS FLOW DIAGRAM

PROCESS CATEGORY: HEAT TREATED, SHELF STABLE
PRODUCT: SNACK STICKS, JERKY



* These steps include: grinding, chopping, mixing, stuffing, forming, and slicing. Include all applicable in flow chart and hazard analysis.

** No interventions (acid dip, heating in marinade) used in this process.

No product is reworked back into the process.

Figure 1

PRODUCT DESCRIPTION

PROCESS CATEGORY: HEAT TREATED, SHELF STABLE	
PRODUCT: SNACK STICKS, JERKY	
1. COMMON NAME?	SNACK STICKS (SOME FERMENTED)
TYPES: COMMON NAME?	BEEF JERKY (NON-FERMENTED)
2. HOW IS IT TO BE USED?	CONSUME AS PURCHASED (READY TO EAT)
3. TYPE OF PACKAGE?	BULK-PACKED (E.G., PLASTIC BAG, VACUUM PACKED)
4. LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?	VARIABLES WITH PACKAGING AND STORAGE TEMPERATURE: MAY LAST 6 MONTHS NON-REFRIGERATED & INDEFINITELY UNDER REFRIGERATION
5. WHERE WILL IT BE SOLD? CONSUMERS? INTENDED USE?	WHOLESALE TO DISTRIBUTORS ONLY
6. LABELING INSTRUCTIONS?	“REFRIGERATE AFTER OPENING”
7. IS SPECIAL DISTRIBUTION CONTROL NEEDED?	NONE

Figure 2

HAZARD ANALYSIS – HEAT TREATED, SHELF STABLE – Snack Sticks, Jerky

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Receiving – Raw Meat/Poultry	Biological: Pathogens <i>Salmonella</i> <i>Listeria monocytogenes</i> <i>E. coli</i> O157:H7 <i>Trichinella spiralis</i> *	Yes	Pathogens may be present on incoming raw product.	Pathogens will be controlled at a subsequent step through heat treatment and drying (jerky & snack sticks) and/or fermentation (snack sticks).	
	Chemical – None				
	Physical – Foreign materials such as metal fragments	No	Plant records show that there has been no incidence of foreign materials in products received into the plant.		
Receiving – Restricted and Unrestricted Nonmeat/Nonpoultry Food Ingredients; Packaging Materials	Biological – None				
	Chemical – Packaging material acceptable for intended use.	No	Letters of guaranty are received from all suppliers of packaging materials.		
	Physical — None				

* Snack sticks may contain pork. *T. spiralis* may also be present in some game animals.

Figure 3

HAZARD ANALYSIS – HEAT TREATED, SHELF STABLE – Snack Sticks, Jerky

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Storage – Restricted and Unrestricted Nonmeat/Nonpoultry Food Ingredients; Packaging Materials	Biological – None				
	Chemical – None				
	Physical – None				
Storage (Cold – Frozen/Refrigerated) – Raw Meat/Poultry	Biological – Pathogen Growth <i>Salmonella</i> <i>Listeria monocytogenes</i> <i>E. coli</i> O157:H7 <i>Trichinella spiralis</i> *	No	<i>Salmonella</i> , <i>E. coli</i> O157:H7 and <i>Listeria monocytogenes</i> are not likely to grow if the product is maintained at proper temperature. Prerequisite program in place to prevent pathogen growth from being likely to occur.		
	Chemical – None				
	Physical – None				
Tempering Frozen Meat/Poultry	Biological – None				
	Chemical – None				
	Physical – None				
Weighing Restricted and Unrestricted Nonmeat/Nonpoultry Food Ingredients	Biological – None				
	Chemical – Excessive Level of Nitrite	No	Prerequisite program in place to prevent addition of greater than allowed amount of nitrite.		
	Physical – None				

*Snack sticks may contain pork. *T. spiralis* may also be present in some game animals.

Figure 3

HAZARD ANALYSIS – HEAT TREATED, SHELF STABLE – Snack Sticks, Jerky

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Weighing Raw Meat/Poultry	Biological – None				
	Chemical – None				
	Physical – None				
Combining Ingredients/ Processing (Includes one or more of the following: grinding, chopping, mixing, stuffing, forming, and slicing)	Biological – None				
	Chemical – None				
	Physical – Metal Contamination	Yes	Plant records show that during mechanical processing metal contamination has occurred.	Metal detection is located at a subsequent step in the process.	
Marinating	Biological –None				
	Chemical – None				
	Physical – None				
Racking/Hanging	Biological – None				
	Chemical – None				
	Physical – None				
Fermenting (Used for pH reduction on snack sticks produced with a fermentation step)	Biological – Pathogens <i>Staphylococcus aureus</i> <i>Salmonella</i> <i>E. coli</i> O157:H7	Yes	Potential growth of <i>S. aureus</i> and toxigenesis if fermentation process is inadequate.	Fermentation to the degree-hours required will achieve the pH needed to inhibit <i>S. aureus</i> . Fermentation also reduces levels of <i>Salmonella</i> and <i>E. coli</i> O157:H7.	1B
	Chemical – None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – HEAT TREATED, SHELF STABLE – Snack Sticks, Jerky

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Heat Treatment	Biological – Pathogens <i>Listeria monocytogenes</i> <i>Salmonella</i> <i>Staphylococcus aureus</i> <i>E. coli</i> O157:H7 <i>T. spiralis</i>	Yes	Potential survival and growth of pathogens and toxigenesis from <i>S. aureus</i> with inadequate process time/temperature/humidity.	Heat treatment using appropriate time/temperature/humidity to produce lethality/pasteurization.	2B
	Chemical – None				
	Physical – None				
Drying	Biological – Pathogens <i>Staphylococcus aureus</i> <i>Listeria monocytogenes</i>	Yes	<i>L. monocytogenes</i> can grow if a_w above 0.92 and <i>S. aureus</i> growth & toxigenesis can occur if <i>S. aureus</i> survived heat treatment.	Low water activity (a_w) precludes bacterial pathogen growth. The a_w required to prevent growth of <i>S. aureus</i> (0.86) is lower than that for other pathogens.	3B
	Chemical – None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – HEAT TREATED, SHELF STABLE – Snack Sticks, Jerky

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	Critical Control Point
Metal Detector	Biological – None				
	Chemical – None				
	Physical – Metal Contamination	Yes		Metal detector.	4P
Packaging/Labeling	Biological – Pathogens Growth of <i>Listeria monocytogenes</i>	No	<i>L. monocytogenes</i> growth precluded by previous drying step - water activity of product much less than 0.92 min required for Lm growth. The drying process meets the criteria described in 9 CFR 430.4 for Alternative 2.		
	Chemical – None				
	Physical – None				
Finished Product Storage	Biological – None				
	Chemical – None				
	Physical – None				
Shipping	Biological – None				
	Chemical – None				
	Physical – None				

Figure 3

HACCP PLAN

PROCESS CATEGORY: HEAT TREATED, SHELF STABLE
PRODUCT EXAMPLE: SNACK STICKS, JERKY

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions																		
1B Fermenting (Snack Sticks produced with a fermentation step)	<p>pH ≤ 5.3 - achieved by using one of the following combination of chamber temperature – maximum hours of fermentation</p> <table border="1"> <thead> <tr> <th>Constant Chamber Temp (°F)</th> <th>Max Hrs*</th> </tr> </thead> <tbody> <tr><td>75</td><td>80</td></tr> <tr><td>80</td><td>60</td></tr> <tr><td>85</td><td>48</td></tr> <tr><td>90</td><td>33</td></tr> <tr><td>95</td><td>28</td></tr> <tr><td>100</td><td>25</td></tr> <tr><td>105</td><td>20</td></tr> <tr><td>110</td><td>18</td></tr> </tbody> </table>	Constant Chamber Temp (°F)	Max Hrs*	75	80	80	60	85	48	90	33	95	28	100	25	105	20	110	18	<p>QA technician or designee will take 5 individual product samples for pH measurement from each lot at the completion of the fermentation cycle. Before removal from fermentation, determine compliance with the time critical limit related to the specified fermentation chamber temperature in order to meet the documented degree-hour limit.</p> <p>The pH is measured by placing a pH electrode in a 1:1 (w/w) meat/distilled water slurry of each sample. Methodology reference on file.</p> <p>QA technician or designee will record chamber temperature and time to pH ≤ 5.3.</p>	<p>Fermentation Log</p> <p>Corrective Action Log</p> <p>Thermometer Calibration Log</p>	<p>QA Supervisor or designee will review the Fermentation Log and Corrective Action Log once per shift.</p> <p>QA technician or designee will check all thermometers for accuracy daily against thermometer of known accuracy and calibrate to ±1° F accuracy as necessary.</p> <p>QA or designee will check all pH meters used for monitoring and verification for accuracy daily against a known standard and calibrate for accuracy to ± 0.1.</p> <p>QA supervisor or designee will observe QA technician or designee perform monitoring activity once per shift.</p>	<p>If a deviation from a critical limit occurs, the QA supervisor or designee is responsible for corrective action protocols:</p> <ol style="list-style-type: none"> 1. The cause of the deviation will be identified and eliminated. 2. The CCP will be under control after the corrective action is taken. 3. Measures to prevent recurrence are established. 4. No product that is injurious to health or otherwise adulterated as a result of the deviation will be permitted to enter commerce.
Constant Chamber Temp (°F)	Max Hrs*																						
75	80																						
80	60																						
85	48																						
90	33																						
95	28																						
100	25																						
105	20																						
110	18																						

*Maximum time critical limits at specified fermentation chamber temperature for product to reach pH ≤ 5.3 at the end of the fermentation step in order to meet the relative degree hour limits for control of *S. aureus* toxin production. (Validated support on file.)

Signature: _____ **Date:** _____

Figure 4

HACCP PLAN					
PROCESS CATEGORY: HEAT TREATED, SHELF STABLE					
PRODUCT EXAMPLE: SNACK STICKS, JERKY					
CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
2B Heat Treatment (snack sticks with fermentation step)	Snack sticks to be cooked to an internal temperature of $\geq 160^{\circ}\text{F}$.	QA technician or designee will take the internal temperature using an internal probe and check 10 sticks in coldest part of smokehouse for each lot at completion of cook cycle and before removal from smokehouse.	Smokehouse/ Product Temperature Log Thermometer Calibration Log Corrective Action Log	Once per shift the QA supervisor or designee will review the Smokehouse/Product Temperature Log, Corrective Action Log, and Thermometer Calibration Log. Once per shift QA supervisor or designee will observe the QA technician or designee perform the monitoring activity.	If a deviation from a critical limit occurs, the QA supervisor or designee is responsible for corrective action protocols: 1. The cause of the deviation will be identified and eliminated. 2. The CCP will be under control after the corrective action is taken. 3. Measures to prevent recurrence are established. 4. No product that is injurious to health or otherwise adulterated as a result of the deviation will be permitted to enter commerce.

Signature: _____ **Date:** _____

Figure 4

HACCP PLAN					
PROCESS CATEGORY: HEAT TREATED, SHELF STABLE					
PRODUCT EXAMPLE: SNACK STICKS, JERKY					
CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
2B Heat Treatment (jerky)	Jerky to be cooked at an oven temperature of $\geq 180^{\circ}\text{F}$ for ≥ 2 hours with $\geq 90\%$ humidity throughout the cook.	Oven temperature monitored with dry bulb thermometer. Humidity* will be monitored by comparison of wet and dry bulb thermometers every 30 minutes. Wet bulb temperature must be within 4.5°F of the dry bulb temperature.	Oven Temperature / Humidity Log Thermometer Calibration Log Corrective Action Log Documentation on file for lethality.	Maintenance supervisor or designee will verify that the wet bulb water wick well contains the appropriate amount of water prior to startup and during operation if necessary. Once per shift the QA supervisor or designee will review the Oven Temperature/Humidity Log and Corrective Action Log. Once per shift QA supervisor or designee will observe the QA technician or designee perform the monitoring activity.	If a deviation from a critical limit occurs, the QA supervisor or designee is responsible for corrective action protocols: 1. The cause of the deviation will be identified and eliminated. 2. The CCP will be under control after the corrective action is taken. 3. Measures to prevent recurrence are established. 4. No product that is injurious to health or otherwise adulterated as a result of the deviation will be permitted to enter commerce.

*Humidity control is critical during the heat treatment. Without adequate humidity, the required level of pathogen reduction will not be achieved.

Signature: _____ Date: _____

Figure 4

HACCP PLAN					
PROCESS CATEGORY: HEAT TREATED, SHELF STABLE					
PRODUCT EXAMPLE: SNACK STICKS, JERKY					
CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
3B Drying	a_w^* of ≤ 0.80	a_w checks will be done by separately placing portions of 5 product samples from each lot in a <u>a_w meter</u> .	Water Activity (a_w) Log Corrective Action Log	QA technician or designee will check all water activity meters used for monitoring and verification for accuracy daily against a known standard and calibrate to ± 0.003 of the standard. QA supervisor or designee will review the a_w Log and Corrective Action Log once per shift. Once per shift QA supervisor will observe the QA technician or designee perform the monitoring activity.	If a deviation from a critical limit occurs, the QA supervisor or designee is responsible for corrective action protocols: 1. The cause of the deviation will be identified and eliminated. 2. The CCP will be under control after the corrective action is taken. 3. Measures to prevent recurrence are established. 4. No product that is injurious to health or otherwise adulterated as a result of the deviation will be permitted to enter commerce.

* Manufacturers should not use MPR as a measure of proper drying for shelf-stability or safety. MPR is a product standard and the water activity can vary greatly at any given MPR (as a result of the different solutes such as sugar and salt). It is product water activity that can be easily correlated to inhibition of each pathogen's growth.

Signature: _____

Date: _____

Figure 4

HACCP PLAN					
PROCESS CATEGORY: HEAT TREATED, SHELF STABLE					
PRODUCT EXAMPLE: SNACK STICKS, JERKY					
CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
4P Metal Detector	Metal detector functioning.	QA technician or designee will check that the metal detectors are functioning as intended by running a seeded sample through the metal detector(s) every 2 hours and record results in the metal detector log.	Metal Detector Performance Log Corrective Action Log	QA supervisor or designee will review the Metal Detector Performance Log and Corrective Action Log once per shift. Before start of operations and after lunch, maintenance supervisor or designee will check calibration of metal detector by running a seeded sample (≤ 7 mm seed) through the detector and adjusting when necessary. Twice a week QA supervisor or designee will observe the QA technician or designee perform the monitoring activity.	If a deviation from a critical limit occurs, the QA supervisor or designee is responsible for corrective action protocols: <ol style="list-style-type: none"> 1. The cause of the deviation will be identified and eliminated. 2. The CCP will be under control after the corrective action is taken. 3. Measures to prevent recurrence are established. 4. No product that is injurious to health or otherwise adulterated as a result of the deviation will be permitted to enter commerce.

Signature: _____ **Date:** _____

Figure 4

FERMENTATION LOG

Critical Limit: pH ≤ 5.3 at the appropriate degree-hour limit for the fermentation chamber temperature.

Date	Product ID	Chamber Temperature [°F]	Time In	Time Out	pH*	Time to pH ≤5.3 [max hrs.]	Monitor Initials	Verification**	
								Initial/Time	Comments/Results

Constant Chamber Temperature (°F):	75	80	85	90	95	100	105	110
Max. Hours to pH ≤ 5.3	80	60	48	33	28	25	20	18

Instructions: Enter the appropriate chamber temperature in the brackets under Chamber Temperature and associated maximum time to pH ≤ 5.3 in the brackets under Time to pH ≤5.3. If the chamber temperature lies between two values, select the next highest value. These will serve as the control values. Record requested information. **Do not remove the product from the fermentation chamber until the product pH is equal to or less than 5.3.** Time and temperature may be recorded directly on the log or taken from a chart recorder. The constant

*pH meter is checked against known standard at the beginning of each sample lot.

**Direct observation verification – results per HACCP plan

**Records review – results per HACCP plan

CORRECTIVE ACTIONS LOG

Product: _____ **Lot #** _____

Date/Time: _____ **Responsible Person/Date:** _____

Deviation	
Cause of Deviation	
Cause of Deviation Eliminated By	
CCP Under Control After Corrective Actions Taken	
Preventive Measures	
Product Disposition	

Verification by and Date: _____

Verification Comments: _____

SMOKEHOUSE/PRODUCT TEMPERATURE LOG*

Date: _____

Critical Limit: Smokehouse Temperature will be $\geq 180^{\circ}\text{F}$ for ≥ 2 hours.

		Smokehouse/Product Temperature						
Product ID	TIME	TEMP	TEMP	TEMP	TEMP	TEMP	Monitor Initials	Verified by

Smokehouse/Product Temperature Log may be used if smokehouse chart is not available.

*Direct observation verification – results per HACCP plan

** Records review – results per HACCP plan

Verification comments: _____

GENERIC ESTABLISHMENT X: OVEN TEMPERATURE/HUMIDITY LOG

PRODUCT: _____

ROOM: _____

DATE: _____

Critical limit: 90% humidity throughout the cook.

Product ID	TIME IN	TIME OUT	TEMP		Calculated Relative Humidity	Deviation from CL? (Check if yes)	If Yes, Action Taken?	Monitor Initials	Verification	
			DRY BULB	WET BULB					Date/Time/Initial	Comment

Instructions: If a recording chart is not used, the wet and dry bulb temperatures should be recorded every 30 minutes. Attach the recording chart.

*Direct observation verification – results per HACCP plan

**Records review – results per HACCP plan

WATER ACTIVITY (a_w) LOG

Date: _____

Critical Limit: Water activity will be ≤0.80 at the end of drying

Product ID	a _w * NaCl (.753)	a _w Distilled H ₂ O (1.000)	a _w Product	Time	Comments	Monitor Initials	Verification **	
							Initial/Date	Comments

*Water activity of control solutions (saturated solution of NaCl) and product conducted at 77°F.

**Direct observation verification – results per HACCP plan

**Records review – results per HACCP plan

GENERIC ESTABLISHMENT X: METAL DETECTOR PERFORMANCE LOG

Date	Time	Product ID	Metal Detector Functioning (Yes or No)	Size of Seeded Sample	Adjustment(s) Made	Monitor Initials	Verified by

+Seed sample verification results recorded in “Size of Seeded Sample” column.

*Direct observation verification – results per HACCP plan

**Records review – results per HACCP plan

Verification comments: _____

PRE-SHIPMENT REVIEW LOG			
PRODUCT ID	LOT RELEASED FOR SHIPMENT? SIGNATURE	DATE	COMMENTS