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Generic HACCP Model for Thermally Processed, Commercially Sterile 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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United States Department of Agriculture
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TO THE USERS OF THESE VOLUMES

As some of you may know, the Food Safety and Inspection Service (FSIS) received a substantial package of comments on its Guidebook for Hazard Analysis and Critical Control Point (HACCP) Plan Development and the 13 Generic HACCP models, from a coalition of industry and trade associations. This package represents a large and thoughtful effort on the part of these organizations. FSIS intends to give it the careful attention and response that it deserves.

The comments included many technical suggestions for improvements in the FSIS documents. It also included reiteration of longstanding differing policy viewpoints that have been frequently discussed by the Agency and the regulated industry. For the first time, the comments revealed substantially differing expectations on the part of these organizations and FSIS with respect to the purpose of the FSIS documents and their intended use. We want to address some aspects of this latter point.

When the Pathogen Reduction/Hazard Analysis and Critical Control Point systems (PR/HACCP) final regulation was published on July 25, 1996, the DRAFT Guidebook was included as an appendix. The Generic Models, developed for FSIS under contract, were available shortly thereafter in April 1997. It was probably inevitable that there were significant differences between the final regulatory language of CFR Part 417 and the DRAFT Generic Models as they were developed independently. It would have been inappropriate for FSIS to discuss its final regulatory language with any outside group. The contractor was appropriately proceeding from what it knew best, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) documents on the subject of HACCP. Therefore, FSIS accepted that work product with full knowledge that significant revisions would be necessary.

As time passed, FSIS managers became increasingly uncomfortable with the situation in which its major technical assistance documents did not appropriately and completely inform the regulated industry of Agency expectations regarding regulatory compliance. Because the intended audience for these technical assistance materials was primarily the very small establishments, which the Agency believed to have the least HACCP-experience, the Agency began the systematic revision of the documents to overcome this problem. We targeted the summer of 1999 as the completion date for this effort.

FSIS now believes that others had very different ideas about the purpose and use of the documents than it did. As is consistently reiterated in the documents themselves, they are not designed to be used "as is." That is, they cannot be copied and used by an establishment to meet all the regulatory requirements of 9 CFR Part 417. Nor were they designed to be the ultimate teaching and training materials, as some would suggest. The development of ideal generic models is left to others who may have an interest in doing so. The generic models are not

designed to extend or further 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 designed to present new or alternative methods of producing and processing meat and poultry products. That is also left to others with an interest in doing so.

FSIS envisioned that the generic models might be used in the following way: Suppose a HACCP team leader of a three-person HACCP team in a very small establishment attended a training course, but the others on his/her team were not able to do so. Suppose the HACCP training course met all the requirements of 417.7 but did not provide participants with much in the way of "take away materials" like workbooks, practical questions and answers, access to follow-up resources, etc., which the Research Triangle Institute (RTI) needs assessment indicated were so important to these establishments. The trained HACCP team leader returns to the establishment and begins the process of attempting to develop HACCP plans for the company's products and processes. He/she is quite confident that he/she has grasped the material presented in the training course and begins to work with this team immediately, while the concepts are fresh in his/her mind.

First, he/she has the rest of the team review the Canadian video and the Guidebook from FSIS so that all members of his team have a basic level of information.

The 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 discover what are some typical food safety hazards that are reasonably likely to occur, as explicitly defined in 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 like the ones for rapid chilling of poultry products. They can also see that in the absence of settled regulatory requirements, there may be several sources of scientific expertise, and they 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 publishing these updated revisions of the generic models, beginning with the Guidebook and the Generic Model for Raw, Ground Product, because a large backlog of requests exists for these two documents. FSIS intends to publish revisions of all the generic models no later than September 30, 1999. Moreover, as a result of public consultation, it may publish an additional revision of some of these models, but given the backlog and the impending HACCP implementation date, we considered it important to get a version of these documents out now.

We hope that these documents are helpful.

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GENERIC HACCP MODEL

FOR

THERMALLY PROCESSED, COMMERCIALLY STERILE 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.

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.

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).

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> *(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 fourth process category: Thermally processed -- commercially sterile.

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 that 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:

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.

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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 thermally processed, commercially sterile product(s), the fourth process category. The model can be used for all thermally processed, commercially sterile products: either meat or poultry; with or without cure; whether low-acid or acidified low-acid product. The model can be used for those products generally referred to as canned. 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. 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 samples; 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 are discussed in the text.

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 definitions 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.*

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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 the steps the company uses when it produces the product, and
(2) in a brief written description which provides key facts about the product and its use.

In this generic model, there is an example for thermally processed, commercially sterile - beef stew. 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 of thermally processed, commercially sterile beef stew in generic establishment X. Figure 2 is an example of a **PRODUCT DESCRIPTION** for the thermally processed, commercially sterile beef stew produced by 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.

By completing a Process Flow Diagram and a Product Description, you have met the requirements of 417.2(a)(2). You can use the Process Flow Diagram in particular to help you complete the rest of the hazard analysis. 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 at this step?" In answering the question, your HACCP team needs to consider biological (including microbiological), chemical, and physical hazards.

Hazard Analysis

Once your 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 and one that meets regulatory requirements. The regulatory requirements for a hazard analysis are found at 417.2(a).

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§ 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)**. 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, 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 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 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 “Receiving-Non-meat Food Ingredients” on the first page of the six column form; the HACCP team has determined that even though bacterial spore loads may be present at high levels in incoming product, they put a “No” in the third column. Column four explains the basis for the team’s determination. The bacterial spore load which is introduced into the product either at the producer or supplier operations, can be controlled at the canning

establishment. Therefore, the team decided that the hazard can be controlled by the thermal process or by using irradiated spices.

You will notice that on our generic hazard analysis for thermally processed, commercially sterile beef stew, there are seven food safety hazards in which the HACCP team has identified a point in the process at which a food safety hazard is reasonably likely to occur. For each one of these they have identified a measure which can be used to control the hazard.

When your 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 you are using this generic model to produce a different thermally processed, commercially sterile product or if you use a different process flow, you may have different hazards which are reasonably likely to occur. For these different hazards, there may be different measures that could be used for control purposes.

This, and all other FSIS generic models, contains a list of references which can help your HACCP team in making sure the hazard analysis is complete. The references for thermally processed, commercially sterile product are found in Appendix A. A member of your 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 your HACCP system. Your 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 it 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 that 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:*

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(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 thermally processed, commercially sterile beef stew 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 this particular form is used to enter information 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 seven process steps on the hazard analysis form where food safety hazards reasonably likely to occur were identified: microbial growth on incoming meat; presence of foreign material on non-meat food ingredients; presence of foreign materials in cans and packaging materials; presence of foreign materials after can washing; improper product formulation; improper filling of can; and, improper application of the thermal process and cooling.

The establishment HACCP team has chosen to have seven CCPs to address these seven hazards: temperature monitoring of incoming meat; visual inspection of incoming meat; letter of guaranty for non-meat food ingredients; visual inspection of non-meat food ingredients; visual inspection of cans and packaging on receipt; visual inspection of cans after exiting washer; and the processing authority specifications for product formulation, filling of cans, and the process schedule.

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. If the plant decided to use the current regulations for thermally processed, commercially sterile product to address bacterial hazards, only physical and chemical hazards would have to be addressed in the HACCP Plan. However, the team decided to address bacterial hazards in their plan and set limits that met or exceeded regulatory requirements.

Although meat would remain frozen below 32°F, the team decided that 10°F or below would be

more conservative and protective of the frozen product. There would be less chance of the product reaching thaw temperature before use and, thus, reducing the chance for temperature abuse.

In addition to the critical limit regarding metal in the packaging and non-metal containers, the team decided that any other visible hazardous non-food material, such as glass, was unacceptable not only at receipt of packaging materials and containers but also during the washing of the cans.

For non-meat ingredients, the bacterial spore load in spices is the bacteriological concern. However, the bacteriological load is incorporated before the non-meat ingredients reach the thermal processing establishment. The team therefore decided that purchase specifications and/or letters of guarantee would be the best method for controlling the bacterial hazards.

With respect to metal contamination, the team knew that their detector was capable of identifying particles as small as 1/32 of an inch, as long as it was working well. Therefore, they decided that their critical limit would be the capability of a properly functioning metal detector.

The processing authority determines the formulation, container filling, and thermal process and cooling specifications that will produce a safe and stable product. Therefore, the critical limits for these steps in processing are those specified by the processing authority for the specific product.

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

For their Receiving – Frozen Cooked Diced Beef and Non-meat Food Ingredient controls on incoming product, they decided the operational personnel who normally checked arriving products would check product temperature for each load. This individual would also visually inspect each load of frozen cooked diced beef, non-meat ingredients, and packaging in addition to checking letters of guarantee and ensuring that all goods are from approved suppliers. The team determined that this might be an excessive frequency for suppliers with good performance, and decided that when they validated their HACCP plan (by actually trying it out and recording results), they would consider whether another frequency should be used.

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 determined that since receiving personnel were performing the temperature checks on incoming meat, their supervisor would be a good person to involve in verification. He will review the temperature logs and receiving logs, and may either observe the employee taking the temperature or take a temperature of his own, once per shift.

There is a regulatory requirement (Part 417.4(a)(2)(i)) for including as a verification, the calibration of process-monitoring instruments; the thermometers being used to take the temperature checks are obviously process monitoring instruments, so someone outside the maintenance unit, in this case the Quality Assurance unit, will check those thermometers for accuracy on a daily basis, and calibrate them to within 1 degree as necessary.

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 team created a separate form to be used by the QA personnel who were checking the thermometers and calibrating them as necessary. Each employee who was performing a temperature check had a thermometer assigned to him, which was identifiable by its serial number. QA personnel picked up thermometers from employees throughout the day when employees were not using them, and checked them against a known standard; recalibration was performed immediately if it was necessary. There were only four different employees and different thermometers being used in the HACCP monitoring and verification activities, and they were to be checked once a day, so the HACCP team decided that this form could be used by QA for more than one day. QA personnel were located in a different part of the plant; employees delivered their thermometers to QA once a day immediately after they had performed a temperature check. QA checked the thermometer and returned it to the employee with a copy of the record showing results; in addition, QA e-mailed the results to the HACCP coordinator at the end of each day, and each time there was a variation of more than 2° F noted when the thermometer was checked.

The HACCP team also created a form to be used by employees with assigned tasks concerning the functioning of the metal detector. The Metal Detector Performance Log includes both monitoring and verification checks results; the form has entries from both the packaging supervisor and from QA personnel. The form is kept near the metal detector and is turned in to the HACCP coordinator at the end of each day.

The Process Operating Log was designed to include all the information required by the regulations Part 318.306. The team also designed a form to be used in the event of a deviation in processing. The Process Deviation Log includes date of the deviation, product information, and disposition of the product after evaluation by the processing authority.

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On its HACCP Plan, generic establishment X has listed the names of the forms it will be using for monitoring and verification records.

Another form is included in column four, where the establishment has described its recordkeeping system. That is the Corrective Actions Log; it is used to create the records of any corrective actions taken because of deviations from critical limits at CCPs. Column six references 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 specific corrective action plan which will be followed whenever there is a deviation from a critical limit at a CCP; each of the planned corrective actions meets the four regulatory requirements of 417.3(a). For example, this is the establishment's planned corrective action whenever there is a deviation from the thermal processing and cooling critical limit, i.e., an improper application of the process schedule as specified by the processing authority.

Planned Corrective Actions for CCP 9:

1. The plant designee will apply a filed alternate process schedule appropriate for the situation or

2. The plant designee will place product on hold pending evaluation of the process deviation by the processing authority.

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The HACCP team also develops planned corrective actions for each of the other CCPs and attaches them to the HACCP plan. Whenever a deviation from a critical limit occurs, company employees follow the corrective action plan and use the Corrective Action Log to create a record of their actions. The Corrective Action Log forms are available at CCPs, so they can be used immediately when an employee performing a monitoring check discovers and records a deviation. All Corrective Action 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 Action Logs to make sure all appropriate planned responses 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 which it has encountered 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.

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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 thermally processed, commercially sterile beef stew production process. They have secured a copy of FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to HACCP System Requirements, the HACCP Basic Compliance Checklist which 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 HACCP Teams

1. Agriculture Canada. *Food Safety Enhancement Program – HACCP Implementation Manual*. Camelot Drive, Nepean, Ontario, Canada, 1996.

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

   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. *Application of Modeling in HACCP Plan Development.* Int. J. Food Microbiol. 25:251-261, 1995.

4. Corlett, D.A., Jr. and Stier, R.F. *Risk Assessment within the HACCP System.* Food Control 2:71-72, 1991.

5. Council for Agriculture Science and Technology. *Risks Associated with Foodborne Pathogens.* February 1993.

6. Easter, M.C., *et al. The Role of HACCP in the Management of Food Safety and Quality.* J. Soc. Dairy Technol. 47:42-43, 1994.

7. Environmental Protection Agency. *Tolerances for Pesticides in Foods.* Title 40, Code of Federal Regulations, Part 185. U.S. Government Printing Office, Washington, D.C., 1998.

8. Food and Drug Administration. *The Food Defect Action Levels*. FDA/CFSAN. Washington, D.C., 1998.

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. *HACCP in Microbiological Safety and Quality.* Blackwell Scientific Publications, Oxford, 1988.

    Useful sections in particular are:

Thermally Processed, Commercially Sterile

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. *Microorganisms in Foods 4. Application of Hazard Analysis and Critical Control Point (HACCP) Systems to Ensure Microbiological Safety and Quality*. Blackwell Scientific Publications, Boston, 1989

12. National Advisory Committee on Microbiological Criteria for Foods. *March 20, 1992 -- Hazard Analysis and Critical Control Point System.* Int. J. Food Microbiol. 16: 1-23, 1993.

13. National Advisory Committee on Microbiological Criteria for Foods. Adopted August 14, 1997-- *Hazard Analysis and Critical Control Point Principles and Application Guidelines.* J. Food Protect. 61(9): 1246-1259, 1998.

14. National Advisory Committee on Microbiological Criteria for Foods. DRAFT document - *FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants.* 1-22, August 1999.

15. National Advisory Committee on Microbiological Criteria for Foods. *June 1993 -- Report on Generic HACCP for Raw Beef.* Food Microbiol. 10: 449-488, 1994.

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

    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., et al. *The HACCP Concept: Identification of Potentially Hazardous Microorganisms.* Food Microbiol. 11:203-214, 1994.

18. Pierson M.D. and Dutson, T. Editors. *HACCP in Meat, Poultry, and Fish Processing.* Blackie Academic & Professional. Glasgow, 1995.

    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

Thermally Processed, Commercially Sterile

Chapter 13 – predictive modeling, pp. 330-354

19. Pierson, M.D. and Corlett, D.A., Jr. Editors. *HACCP Principles and Applications*. Van Nostrand Reinhold, New York, 1992.

20. Stevenson, K.E. and Bernard, D.T. Editors. *HACCP: Establishing Hazard Analysis Critical Control Point Programs, A Workshop Manual.* The Food Processors Institute, Washington, D.C., 1995.

    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. *HACCP: A Systematic Approach to Food Safety. 3rd Edition.* The Food Processors Institute, Washington, D.C., 1999.

22. Tompkin, R.B. *The Use of HACCP in the Production of Meat and Poultry Products.* J. Food Protect. 53(9): 795-803, 1990.

23. Tompkin, R.B. *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, 1995.

References for Thermally Processed, Commercially Sterile Meat and Poultry Products

Part I – Epidemiology of Foodborne Illness

1. Barker, W. H., Jr., J. B. Weissman, V. R. Dowell Jr., L. Gutmann, and D. A. Kautter. *Type B botulism outbreak caused by a commercial food product. West Virginia and Pennsylvania, 1973.* JAMA 237(5):456-459, 1977.

2. Billon, J., A. Perpezat, and M. Charrier. *[Studies on 114 cases of food poisoning.]* Medecine et Nutrition 13(4):277-280, 1977.

3. Blake, P. A., M. A. Horwitz, L. Hopkins, G. L. Lombard, J. E. McCroan, J. C. Prucha, J.C. and M. H. Merson. *Type A botulism from commercially canned beef stew.* South. Med. J. 70(1):5-7, 1977.

4. Gilbert, R. J., J. L. Kolvin, and D. Roberts. *Canned foods – the problems of food poisoning and spoilage.* Health and Hygiene 4(2/3/4):41-47, 1982.

5. Guilfoyle, D. E. and J. F. Yager. *Survey of infant foods for Clostridium botulinum spores.* J. Association Official Analytical Chemists 66(5):1302-1304, 1983.

6. Odlaug, T. E. and I. J. Pflug. *Clostridium botulinum and acid foods.* J. Food Protect. 41(7):566-573, 1978.

7. Osherhoff, B. J., G. G. Slocum, and W. M. Decker. *Status of botulism in the United States.* Public Health Reports 79(10):871-878, 1964.

8. Sours, H. E. and D. G. Smith. *Outbreaks of foodborne disease in the United States, 1972-1978*. J. Infect. Dis. 142(1):122-125, 1980.

9. Stersky, A., E. Todd, and H. F. Pivnick. *Food poisoning associated with post-process leakage (PPL) in canned foods.* J. Food Protect. *43(6):465-476, 483, 1980.*

10. Terranova, W., J. G. Breman, R. P. Locey, S. B. Speck. *Botulism type B: epidemiologic aspects of an extensive outbreak.* Am. J. Epidemiol. 108(2):150-156, 1978.

11. Thompson, R. C. *A tin of salmon had but a tiny hole.* FDA Consumer 16(5).7-9, 1982.

Part II – Product Spoilage

1. Ashton, D. H. *Thermophilic organisms involved in food spoilage: thermophilic anaerobes not producing hydrogen sulfide.* J. Food Protect. 44(2):146-148, 1981.

2. Davidson, P. M., I. J. Pflug, and G. M. M. Smith. *Microbiological analysis of food product in swelled can of low-acid foods collected from supermarkets.* J. Food Protect. 44(9):686-691, 1981.

3. Howitz, M. A., J. S. Marr, M. H. Merson, V. R. Dowell, and J. M. Ellis. *A continuing common-source outbreak of botulism in a family.* Lancet 2(7940):861-863, 1975.

Thermally Processed, Commercially Sterile

4. Lake, D. E., R. R. Graves, R. S. Lesniewski, and J. E. Anderson. *Post-processing spoilage of low-acid canned foods by mesophilic sporeformers.* J. Food Protect. 48(3):221-226, 1985.

5. Lynt, R. K., D. A. Kautter, and R. B. Read, Jr. *Botulism in commercially canned foods.* J. Milk Food Technol. 38(9):546-550, 1975.

6. Matsuda, N., M. Komaki, R. Ichikawa, and S. Gotoh. *[Cause of microbial spoilage of canned foods analysed during 1968-1980.]* J. Japanese Society Food Science Technology 32(6):444-449, 1985.

7. McDaniel, M. R., R. Diamant, E. R. Loewen, and D. H. Berg. *Dangerous canning practices in Manitoba.* Canadian J. Public Health 72(1):58-62, 1981.

8. Pflug, I. J., P. M. Davidson, and R. G. Holcomb. *Incidence of canned food spoilage at the retail level.* J. Food Protect. 44(9):682-685, 1981.

9. Rhodehamel, E. J., N. R. Reddy, and M. D. Pierson. *Botulism: the causative agent and its control in foods.* Food Control 3(3):125-143, 1992.

10. Tsai, S. J., Y. C. Chang, J. D. Wang, and J. H. Chou. Outbreak of type A botulism caused by a commercial food product in Taiwan: clinical and epidemiological investigations. Chung Hua I Hsueh Tsa Chih. 46(1):43-48, 1990.

11. United States of America, National Food Processors Association/Can Manufacturing Institute, Container Integrity Task Force. *Botulism risk from post-processing contamination of commercially canned foods in metal containers. NFPA/CMI container integrity task force, microbiological assessment group report.* J. Food Protect. 47(10):801-816, 1984.

Part III – Physical and Chemical Contamination

1. Andres, C. *Food processors benefit from 2-piece vs. 3-piece can technology race.* Food Processing 42(6):124-126, 1981.

2. Barbieri, G. *[Tinplate cans for foods, soldered with Pb/Sn alloys.]* Rivista della Societa Italiana de Scienza dell'Alimentazione 12(2):125-126, 1983.

3. Biffoli, R. et al. *[Contamination of canned foods with metals.]* Rivista della Societa Italiana de Scienza dell'Alimentazione 9(4):241-246, 1980.

4. Brand, N. G. *[Broken glass in bottles.]* Brygmesteren 35(2):55-56, 1978.

Thermally Processed, Commercially Sterile

5. Gibson, R. *[Food contamination is not an isolated occurrence.]* Voedingsmiddelentechnologie 26(24):23, 1993.

6. Jorhem, L. and S. Slorach. *[Less lead and tin in canned foods.]* Var Foeda 43(6):312-316, 337, 1991.

7. Lopez-Martinez, C., et al. *[Levels of Pb contamination in canned foods: meat, sea-foods, vegetables and prepared dishes.]* Anales de Bromatologia 39(2):239-246, 1987.

8. Ludwigsen, R. J. *Container contribution to lead in canned foods.* Rivista della Societa Italiana de Scienza dell'Alimentazione 11(6):369-382, 1982.

9. Prosic, Z., et al. *[Organochlorine pesticides in canned meat.]* Hrana I Ishrana 28(4):199-202, 1987.

10. Renesse, R. L., van and J. W. Klumper. *[Glass in foods: prevention is not always possible.]* Voedingsmiddelentechnologie 26(24):31-34, 1993.

11. Sanchez-Saez, J. J., et al. *[Pb and Cu contents of canned cooked meals.]* Boletin del Centro Nacional de Alimentacion y Nutricion No. 5, 14-17, 1981.

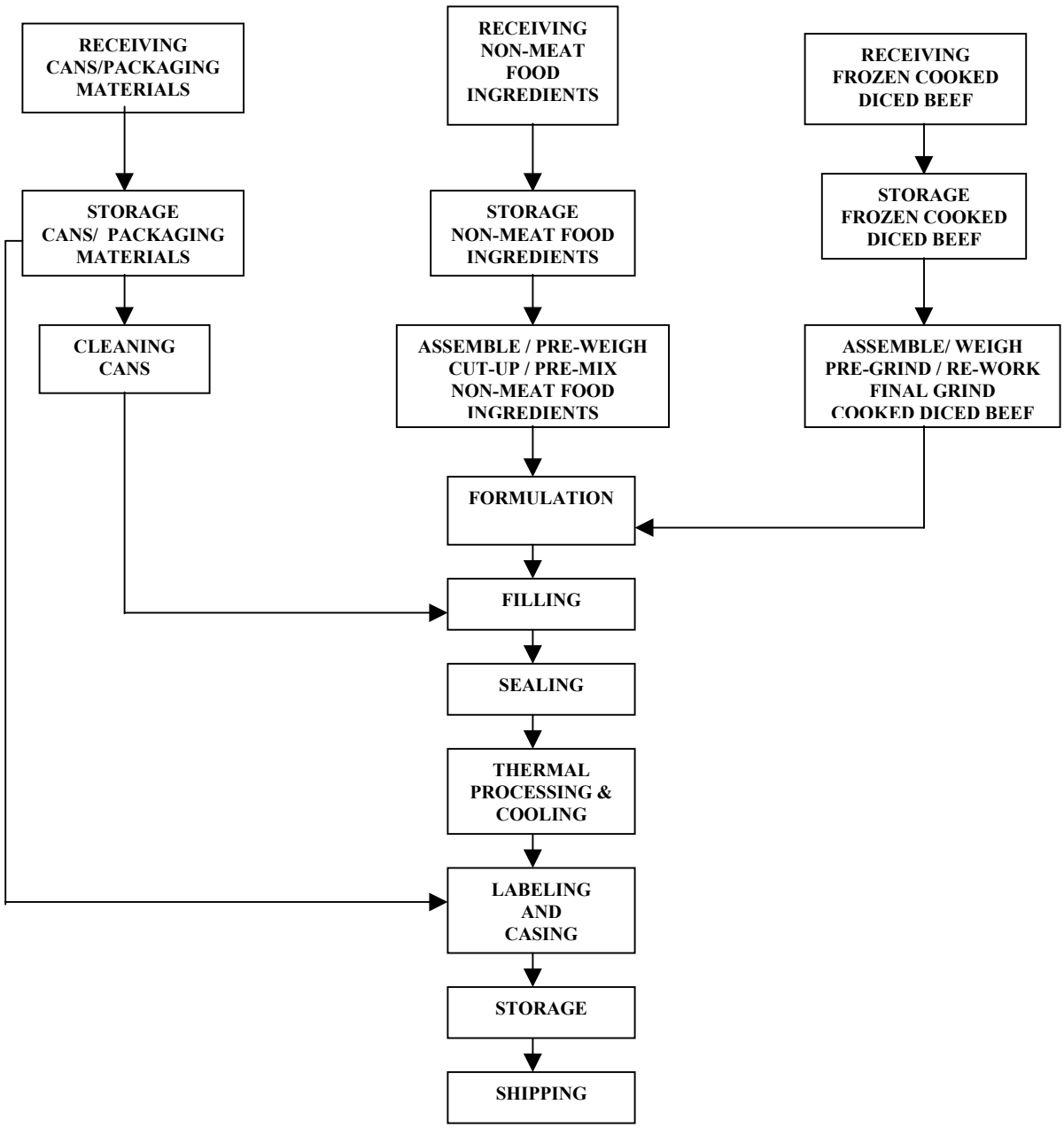
12. Thomas, G. *[Measures for prevention of contamination of canned foods.]* Revue Francaise de Dietetique 18(71):27-31, 1974.

13. Yokomizo, Y. *[Contamination of processed foods with pesticide residues.]* Boletin del Centro Nacional de Alimentacion y Nutricion 16(1):41-51, 1979.

APPENDIX B

PROCESS FLOW DIAGRAM Figure 1

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE
PRODUCT: BEEF STEW



PRODUCT DESCRIPTION **Figure 2**

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE PRODUCT: BEEF STEW	
1. COMMON NAME?	BEEF STEW
2. HOW IS IT TO BE USED?	PRODUCT IS READY-TO-EAT; TYPICALLY HEATED BEFORE CONSUMPTION. INTENDED FOR PERSONS WITHOUT SPECIAL DIETARY REQUIREMENTS OR PROBLEMS
3. TYPE OF PACKAGE?	METAL, DOUBLE-SEAMED("SANITARY") CAN
4. LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?	2-3 YEARS UNDER COOL (e.g., 75°F OR LOWER), DRY CONDITIONS; MUST BE PROTECTED FROM FREEZING
5. WHERE WILL IT BE SOLD? CONSUMERS? INTENDED USE?	RETAIL GENERAL PUBLIC HEAT AND CONSUME
6. LABELING INSTRUCTIONS?	NO SPECIAL INSTRUCTIONS
7. IS SPECIAL DISTRIBUTION CONTROL NEEDED?	NONE REQUIRED

HAZARD ANALYSIS – THERMALLY PROCESSED, COMMERCIALLY STERILE – Beef Stew

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 – Frozen Cooked Diced Beef	**Biological:** *Listeria monocytogenes*	**Yes**	**Growth of pathogens due to improper temperature and handling.**	**Measure and record temperature of incoming lots. Check container integrity.**	**1B**
	Chemical – Antibiotic and pesticide residues.	**No**	**Supplied by inspected establishments.**		
	Physical – Foreign materials	**No**	**Pieces of broken glass, metal, or plastic has been found in product in the past.**	**Visual examination**	**2P**
Receiving – Non-meat Food Ingredients	**Biological – Bacterial spores** *Clostridium botulinum*	**No**	**The bacterial spore load is controlled at the establishment by the thermal process sufficient to destroy $\geq 10^{12}$ spores of** *Clostridium botulinum***.**	**Proper application of the thermal process**	
	Chemical –Pesticides	**No**	**Plant records show that there has not been a problem in the past.**		
	Physical – wood, metal in dried beans, potatoes, etc.	**Yes**	**Pieces of broken glass, metal, or plastic have been found in ingredients in the past.**	**Visual examination and metal detectors used at receiving.**	**3P**

Figure 3

HAZARD ANALYSIS – THERMALLY PROCESSED, COMMERCIALLY STERILE – Beef Stew

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 – Cans/ Packaging Materials	**Biological – None**				
	Chemical – None				
	Physical –Foreign Material	**Yes**	**Wood, metal, or glass may get on the cans during storage and shipping if protective packaging or containers are damaged.**	**Control can be applied most effectively at process steps where cans are inverted and cleaned.**	
Storage -Frozen Cooked Diced Beef	**Biological - Pathogens**	**No**	**Pathogens are not reasonably likely to grow in this product if temperature is maintained at or below a level sufficient to preclude their growth.**		
	Chemical – None				
	Physical – None				
Storage – Non-meat Food Ingredients	**Biological – None**				
	Chemical – None				
	Physical - None				

Figure 3

HAZARD ANALYSIS – THERMALLY PROCESSED, COMMERCIALLY STERILE – Beef Stew

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 – Cans/ Packaging Materials	Biological - None				
	Chemical – Chemicals	No	Packing materials stored in a location that does not allow chemical contamination.		
	Physical – Foreign Material	No	Packing materials stored in a location that does not allow foreign material contamination.		
Assemble /Weigh Pre-grind / Re-work Final Grind – Cooked Diced Beef	Biological – None				
	Chemical – None				
	Physical - None				
Assemble / Pre-weigh Cut-up / Pre-mix Non-meat Food Ingredients	Biological – None				
	Chemical- None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – THERMALLY PROCESSED, COMMERCIALLY STERILE – Beef Stew

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
Cleaning Cans	**Biological --None**				
	Chemical – None				
	Physical – Foreign Material	**Yes**	**Foreign material in container.**	**Control of cleaning operation. Use of removable can twists.**	**4P**
Formulation	**Biological – Improper formulation may allow survival of *Clostridium botulinum* spores.**	**Yes**	**Improper application of thermal process may allow the survival of *Clostridium botulinum* spores.**	**Operational formulation controls as defined by a Process Authority.**	**5B**
	Chemical – None				
	Physical - None				
Filling	**Biological – Improper Fill**	**Yes**	**If the containers are not filled per the processing authority's recommendations, the thermal process may be inadequate.**	**Operational filling controls.**	**6B**
	Chemical- None				
	Physical – None				

Figure 3

HAZARD ANALYSIS – THERMALLY PROCESSED, COMMERCIALLY STERILE – Beef Stew

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
Sealing	**Biological – None**				
	Chemical- None				
	Physical – None				
Thermal Processing and Cooling	**Biological – Survival of** *Clostridium botulinum* **spores due to inadequate process.**	**Yes**	**Improper application of thermal process may allow the survival of** *Clostridium botulinum* **spores.**	**Operational thermal processing controls.**	**7B**
	Chemical- None				
	Physical – None				
Labeling and Casing	**Biological – None**				
	Chemical- None				
	Physical – None				
Storage	**Biological – None**				
	Chemical- None				
	Physical – None				
Shipping	**Biological – None**				
	Chemical- None				
	Physical – None				

Figure 3

HACCP PLAN

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE
PRODUCT EXAMPLE: BEEF STEW

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
1B Receiving – Frozen Cooked Diced Beef	Temperature within plant specifications. Meat must be received at 10°F or below to maintain in frozen state.	Receiver will check the temperature of each load of meat received. Results will be recorded, initialed, signed & dated in the Product Temperature Receiving Log.	Product Temperature Receiving Log Thermometer Calibration Log Corrective Action Log	Receiving supervisor will observe receiving employee taking product temperature or will take product temperature once per shift Receiving supervisor will review Product Temperature Receiving Log, Corrective Action Log, Calibration Log & Verification records once per shift. QA will check all thermometers used for monitoring and verification for accuracy daily and calibrate to within 2° F accuracy as necessary.	Receiver will hold meat that exceeds 10°F and notify supervisor. Any rejected meat will be returned to supplier. Supplier history will be reviewed. Condemned meat will be denatured at the plant.

Signature : _____ **Date:**_____

Figure 4

HACCP PLAN

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE
PRODUCT EXAMPLE: BEEF STEW

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
2P Receiving – Frozen Cooked Diced Beef	No visible hazardous foreign material (e.g., glass); no visible metal contamination.	Receiver will visually examine a random sample from each lot received for foreign material.	Receiving Log Corrective Action Log	QA supervisor will review Receiving Log twice per shift. QA supervisor will observe visual inspection of incoming product by receiver once per shift.	Receiver will ensure that all meat received is from establishments on company approved list. Supplier history will be reviewed and if there is a trend in supplier inability to meet the critical limit, the supplier will no longer be used. If hazardous foreign material is detected in or on the meat, QA will identify and control affected product for disposition; condemn or return controlled product to supplier. QA will take action to prevent reoccurrence.

Signature : _____ **Date:**_____

Figure 4

HACCP PLAN

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE
PRODUCT EXAMPLE: BEEF STEW

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
3P Receiving - Non-meat Food Ingredients	No visible hazardous foreign material (e.g., glass); no metal contamination ∃1/32 inch.	Receiver will examine each lot for foreign material using metal detector and visual examination. QA will examine a random sample from each lot for foreign material using metal detector and visual examination.	Receiving Log Metal Detector Log Corrective Action Log	Maintenance supervisor will verify metal detectors are functioning. QA will verify that the metal detectors are functioning as intended by running a seeded sample through the metal detectors twice per shift (once in the AM and once in the PM).	Receiving supervisor will control and segregate affected product. Maintenance personnel will identify and eliminate the problems with the metal detectors. Preventive maintenance program will be implemented. QA will run a seeded sample through the metal detectors after repair.

Signature : _____ **Date:**_____

Figure 4

HACCP PLAN

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE
PRODUCT EXAMPLE: BEEF STEW

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
4P Cleaning Cans	No visible hazardous foreign material (e.g., glass, metal).	Can washer operator will visually examine cans as they exit washer to ensure unit is operating properly and cans are adequately cleaned. QA will randomly visually check cans as they exit washer at a frequency determined using a statistical randomization chart. Daily check to determine that can twists are installed & working properly.	Can Washer Log Corrective Action Log	QA supervisor will review Can Washer Log and Corrective Action Log twice per shift. QA supervisor will observe can washer operator. Maintenance will verify can twists are properly installed and operating on a weekly basis.	If can washer or can twist malfunctions, operator will stop line, remove uncleaned cans, and notify plant designee. When proper functioning is restored, cans removed will be examined by QA, then recycled through washer. QA will take action to prevent reoccurrence. Maintenance will make appropriate repairs to cleaners or twists and alter maintenance schedule as required.

Signature : _____ **Date:**_____

Figure 4

HACCP PLAN

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE
PRODUCT EXAMPLE: BEEF STEW

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
5B Formulation	Criteria as specified by the Processing Authority (e.g. maximum sauce viscosity value).	Head formulation cook will check ingredient characteristics, quantities, sauce viscosity and conformance with specified formulation procedure for each batch prepared. Plant designee will check the time elapsed from assembly to commercial sterilization for each batch to determine that it meets limits specified by the processing authority. *	Formulation Log Process Deviation Log Corrective Action Log	QA will review the formulation log twice a week to verify that every batch is properly formulated. QA will audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limits are adequate for hazard; assure corrective actions are adequate, document findings.	Head formulation cook will not pass batch for transfer to the filler that has not been formulated correctly or has exceeded the time specification. If possible, rejected batches will be reformulated. Otherwise, the product will be condemned. QA will take action to prevent reoccurrence.

***** Time elapsed will not always be specified as critical factor by a Processing Authority.

Signature : _____ **Date:**_____

Figure 4

HACCP PLAN

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE
PRODUCT EXAMPLE: BEEF STEW

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
6B Filling	Criteria as specified by the Processing Authority (e.g. maximum fill weight).	Fill operator will ensure that filled containers are run through an automatic over/under check weigher set to reject above the weight limit once per hour. Also, the "toppers" on the seamer will be set to produce headspace in excess of prescribed minimum.	Weight / Headspace Log Process Deviation Log Corrective Action Log	QA will review the records and twice weekly verify the accuracy and measure sample weights and headspaces daily to ensure that weight and headspace standards are met. QA will audit to verify sampling techniques and accuracy of the records; determine if the critical limit corresponds to the plant records; check to see if critical limits are adequate for hazard; assure corrective actions are adequate, document findings. Weekly calibration of filler.	Production foreman and QA will ensure that all rejected containers are emptied and contents reworked or condemned. QA will take action to prevent reoccurrence.

Signature : _____ **Date:**_____

Figure 4

HACCP PLAN

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE
PRODUCT EXAMPLE: BEEF STEW

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
7B Thermal Processing and Cooling	Criteria as specified by the Processing Authority (e.g. minimum product initial temperature, minimum retort temperature, minimum process time, etc.).	Retort operator will monitor and record thermal processing conditions at intervals determined to be sufficient by the processing authority to ensure that the process schedule is properly applied, including process application, venting procedures.	Process Operating Log Recorder Charts Process Deviation Log Corrective Action Log	QA will review the logs and charts within one working day after the thermal process. QA will audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limits are adequate for hazard; assure corrective actions are adequate, document findings. Quarterly calibration of retort.	If a process deviation occurs, the plant designee will apply a filed alternate process schedule appropriate for the situation or hold the product pending a processing authority's evaluation. QA will take action to prevent reoccurrence. Product will be reworked if applicable using the alternate process schedule.

Signature : _____ **Date:**_____

Figure 4

THERMOMETER CALIBRATION LOG

Calibrate to 32^0 F while thermometer is in slush ice water.

Date	Time	Department or Area	Thermometer ID#	Personal Thermometer Reading	Adjustment Required (Yes or No)	Initials	Comments

- **If a thermometer is broken or taken out of service, document this in the comment column**.

Reviewed by: _____ Date: _____

GENERIC ESTABLISHMENT X: METAL DETECTION LOG

Date	Product	Lot #	Results	Seeded Sample	Time	Monitored By	Verified By

GENERIC ESTABLISHMENT X: PROCESS OPERATING LOG

Product _____
Code _____
Can Size _____
No. Cans/Retort _____
Min. Product Int. Temp. _____
Process Time/Temperature _____/_____

Retort Operator _____
Date _____

Batch No.	**Retort No.**	**Int Temp**	**Time Steam On**	**Time Vent Closed**	**Retort Temp at End of Vent**	**Actual Process Time**			**Temperature**		**Initial**
						Start	**Stop**	**Total**	**MIG**	**Chart**	

GENERIC ESTABLISHMENT X: PROCESS DEVIATION LOG

Date of Deviation	Retort No.	Product	Product Code	Product Disposition	Reviewed by:

CORRECTIVE ACTIONS LOG

Product: _____ **Lot # _____**

CCP	Deviation/ Problem	Corrective Action Procedures/Explain	Disposition of Product	Responsible Person	Date/Time

SIGNATURE: _____ **DATE: _____**

PRE-SHIPMENT REVIEW LOG

Date:_____

PRODUCT	LOT ID	TIME RECORDS REVIEWED	BY WHOM	LOT RELEASED FOR SHIPMENT? SIGNATURE	COMMENTS *

*Monitoring frequency as per plan; Critical limits met; Certification (if applicable) as per plan; Deviations if occurred were reviewed for appropriate corrective actions; Records complete and accurate.