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HACCP-7

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

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Introduction

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

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

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

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

Principles of HACCP

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

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

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

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

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

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

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

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

Definitions

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

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

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

Critical Control Point (CCP). A point, step, or procedure at which control can be applied and as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

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

Deviation. Failure to meet a critical limit.

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

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

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

Hazard (Food Safety). Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

Hazard Analysis. The identification of any hazardous biological, chemical, or physical properties in raw materials and processing steps, and an assessment of their likely occurrence and potential to cause food to be unsafe for consumption.

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

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

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

Development of the Plant Specific HACCP Plan

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

PRELIMINARY STEPS

1) Assemble the HACCP team.
2) Describe the food and its method of distribution.
3) Identify the intended use and consumers of the food.
4) Develop a flow diagram which describes the process.
5) Verify the flow diagram.

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

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

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

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

following the production steps involved in the particular product or process.

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

Remember that in your hazard analysis there are three categories of hazards to consider: chemical, biological, and physical, Appendix 3 includes a table of hazards that are controlled in a HACCP program. Each process step will be evaluated to determine if significant hazards from one or more of these categories are present. The hazards will be listed at each process step along with the specific preventive measures that can control the hazard. For example, if your plant-specific HACCP plan identifies foreign material as a physical hazard for receiving non-meat ingredients, a preventive measure must be included ensuring that the materials are handled and stored in a manner so as not to contaminate the product.

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

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

[1] NACMCF, HACCP, 1992

hazards have been addressed.

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

HACCP Plan Development: This portion of the plan development will be used to designate the specific activities, frequencies, critical limits, and corrective actions that ensure that your process is under control and adequate to produce a safe product. This part will include all the information gathered to this point in your plan development process steps. In addition, the HACCP plan will include specification of critical limits. These limits will be specified after the identification of the CCP's for the process and will be listed in the HACCP Plan. The critical limit must, at a minimum, meet the regulatory requirement for that specific process step if one exists. An equivalent limit based on a process or technology proven to render the product unadulterated may also be used.

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

A copy of the Decision Tree developed by the NACMCF is included at the end of this section. The use of the Decision Tree is optional. The questions in the Decision Tree are listed at the top of each page of the CCP Determination form of the generic model. These questions should be answered when identifying critical control points for your HACCP plan. Remember that the HACCP plan should cover health and safety CCP's, not economic and quality concerns. A CCP should be identified when it presents a significant hazard and has a significant likelihood of occurrence. Hazards that are unlikely to occur or do not present significant hazards will not be considered during Hazard Analysis and, therefore, will not be identified as a CCP.

Remember that HACCP is a system of process control for the plant and not an inspection system. The creation of the plant-specific plan and its successful operation is the responsibility of each establishment. The plant-specific plan that you have developed will be used to help you monitor your process. The plan should be reassessed routinely by the plant to determine if updates are needed. Such cases may include, but are not limited to changes in: the types products produced; a process such as in raw materials or their source; product formulation; processing or slaughter methods or systems; production volume; packaging; finished product distribution systems; the intended use or consumers of the finished product; or it is determined that the plan does not adequately ensure process control, defined as when critical limits are not being met. Revision of the HACCP plan should be conducted with the advice and assistance of an individual trained to meet the requirement in 9CFR 417.7.

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

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

Steps for Selecting a Generic Process Model

Process Platform for Use of Generic Models

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

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

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

1) Make a list of all products produced in the plant. Examine the list and group all like products according to common processing steps and equipment used. Compare these to the list of Process Models in Appendix 1. After reviewing and grouping the products produced, you will know the number of models that are needed to develop your plant-specific plans.

2) Refer to the process flow chart (Appendix 2). This will show which process models will fit your product(s) groups most closely. To use the flow chart effectively, move in a step-by-step fashion by asking yourself these questions:

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

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

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

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

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

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

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

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

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

> If a product is not shelf stable but fully cooked, then the "Generic HACCP Model for Fully Cooked, Not Shelf-Stable Meat and Poultry Products" model will be most useful. "Fully Cooked" implies that the process includes an acceptable heat treatment that renders a final product ready to eat without further cooking, although the product may be warmed or reheated by the consumer.
>
> If a product is not shelf stable and not fully cooked, but receives other processing that does not involve a heat treatment, the model "Generic HACCP Model for Meat and Poultry Products with Secondary Inhibitors, Not Shelf-Stable" will be most useful. If some heat treatment is involved in the process that does not result in a fully cooked product - for example, a cold smoke - the generic model "Heat Treated Not Fully Cooked Not Shelf Stable Meat and Poultry Products" will be most useful.
>
> If a product is not shelf stable and is raw, the "Raw, Ground Meat and Poultry Products" or "Raw, Not Ground Meat and Poultry Products" models will be most useful. Products in the "Raw-Not Ground" category may contain process steps in addition to cutting, boning, or breaking, but should not contain a process step that significantly alters the raw nature of the product. Products in the "Raw, Ground" process category are subjected to the grinding process and may include products such as fresh sausage.

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

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

Model Plan for Thermally Processed/Commercially Sterile

Hazard Analysis

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

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

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

The biological, chemical, or physical hazard information gathered will aid in determining where a hazard may occur in the process, what could cause the hazard, how it can

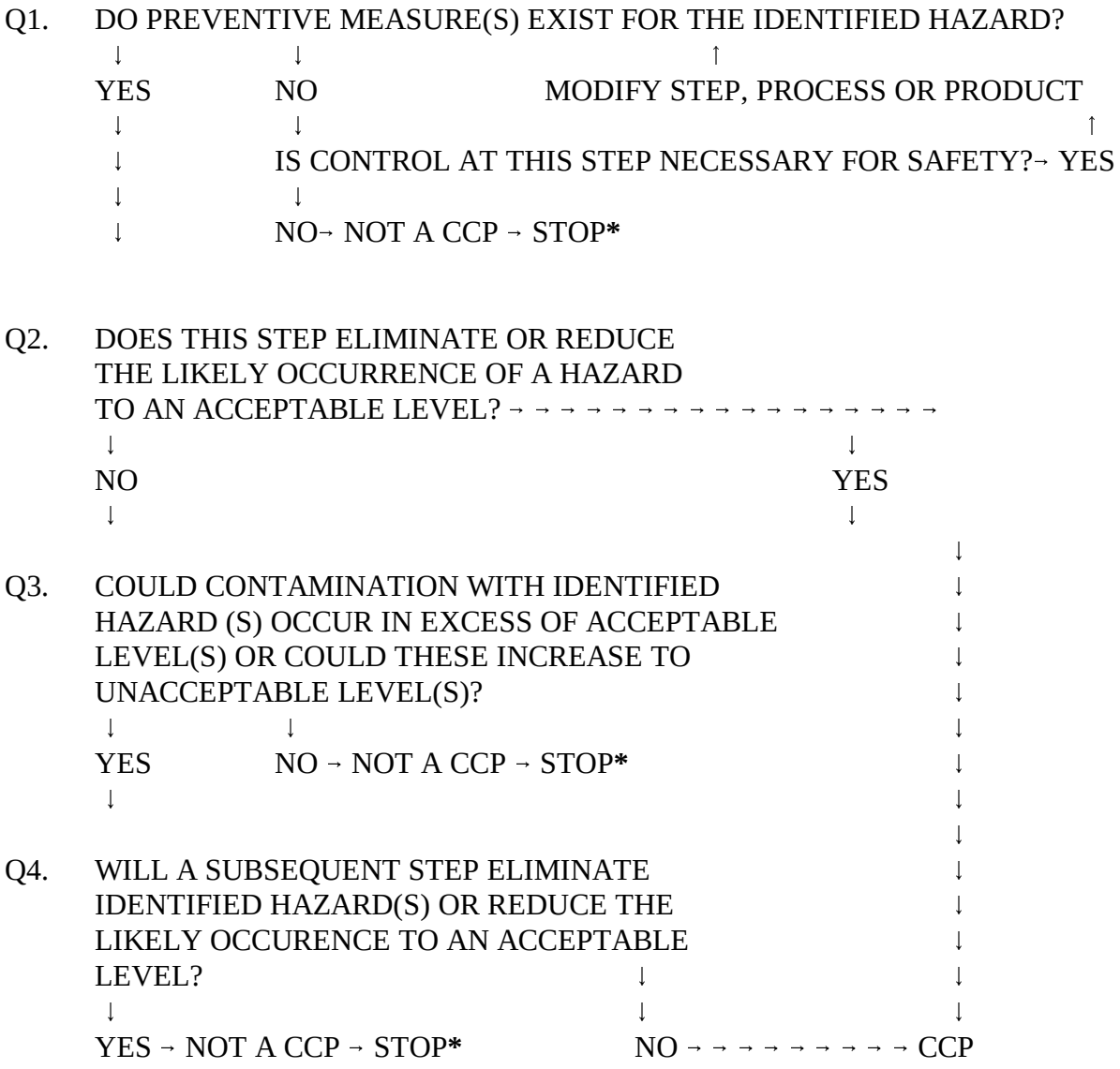
be prevented, and actions to be taken if conditions which could result in a hazard occur. Information on physical hazards may be more general and may consist simply of items found in foods that are injurious to human health such as glass, metal, broken needles, etc. The evaluation of physical hazards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

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

Appendix 1

CCP DECISION TREE

(Apply at each step of the process with an identified hazard.)



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

Preparing Your HACCP Plan

Assemble the HACCP team.

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

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

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

1. HACCP in Meat, Poultry and Fish Processing. 1995. eds. Pearson and Dutson. Blackie Academic and Professional, Glasgow.

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

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

4. A Complete Course in Canning. 13th ed.. 1996. D. Dowing (Ed.), CJJ Publications.

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

Process Description Form

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

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

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

PROCESS DESCRIPTION

PROCESS CATEGORY : THERMALLY PROCESSED, COMMERCIALLY STERILE

PRODUCT EXAMPLE : BEEF STEW

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

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.

Product and Ingredients Form

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

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

LIST PRODUCT(S) AND INGREDIENTS

PROCESS CATEGORY: THERMALLY PROCESSED-COMMERCIALLY STERILE

PRODUCT EXAMPLE : BEEF STEW

MEAT*

FROZEN COOKED DICED BEEF

INGREDIENTS*

FROZEN SLICED CARROTS
FROZEN DICED POTATOES
FROZEN SLICED CELERY

REFRIGERATED ONION JUICE CONC.
REFRIGERATED GARLIC PUREE

VEGETABLE OIL
STARCH
HVP
PLANT GUM
DEHY. BEEF STOCK
SALT
SPICE MIX
WORCESTERSHIRE SAUCE

*The dice size of the ingredients should be listed in a specific plan if it is a critical formulation factor. Amounts of each ingredient may also be included.

Process Flow Diagram

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

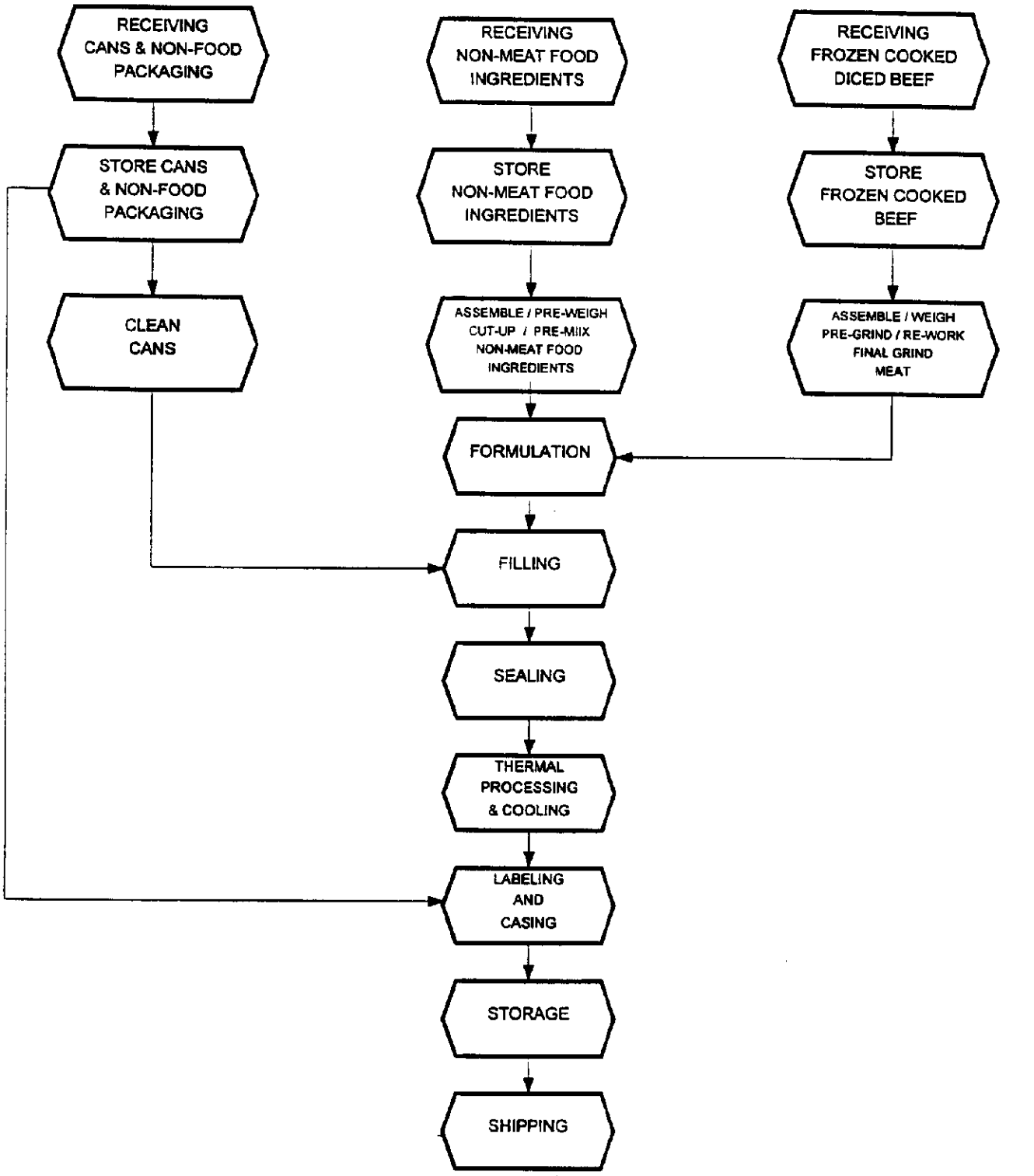
The flow diagram must cover all the steps in the process which are directly under the control of the establishment. It can also include steps in the food chain which are before and after the processing that occurs. For the sake of simplicity, the flow diagram should consist solely of words, not engineering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

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

PROCESS FLOW DIAGRAM

PROCESS CATEGORY: THERMALLY PROCESSED/COMMERCIALLY STERILE

PRODUCT: BEEF STEW



Hazard Analysis/Preventive Measures Form

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

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

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

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

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

HAZARD ANALYSIS/PREVENTIVE MEASURES

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

Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures	Examples of How Hazard Is Introduced *
RECEIVING - FROZEN COOKED DICED BEEF	B- Excessive microbial load *(staphylococcus aureus*) due to improper temperature and handling.	Measure and record temperature of incoming lots. Check container integrity.	B-Transport refrigeration unit is not functioning properly (out of freon).
	C-Antibiotic and pesticide residues.	Supplied by inspected establishments.	B-The shipping container (the cardboard combo bin) was crushed by a forklift and the immediate container (the film wrapped around the individual trays) was torn and punctured introducing harmful microbes into the product.
	P- (Foreign Material) - Visible hazardous foreign material that could compromise product safety.	Provided by supplier inspected establishments and visual examinations.	P-Pieces of glass found in product from a broken light bulb, metal clips, knives, plastic, etc.
RECEIVING - NON-MEAT INGREDIENTS	B-Excessive bacteriological (spore) load. Meat and Poultry Products Hazard and Control Guide.	Verify that the letter of guarantee is on file and appropriate for product use from third party audit of a supplier or other means. Suppliers letter of guarantee and ingredient specification.	B-Spices have not received a treatment to reduce or eliminate bacteriological (spore) load.
	C- Pesticide		C-Improper pesticide usage by producers and previous processors.
	P- (Foreign Material) - Visible hazardous foreign material that could compromise product safety; metal, glass , etc.		P-Pieces of glass found in product from a broken light bulb, metal clips, knives, etc. when received from supplier.
	P- (Foreign Material/Adulteration) - All non-meat ingredients, packaging materials, etc. must be stored to prevent contamination due to foreign material.		
RECEIVING - CANS	P (Foreign Materials) - Visible hazardous foreign material that could compromise product safety; metal, and other materials.	Suppliers' letters of guarantee and cleaning step.	P-Dirt, wood, metal or glass may get on the cans during storage and shipping if protective packaging or containers are damaged.
STORAGE - MEAT	B- Insufficient control of cooling during storage could result in unacceptable levels of pathogens.	Monitor the internal product temperature to ensure that it is maintained at or below a level sufficient to preclude microbial growth.	B- Product is stored in such a manner that the cooler does not keep some boxed beef at an unacceptable temperature permitting excess microbial growth.
STORAGE - NON-MEAT	No significant hazards identified that are likely to occur.		
STORAGE - PACKAGING	C- Chemicals P- Packaging materials are stored in a location or manner that allows contamination from foreign material or chemicals.	Verify that packaging materials are stored separately from chemicals and are kept covered and not directly contacting floors or walls.	C- Packaging materials are stored on the same shelf with open buckets of boiler cleaning compounds.

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

HAZARD ANALYSIS/PREVENTIVE MEASURES

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

Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures	Examples of How Hazard Is Introduced *
PREPARATION - MEAT	Significant hazards are not likely to occur	Physical or chemical hazards from equipment or facilities shoul be prevented by routine maintenance (GMP's).	Physical hazards from lack of equipment or facility maintenance.
PREPARATION - NON-MEAT	No significant hazards likely to occur identified		
CAN CLEANING	P (Foreign Material) -Foreign material remains. C-No significant hazards - toxic metal poisoning not likely to occur.	Cleaning operation.	P-The foreign material present at receiving plus any that may have entered the containers during storage and handling since then remains in the container.
FORMULATION	B-If not formulated per processing authority's recommendations, the thermal process may be inadequate.	Operational formulation controls.	B-The wrong type of starch is used in formulating a gravy or too much of a dry ingredient is used.
FILLING	B-If not filled per processing authority's recommendations, the thermal process may be inadequate.	Operational filling controls.	B-In a two-stage fill, too many solids such as potatoes, carrots, etc., are filled leaving insufficient volume for the proper amount of gravy
SEALING	No significant hazards likely to occur identified.		
THERMAL PROCESSING AND COOLING	B-Improper application of the thermal process may not provide sufficient lethality to achieve shelf stability.	Operational thermal processing controls.	B-Retort temperature drops, the thermal process is terminated early, the retort is not vented properly, condensate accumulates in the retort, cooling water enters the retort during cooking.
LABELING AND CASING	No significant hazards, likely to occur identified.		
STORAGE	No significant hazards likely to occur identified		
SHIPPING	No significant hazards likely to occur identified		

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

CCP Determination Form

The Critical Control Point (CCP) Determination form is used to identify the critical control points in the process. A critical control point is defined as a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. All significant hazards identified in the hazard analysis must be addressed. Identification of each CCP can be facilitated by the use of a CCP Decision Tree (See Attachment 2). The Decision Tree asks a series of four, yes or no, questions to assist in determining if a particular step is a CCP for a previously identified hazard. These four questions are listed at the top of the CCP Determination form. Use this as a guide when determining if an identified significant hazard is a critical control point. **CCP's must be carefully developed and documented and must be for product safety only. Different facilities preparing the same food can differ in the risk of hazards and the points, steps, or procedures which are CCP's.** This can be due to differences in each facility such as layout, equipment, selection of ingredients, or the process that is employed.

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

CCP DETERMINATION

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

PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. COULD CONTAMINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP. *If yes=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP
RECEIVING FROZEN, COOKED BEEF	B - Microbial Growth.	YES	YES			CCP 1B
	C - Deleterious Chemicals	YES	YES			CCP 1C
	P - Foreign Material	YES	YES			CCP 1P
RECEIVING NON-MEAT INGREDIENTS	B - Microbial Growth	YES (Spices)	YES			CCP 2B
	*C - Deleterious Chemicals pesticides in vegetables	YES	YES			CCP 2C
	P - Foreign Material.	YES	YES			CCP 2P
RECEIVING CANS	B - N/A					
	C - N/A -					
	P - Foreign Material.	YES	YES		*This may also be controlled in a plant's GMP's or as a CCP in lieu of CCP 4P.	*CCP 3P
STORAGE MEAT	B - Microbial Growth	YES	NO	YES	YES	
	C - N/A					
	P - N/A					
STORAGE NON-MEAT	B -Microbial Growth	No- Controlled at receiving and thermal process step				
	C - N/A					
	P - N/A					
STORAGE PACKAGING MATERIAL	B -N/A					
	C - N/A					
	P - Foreign Material	YES	NO	YES	YES	

*Chemical hazards identified for spices can be controlled through use of a sole supplier and letter of continuing guarantee. This can be monitored as a GMP.

CCP DETERMINATION

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

PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. COULD CONTAMINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP. *If yes=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP
PREPARATION MEAT	B -N/A					
	C -N/A					
	P -N/A					
PREPARATION NON-MEAT	B - N/A					
	C - N/A					
	P - N/A					
CLEANING CANS	B - N/A					
	C - N/A					
	P - Foreign Material.	YES	YES		*This may also be controlled by a plant's GMP's or as a CCP lieu of CCP 3P.	*CCP 4P
FORMULATION	B - Microbial Growth.	YES	YES* This process step is specified as a critical factor in the scheduled process. If not a critical factor, this may not be a CCP.			CCP 3B
	C - N/A					
	P - N/A					

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

PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. COULD CONTAMINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP. *If yes=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP
FILLING	B-Microbial growth	YES	YES This is a CCP since filling is a critical factor in the scheduled process due to the agitating process. If not a critical factor, this may not be a CCP.			**CCP-4B**
	C-N/A					
	P-N/A					
SEALING	B-N/A					
	C-N/A					
	P-N/A					
THERMAL PROCESSING AND COOLING	B-Microbial growth (*Clostridium botulinum*)	YES	YES			**CCP-5B**
	C-N/A					
	P-N/A					
LABELING AND CASING	B-N/A					
	C-N/A					
	P-N/A					
STORAGE	B-N/A					

CCP DETERMINATION

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

PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. COULD CONTAMINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP. *If yes=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP
	C-N/A					
	P-N/A					
SHIPPING	B-N/A					
	C-N/A					
	P-N/A					

HACCP Plan Form

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

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

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

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

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

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

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

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

HACCP PLAN

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

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING - MEAT	B - Microbial Growth.	1 B	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. Receiver will record all findings in HACCP receiving log. Include lot #, date, condition, time of inspection and sign the record.	Receiver will hold rejected meat and notify supervisor. Any rejected or condemned meat will be returned to supplier. Receiver documents actions taken in HACCP receiving log. Sign, date, and record time of action.	Record all results and/or corrective/ preventive action(s) in receiving log. Sign record and record time and date of observation.	An individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official will review the log and randomly perform the same checks at sufficient frequency to ensure compliance with critical limits.
	C - Antibiotic and Pesticide Residue	1 C	Residue Free.	Receiver will ensure that all meat received is from establishments on company approved list.	Receiver will reject meat from unauthorized sources and notify supervisor. Rejected meat will be returned to supplier. Receiver will document actions and results in the HACCP receiving log. Sign, date, and record time of action. Notify plant designee.		Audit to verify sampling techniques and accuracy of record; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings. Weekly calibration of thermometers.

HACCP PLAN

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

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING-MEAT (CONT.)	P - Foreign Material.	1 P	No visible hazardous foreign non-food material (i.e. glass); no metal contamination þ1/32 inch.	Receiver will examine a random sample from each lot received for foreign material. Receiver will sign, date, and record the results of the examination in the receiving log.	Receiver will ensure that all meat received is from establishments on company approved suppliers list. Receiver will sign, date and include time of action in receiving log. Notify plant designee. If hazardous foreign material is detected in or on the meat, identify and control affected product for disposition; condemn; or return controlled product to supplier. Take action to prevent reoccurrence. Plant designee documents all action taken in appropriate log.	Record all results in receiving log and/or corrective and preventive action log.. Sign, date, and record time of action. .	An individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official will review the log and randomly check meat supplies at sufficient frequency to ensure that meat received is only from approved suppliers and is free of foreign material. Audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings.

HACCP PLAN

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

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING -NON MEAT INGREDIENTS	B - Excessive bacterial (spore) load	2 B	As specified in purchase specifications.	Receiver will ensure that all non-meat ingredients are received from suppliers list and that compliance with purchase specifications is indicated. Current letters of guarantee are on file, and sign, date, and record time and results of action in receiving log.	Receiver will control non-meat ingredients and notify supervisor. If compliance with purchase specifications cannot be confirmed, the spices will be returned to supplier. Non-meat ingredients from unauthorized supplier will be rejected.	Records all results and corrective action(s) in receiving log and/or corrective/preven-tive action log. Sign, date, and record time of observation.	An individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official will review the log and randomly check non-meat ingredients weekly to ensure that spices received meet purchase specifications.
	C - Pesticide Residue	2 C	As detailed in purchase specifications.	Receiver will ensure that all non-meat ingredients are received from suppliers list and current letters of guarantee are on file. Receiver will date and include time of action in receiving log.	Receiver will reject ingredients from unauthorized sources and notify supervisor. Rejected ingredients will be returned to supplier. Receiving personnel documents actions taken in receiving log. Sign, date, and record time of observation. Notify plant designee.	Records all results and corrective action(s) in receiving log. and/or corrective/preven-tive action log. Sign, date, and record time of observation.	An individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official will review the log and randomly check spices weekly to ensure that non-meat ingredients received meet purchase specifications

HACCP PLAN

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

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING-NON-MEAT INGREDIENTS (CONT.)	P - Foreign material.	2 P	No visible hazardous foreign non-food material (i.e. glass); no metal contamination þ1/32 inch.	Receiver will ensure that all ingredients are received from suppliers on company-approved suppliers list and that current letters of guarantee are on file. Receiver will examine a random sample from each lot for foreign material using metal detector and/or visual examination. Receiver will sign, date, and record the results of the examiniation in the receiving log.	Receiver will reject ingredients that exceed the critical limit and notify supervisor. The ingredients will be returned to the supplier. The corrective/preventive action will be recorded in the receiving log. Receiver will sign, date, and record time of corrective/preventive action in receiving log. Notify plant designee.	Record all results in receiving and/or corrective/preven-tive action(s) receiving log. Sign, date, and record time of action. .	An individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official will randomly check packaging materials are only being received from approved suppliers and contain no visible foreign material. Audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings. Weekly evaluation of metal detector calibrations log.

HACCP PLAN

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

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING - PACKAGING MATERIAL	P - Foreign Material	3P	No visible hazardous foreign non-food material (i.e. glass); no metal contamination þ1/32 inch.	Receiver will ensure that all packaging materials are received from suppliers on company-approved suppliers list and that current letters of guarantee are on file. Receiver will include date, time of action, initials, and results of the examiniation in receiving log.	Receiver will hold packaging materials and notify receiving supervisor. If letter of guarantee cannot be obtained, the materials will be returned to the supplier.	Records all results and corrective and preventive action in receiving log and/or corrective/preventi ve action log. Sign, date, and record time of observation.	An individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official will review the log and randomly check pacakaing materials weekly to ensure that materials are only being received from approved suppliers. Monthly calibration of metal detectors. Audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings.

HACCP PLAN

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

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
FORMULATION	B-If not as authorized by the processing authority, the thermal process may be inadequate. Elaboration and formation of *Staphylococcus* enterotoxin.	3 B	As specified by the processing authority.	Head formulation cook will check ingredient characteristics, quantities, sauce viscosity and conformance with specified formulation procedure for each batch prepared. Head formulation cook will date, sign log, record results, and time of action. 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.	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, product will be condemned. Head formulation cook documents actions taken in HACCP formulation log, signs, dates, and records time of corrective/preventive action. Notify plant designee.	Record all results, corrective and preventive action in formulation log and/or corrective preventive action log. Sign, date, and record time of observation.	An individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official will review formulation log twice a week to verify that every batch is properly formulated. Audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings.

HACCP PLAN

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

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
CLEANING CANS	P - Foreign Material.	4 P	No visible hazardous foreign non-food material (i.e. glass, metal.).	Can washer operator will visually examine cans as they exit the washer to ensure unit is operating properly and cans are adequately cleaned. Can washer will include initials, date, time of action, signature or initials, and the results of the examination in the can washer each hour. Routine maintenance of can washer performed as required. (Maintenance schedule should be included as part of a plant's GMP's.)	If canwasher malfunctions, operator will stop line, remove uncleaned cans, and notify plant designee. When proper functioning is restored, cans removed will be examined, then recycled thru washer.	Record all results, corrective, and preventive action in can washer log. Sign, date, and record time of observation. .	An individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official will review the canwasher log and randomly check the washer and cans in route from it to the filler weekly to ensure that the washer is operating properly and only clean cans reach the filler. Audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings.

HACCP PLAN

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

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
FILLING	B-If not filled per process schedule requirements, the thermal process may be inadequate.	4 B	As specified in the process schedule recommended by the processing authority.	Filler operator will ensure that all filled containers are run through an automatic over/under check weigher set to reject above the limit weight. Also, the "toppers" on the seamer will be set to produce headspace in excess of prescribed minimum. Filler operator will include date and time, sign, and record the results in weight/head space log each hour. Automatic check weigher provides continuous monitoring records.	Production foreman will ensure that all rejected containers are emptied and contents reworked or condemned. Production foreman documents actions taken in HACCP weight/head space log, signs, dates, and records time of corrective/preventive action. Notify plant designee.	Record all results, corrective, and preventive action in weight/head space log and/or corrective/ preventive action log. Sign, date, and record time of observation. .	An individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official will review the records and twice weekly verify equipment accuracy and measure sample weights and headspaces daily to ensure that weight and headspace standards are met. Weekly calibration of filler. Audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings.

HACCP PLAN

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

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL-B CHEMICAL-C PHYSICAL-P	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
THERMAL PROCESSING AND COOLING	B-Improper application of the thermal process may not provide sufficient lethality to achieve shelf stability, ensure commercial sterility, and prevent recontamination of product due to seam expansion.	5B	As specified by processing authority, to ensure commercial sterility.	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, and water chlorination. Retort operator will sign retort log and include date and time of action.	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. Plant designee will document actions taken in retort log, venting, and/or cooling log, and retort temperature recorder charts, sign, date, and record time of corrective/preventive action. Notify plant designee.	Record all results, corrective, and preventive action(s) on daily retort log, venting, cooling, and temperature recorder charts/log and/or corrective/ preventive action log. Sign, date, and record time of observation.	An individual who did not produce the record(s) and who has successfully completed a course of instruction in HACCP or the responsible establishment official will review the log and charts within one working day after the thermal process. Quarterly calibration of retort. Audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings.

Process Category Description Form

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

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

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

PROCESS CATEGORY DESCRIPTION

PROCESS CATEGORY : THERMALLY PROCESSED, COMMERCIALLY STERILE

PRODUCT EXAMPLE : PASTA SAUCE WITH MEAT (ACIDIFIED PRODUCT)

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

1.	COMMON NAME?	PASTA SAUCE WITH MEAT
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?	GLASS JAR, SNAP-ON METAL LID
4.	LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?	2-3 YEARS UNDER COOL (e.g.,75 °F OF LOWER), DRY CONDITIONS; MUST BE PROTECTED FROM FREEZING.
5.	WHERE WILL IT BE SOLD? INTENDED USE? CONSUMER?	RETAIL HEAT AND SERVE GENERAL PUBLIC
6.	LABELING INSTRUCTIONS?	NO SPECIAL INSTRUCTIONS.
7.	IS SPECIAL DISTRIBUTION CONTROL NEEDED?	NONE REQUIRED.

Product and Ingredients Form

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

LIST PRODUCT(S) AND INGREDIENTS

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE

PRODUCT EXAMPLE : PASTA SAUCE WITH MEAT

MEAT*

REFRIGERATED RAW BEEF

INGREDIENTS

WATER

CANNED CRUSHED TOMATOES
VEGETABLE OIL
STARCH
SALT
SPICES
CITRIC ACID

*The dice size of the meat ingredients should be listed in a plant specific plan if it is a critical formulation factor. Amount of each ingredient may also be included.

Process Flow Diagram

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

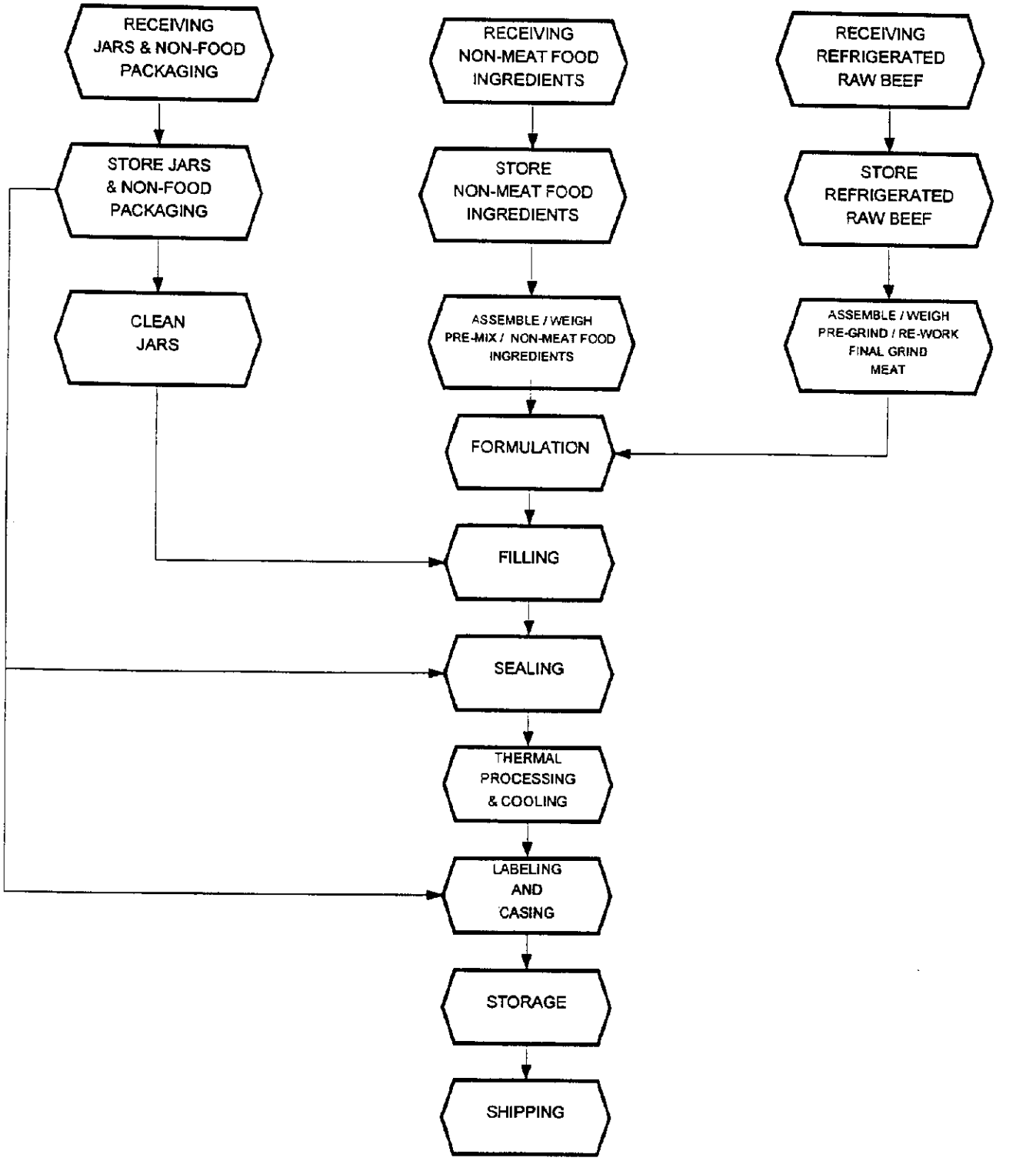
The flow diagram must cover all the steps in the process which are directly under the control of the establishment. It can also include steps in the food chain which are before and after the processing that occurs. For the sake of simplicity, the flow diagram should consist solely of words, not engineering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

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

PROCESS FLOW DIAGRAM

PROCESS CATEGORY: THERMALLY PROCESSED/COMMERCIALLY STERILE

PRODUCT: PASTA SAUCE WITH MEAT



Hazard Analysis/Preventive Measures Form

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

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

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

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

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

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE
PRODUCT EXAMPLE: PASTA SAUCE WITH MEAT

Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures	Examples of How Hazard Is Introduced *
RECEIVING - REFRIGERATED RAW BEEF	B-Excessive microbial load due to improper temperature and handling.	Measure and record temperature of lots. Check container integrity.	B-Transport refrigeration unit is not functioning properly (out of freon). B-The shipping container (cardboard combo bin) was pierced by a bloody forklift and the immediate container (the film wrapped around the individual trays) was torn and punctured introducing harmful microbes into the product.
	C- Antibiotic and pesticide residues.	Supplied by inspected establishments.	C-Improper antibiotic and pesticide usage by producers and previous processors.
	P (Foreign Material) - Visible foreign material that could compromise product safety. Meat and Poultry Products Hazards and Control Guide	Suppliers' letters of guarantee and visual examination.	P-Pieces of glass from broken light bulbs,tramp metal from worn or broken processing equipment, plastic from processing equipment, packaging and utensils.
RECEIVING - NON-MEAT INGREDIENTS	B- Excessive bacteriological (spore) load. Meat and Poultry Products Hazards and Control Guide	Suppliers' letters of guarantee and visual examination. Third party audit of suppliers.	B-Spices received insufficient treatment to reduce or eliminate spore load.
	C- No significant hazards identified. Low occurrence of residue in canned tomatoes.	Suppliers' letter of guarantee. Third party audit of supplier.	
	P- Visible hazardous foreign material that could compromise product safety. Meat and Poultry Products Hazards and Control Guide	Suppliers' letter of guarantee. Third party audit of supplier.	P-Pieces of glass from broken light bulbs,tramp metal from worn or broken processing equipment, plastic from processing equipment, packaging and utensils.
RECEIVING - JARS, LIDS & PACKAGING MATERIALS	P (Foreign Material) - Visible hazardous foreign material that could compromise product safety.	Suppliers letters of guarantee and visual examination. Third party audit suppliers.	P-Dirt, insects, wood, metal, or glass may get in the jars during manufacturing, storage and shipping.

HAZARD ANALYSIS/PREVENTIVE MEASURES

PROCESS CATEGORY: THERMALLY PROCESSED, COMMERCIALLY STERILE
PRODUCT EXAMPLE: PASTA SAUCE WITH MEAT

Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures	Examples of How Hazard Is Introduced *
STORAGE - MEAT	B- inadequate storage temperatures could result in pathogen proliferation	Routine refrigeration maintenance. Monitor product temperature	B-Excessive boxed product is stored exceeding cooler capacity and temperature of boxed product rises above 50 F for two days.
STORAGE - NON-MEAT	B-No significant hazards identified P-(Hazardous Foreign Material)	Visual inspection of non-meat ingredients prior to preparation.	Wood, metal, or glass may get in product if stored in open containers or during manufacture.
STORAGE - PACKAGING	low risk low significance		
PREPARATION - MEAT	low risk no significant hazardous		
PREPARATION - NON-MEAT	B-inadequate pH of tomatoes could result in insufficient acidification to assure product safety. P-no significant hazardous low risk	Monitor pH of all batches of crushed tomatos added at time of preparation.	B-Supplier controls of storage conditions alter the pH of ingredient.
JAR CLEANING	P-Hazardous Foreign Material remains after wash cycle. Meat and Poultry Products Hazards and Control Guide	Cleaning operation	P-Foreign material present at receiving plus any resulting from subsequent storage and handling.
FORMULATION	B-If processing authority's maximum pH recommendation is exceeded, the thermal process may be inadequate.	Control of pH during formulation confirmed by finished product pH testing.	B-Inadequate pH control of meat or tomatoes during thermal process results in a pH >4.5.
FILLING	B-If fill temperatures less than processing authority's recommendation, the thermal process may be inadequate.	Fill temperature control.	B-Fill temperature is not maintained high enough to meet process schedule requirements.
SEALING	None identified		
THERMAL PROCESSING	B-Improper application of the thermal process may not provide sufficient lethality to achieve shelf stable stability.	Operational thermal processing controls.	B-During a hot fill and hold process, closing and/or holding temperatures or holding times are less than specified in the process.
LABELING & CASING	N/A low risk, severity		
STORAGE	N/A low risk, severity		
SHIPPING	N/A low risk, severity		

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

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

CCP Determination Form

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

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

CCP DETERMINATION

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

PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. COULD CONTAMINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP. *If yes=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP
Receiving-Refrigerated Raw Beef	B - Microbial Growth.	YES	NO	YES	YES	
	C - Deleterious Chemicals	YES	YES* This can also be alternatively controlled using plant GMP's for supplier specifications.			CCP 1C
	P - Foreign Material	YES	YES			CCP 1P
Receiving - Non-Meat Ingredients	B - N/A					
	C - N/A					
	P - Foreign Material.	YES	YES			CCP 2P
Receiving -Jar, Lids & Packaging Materials	B - N/A					
	C - N/A					
	P - Foreign Material.	YES	YES*	This may be controlled by a plant's GMP's if 4P-cleaning- is a CCP.		CCP 3P
Storage - Meat	B - Microbial growth	YES	YES	YES	YES* Although subsequent thermal (audification) process will eliminate or reduce hazard a plant may also designate this a CCP or a CP that is controlled by refrigeration maintenence and cooler temp.	
	C - N/A					
	P - N/A					
Storage - Non-Meat	B - N/A					
	C - N/A					
	P - N/A					
Storage - Packaging	B - N/A					
Material	C - N/A					
	P - N/A					

CCP DETERMINATION

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

PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. COULD CONTAMINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP. *If yes=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP
Preparation Meat	B - Microbial Growth	YES	NO	YES	YES* Not necessary to identify in HACCP plan. Plant follows processing authority specifications. These should be included as attachment to the plan for validation and to show thhat the provision of 417.2(b)(3) are met.	
	C - N/A					
	P - N/A					
Preparation Non-Meat	B - N/A					
	C- N/A					
	P - N/A					
Cleaning Jars &Lids	P - Foreign Material	YES	YES*	This may alternatively be controlled by plant GMP's or as a CCP in lieu of 3P.		*CCP 4P
	C - N/A					
	B - N/A					
Formulation	B - Microbial Growth	YES*	NO	YES	YES*This is a control point, however the thermal processing step is the critical control point. This may be noted as a CCP for acidified thermally processed product if formulation is the pH control step.	CP 1B
	C - N/A					
	P - N/A					
Filling	B - Microbial Growth	YES	NO			
Filling (cont.)	C - N/A					

CCP DETERMINATION

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

PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. COULD CONTAMINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP. *If yes=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP
	P - N/A					
Sealing	B - N/A					
	C - N/A					
	P - N/A					
Thermal Processing	B - Microbial Growth	YES	YES * Not required to be listed as a CCP in the HACCP plan since the plant follows processing authority specifications. These specifications should be included as an attachment to the plan for validation and to show the provisions of 417.2(b)(3) are met. Otherwise, this should be a designated CCP with a defined pH and center temperature.			CP 2B
	C - N/A					
	P - N/A					
Labeling & Casing	B - N/A					
	C - N/A					
	P - N/A					
Storage	B - N/A					
	C - N/A					
	P - N/A					

CCP DETERMINATION

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

PROCESS STEP	HAZARD(S)	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. COULD CONTAMINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP. *If yes=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP
Shipping	B - N/A					
	C - N/A					
	P - N/A					

HACCP Plan Form

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

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

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

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

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

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

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

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

HACCP PLAN

PROCESS CATEGORY : THERMALLY PROCESSED COMMERCIALLY STERILE
PRODUCT EXAMPLE : PASTA SAUCE WITH MEAT

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL(B) CHEMICAL(C) PHYSICAL (P)	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING - MEAT	C-Antibiotic and Pesticide Residue	1C	Residue Free	Receiver will ensure that all meat received from establishments on company-approved suppliers	Receiver will reject meat from unauthorized sources and notify supervisor. Meat from approved sources will be examined for foreign material. If any found, supervisor will either authorize reconditioning or return to supplier. Receiving personnel documents actions taken in the receiving log. Dates, signs, and records time of action.	Records all results, corrective, and preventive action(s) in receiving log. Sign record and record time and date of observation.	An individual who did not produce the record(s) and who has successfully completed a course of instructions in HACCP or the responsible establishment official will review the log and randomly check meat supplies three times a week to ensure that meat received is only from approved suppliers and is free of foreign metarial.
	P - Foreign Material.	1P	No visible hazardous foreign non-food material (i.e. glass, metal); no metal contamination þ1/32 inch; no bone particles >0.8 inch (20mm).	Receiver will ensure that all meat is received from establishments on company-approved suppliers list. Receiver will date and include time of action. Receiver will record all findings in receiving log. Include lot #, date, condition, time of inspection and sign the record.			Audit to verify sampling techniques and accuracy of records; determine if the critical limit corresponds to the plant records; check to see if critical limit is adequate for hazard; assure corrective actions are adequate; document findings.
RECEIVING- NON-MEAT	P - Foreign Material.	2 P	No visible hazardous foreign non-food material (i.e. glass, metal); no metal contamination þ1/32 inch	Receiver will ensure that all non-meat ingredients are received from suppliers on company-approved suppliers list and current letters of guarantee are on file. Receiver will date and include time of action.	Receiver will reject ingredients from unauthorized sources and notify supervisor. Rejected ingredients will be returned to supplier. Receiver will document actions taken in receiving log. Sign records, date, and record time of observation.	Records all results, corrective, and preventive action(s) in receiving log. Sign, date, and record time of observation.	An individual who did not produce the record(s) and who has successfully completed a course of instructions in HACCP or the responsible establishment official will review all log entries and invoices to ensure ingredients are from approved sources. For each ingredient, Q.A. will test every tenth lot to determine if foreign material specifications are met.

HACCP PLAN

PROCESS CATEGORY : THERMALLY PROCESSED COMMERCIALLY STERILE
PRODUCT EXAMPLE : PASTA SAUCE WITH MEAT

PROCESS STEP	HAZARD DESCRIPTION BIOLOGICAL(B) CHEMICAL(C) PHYSICAL (P)	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURE/PERSON RESPONSIBLE
RECEIVING - PACKAGING MATERIALS	P-Foreign Material	3P	No visible hazardous foreign non-food material (i.e. glass, plastic); no metal contamination þ1/32 inch.**	Receiver will check source of materials; lots from approved sources will be examined for shipping damage. Receiver will date and include time of action.	Receiver will ensure that glass jars in damaged shippers are 100% examined for suitability. Broken/cracked jars will be discarded; Intact jars containing glass or other foreign materials will be hand cleaned before entering jar washer. Jar closures in damaged packaging will be examined and cleaned in necessary.	Receiving log	An individual who did not produce the record(s) and who has successfully completed a course of instructions in HACCP or the responsible establishment official will verify source of accepted packaging materials and will certify the acceptability of all reconditioned jars and closures.
CLEANING, JARS	P - Foreign Material Remains.	4 P	No visible hazardous foreign non-food or food material (i.e. glass, or food); no metal contamination þ1/32 inch	Washer operator will continually visually examine jars leaving washer to ensure that the unit is operating properly and the jars are being properly cleaned. Washer operator will include date, sign and record results and time of action.	Jar washer operator will remove any unclean jars and notify the production foreman or plant designee if the washer is not operating properly. When proper functioning is restored , jars removed will be recycled thru washer. Corrective/preventive operator signs, dates, and records time of action.	Records all results, corrective, and preventive action(s) in jarwasher log. Sign, date, and record time of observation.	An individual who did not produce the record(s) and who has successfully completed a course of instructions in HACCP or the responsible establishment official will review the log and check the washer and exiting jars every 30 minutes to ensure that the washer is operating properly and only clean jars reach the filler.

FORMULATION (Example: if included as a CCP where pH is determining factor for safety and/or specifics of 9CFR 318.300-311 or 9CFR 381.300-311.)	**B -If not as authorized by the processing authority, the thermal process may be inadequate.**	**1 B**	**As specified in formulation specified by the processing authority.**	**Head formulation cook will check ingredient characteristics quantities, and conformance with specified formulation procedure for each batch prepared. Q.A. personnel will sample each finished batch within 24 hours of processing and check sauce and internal particle pH. Head formulation cook or Q.A. personnel will date and include time of action.**	**Head formulation cook will not release any batch that has not been formulated correctly. If the pH of a finished product batch exceeds 4.5, the product must be cooled to refrigeration temperatures unless reworked, reprocessed as a low-acid canned food or destroyed within 48 hours of initial process.**	**Formulation log.** **Finished pH log.** **Corrective and preventive action log. Sign, date, and record time of observation, corrective/ preventive action.**	**On a daily basis, An individual who did not produce the record(s) and who has successfully completed a course of instructions in HACCP or the responsible establishment official will review the logs and verify pH meter accuracy to ensure batches are properly formulated.** **Calibration of pH meters daily.**
THERMAL PROCESSING	**B - Improper application of the thermal process may not provide sufficient lethality to achieve safety.**	**2 B**	**As specified by processing authority.**	**Steam tunnel operator will monitor and record thermal processing conditions at sufficient frequencies to ensure that the process schedule is properly applied. Steam tunnel operator will date and include time of action.**	**If a process deviation occurs, the production foreman will have the affected production isolated for rework or destruction based on an analysis of the deviation.**	**Daily process log and temperature recorder charts.** **Corrective/ preventive action log.** **Sign, date, and record time of observation and/or corrective/ preventive action.**	**An individual who did not produce the record(s) and who has successfully completed a course of instructions in HACCP or the responsible establishment official will review all log entries and charts within one working day after the thermal process.**

*This is a Control Point, however the Thermal Processing step is the Critical Control Point in this Plant.

Appendix 1 - List of Process Models

Generic HACCP Model for Beef Slaughter

Generic HACCP Model for Poultry Slaughter

Generic HACCP Model for Pork Slaughter

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

Generic HACCP Model for Raw, Ground Meat and Poultry Products

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

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

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

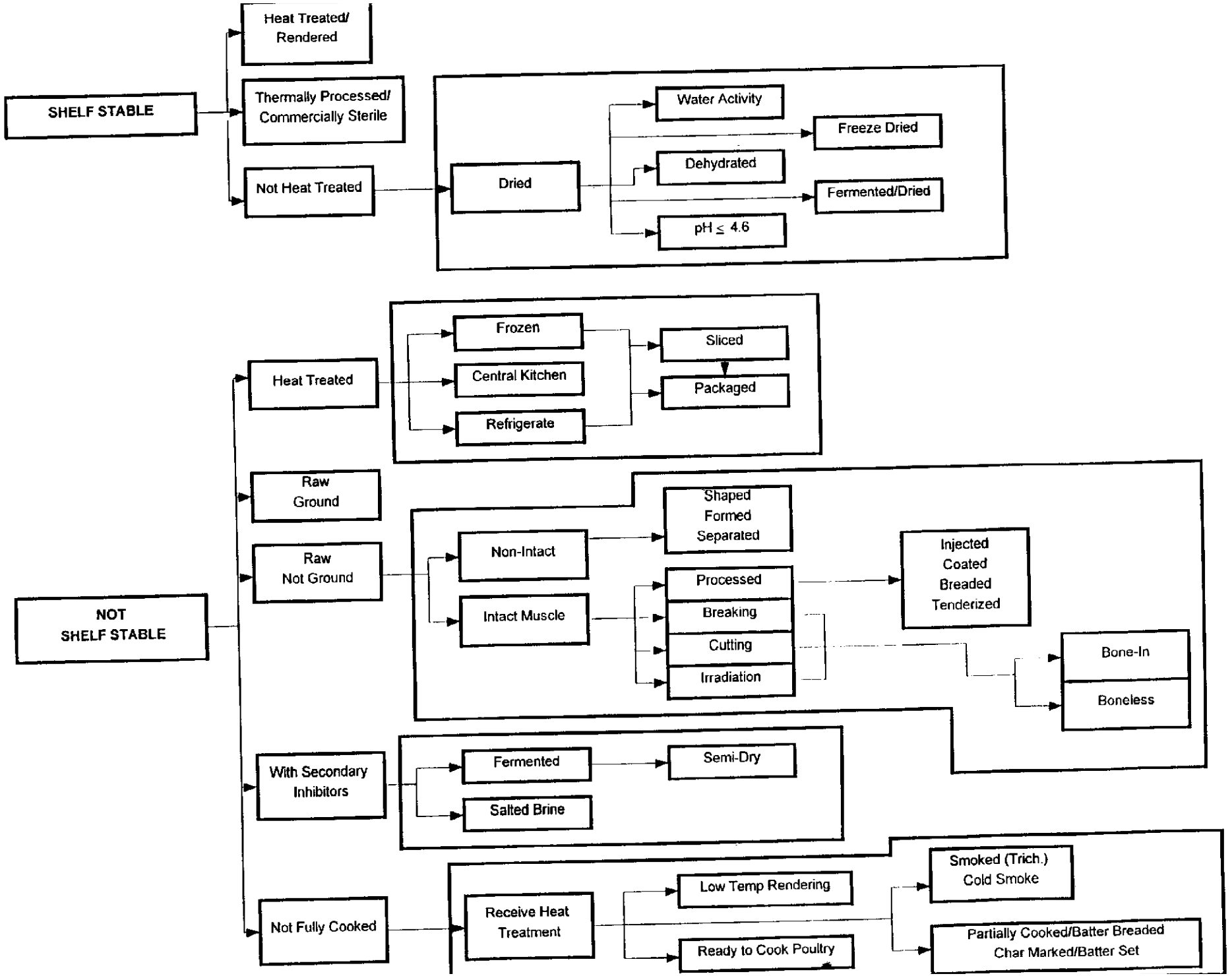
Generic HACCP Model for Not Heat Treated, Shelf-Stable Meat and Poultry Products

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

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

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

Generic HACCP Model for Irradiation


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

Appendix 3

FOOD SAFETY HAZARDS BEING CONTROLLED IN HACCP PROGRAM

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

Appendix 4

Hazard Analysis: Thermally Processed/Commercially Sterile

The attached information was prepared for products covered under the process: Thermally Processed/Commercially Sterile. The literature search focused on foodborne illnesses and processing problems associated with thermally processed, commercially sterile canned products. The sources listed in this bibliography were gathered primarily on a search of databases (e.g., Food Science and Technology Abstracts, Agricola, and Medline) on CD-ROM. Bound abstracts, such as the Food Safety and Technology Abstracts and the Bibliography of Agriculture, also could be used. References cited in scientific journal articles are another source of material.

A 1971 finding of botulinum toxin in canned chicken vegetable soup and the death in 1974 of one person from botulism attributed to a product canned under USDA inspection prompted the revision of the canning regulations for meat and poultry. The new regulations were based on a HACCP concept - identifying critical control points setting critical limits, monitoring procedures, recordkeeping, and defining corrective actions for processing deviations or production errors, such as inadequate can seams. The scientific literature review emphasizes foodborne illnesses associated with thermally processed, commercially sterile product and the types of spoilage that result from processing or production problems.

The attachment, "Incidents of Foodborne Illnesses from Thermally Processed, Commercially Sterile Canned Products," lists scientific journal articles on foodborne illnesses attributable to thermally processed, commercially sterile foods. The incidents of foodborne illness are not confined to commercially processed products but include illness resulting from improper home canning. The processing deviations (hazards), such as inadequate heating or control of acidity, which occur in home-canned product are similar to those which occur in a commercial environment. The extent sources, severity, and type of foodborne illness due to canned product is readily apparent from these references. These references also indicate the importance of controlling and monitoring canning procedures.

The list of references under "Product Spoilage in Thermally Processed, Commercially Sterile Food Products" include spoilage of product resulting from underprocessing, post-process leakage contamination, or growth of thermophilic organisms, usually the result of storage at temperatures above 113þF. Underprocessing can be the result of inadequate time or temperature in retorting or poor control of a critical factor, such as pH. Post-process leakage contamination and thermophilic spoilage result from a break in the production process rather than failure in the process schedule. Can defects, such as dents, may affect the integrity of the can seams which may cause leaker spoilage. While thermophilic spoilage does not represent a potential health hazard, post-process leaker spoilage may result in the growth of gas-forming anaerobes, such as C. botulinum.

In addition to microbial spoilage, various physical and chemical contaminants may represent

potential health hazards. For example, a product may be contaminated by a strong alkali from a cleaning solution. Physical hazards include, but are not limited to, glass in baby food jars, rubber from gaskets, and foreign objects or insecta not removed during cleaning prior to filling. Chemical hazards may involve strong alkali from cleaning solutions, heavy metals, or pesticides. Most of the physical and chemical hazards are introduced prior to filling and are not the result of processing.

However, incidents of physical and chemical contamination are not well documented in the literature since reporting of such incidents is not required as are cases of most foodborne illnesses. The literature on foodborne illnesses that result from microbial contamination may list the number of cases attributable to a certain bacteria or the percentage of persons affected in a defined population. For physical and chemical hazards, on the other hand, the data usually list the number of containers that are involved. For example, the percentage of containers with broken glass or lead from solder are listed rather than the number persons affected. Many of these incidents, if reported, will be reported to the processor rather than a public health department or hospital. In addition, these types of contamination are usually observed before the product is consumed.

Incidents of Foodborne Illnesses from Thermally Processed, Commercially Sterile Canned Products

Barker, W. H., Jr., J. B. Weissmann, V. R. Dowell Jr., L. Gutmann, and D. A. Kautter. 1977. Type B *botulism* outbreak caused by a commercial food product. West Virginia and Pennsylvania, 1973. JAMA. 237(5):456-9.

In the week of May 7, 1973, seven persons contracted botulism after eating together. The most common symptoms were vomiting, constipation, dry mouth, dysphagia, and dysphonia. All were treated with trivalent botulinal antitoxin, and none died. Serum specimens obtained from all seven patients were negative for botulinal toxin, but stool specimens from three patients were positive for type B toxin. Electromyographic studies performed on five patients documented the neurophysiologic abnormalities of botulism. Commercially canned peppers in oil were implicated epidemiologically, and type B toxin was identified in leftover peppers. The processor voluntarily recalled the pepper product, and no further cases were reported.

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

Studies were conducted on 114 cases of food poisoning in various regions of France in 1974 and 1975. The cause was determined in 56 cases: sulphite-reducing anaerobic bacteria (Clostridium perfringens), 16 cases; *staphylococci*, 13 cases; *salmonellae*, 9 cases; Clostridium botulinum toxin, 4 cases; high aerobic mesophilic count (pathogenic organisms not identified), 6 cases; molds, 3 cases; and high levels of histamine and other proteolysis products, 5 cases. Overall, 21 of these cases were of domestic and 35 of institutional origin. Studies on the food responsible for poisoning gave the following results: cured meat products, sausages, etc., 20 cases; cooked dishes, 17 cases; raw meat, 6 cases; fishery products, 5 cases; baked confectionery, 4 cases; milk and dairy products, 3 cases; and eggs and egg products, 1 case. No cases of food poisoning attributable to canned foods were recorded.

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

Two of three persons who ate lunch together became ill with symptoms characteristic of botulism. One died before botulism was suspected and before specimens could be collected for laboratory testing, but a serum specimen from the other patient, who

survived, yielded botulinal toxin, type A. The third person remained asymptomatic, but

Clostridium botulinum type A was cultured from his stool. The three persons had shared two canned foods: home-canned green beans and commercially canned beef stew. The green beans were initially assumed to be the cause of the outbreak. However, the empty stew can was recovered from the garbage, and washings from the can yielded C *botulinum*, type A, and its toxin.

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

Canned foods are incriminated in only a small proportion of recorded outbreaks of food poisoning and food-borne diseases in the UK. Outbreaks reported from freshly opened canned food from 1929 to 1980, and the products incriminated are summarized in tables. Special mention is made of botulism associated with canned salmon in 1978, and staphylococcal food poisoning from corned beef in 1979. Causes of microbial decomposition and origins of spoilage are briefly discussed, and 4 examples are considered in more detail in tables: swollen cans of chopped pork from Poland (due to underprocessing); blown cans of pork shoulder from the Netherlands (due to incorrect storage); safety of canned corned beef from Brazil (water damage from barge sinking in R. Thames); and bottled complete milk formula for babies (underprocessing resulted in Bacillus coagulans counts of 4.5 x 10-6ml). A scheme of microbiological examination for canned meat is given which could be applied to other foods.

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

A total of 236 samples of infant foods, including honey, dry cereal, dried skim milk, evaporated milk, canned formula, and canned baby food, were collected in the New York City area and tested for the presence of *C. botulinum* spores. Methods for recovery of spores were validated using foods spiked with 4 spores/ml or g. None of the products contained *C. botulinum* spores, indicating that their incidence in these commercial foods is not widespread. This limited study did not identify any food types that could be suspected of being involved in the transmission of infant botulism.

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

The problem of botulism in canned acid foods is reviewed, analyzed and discussed. In the period 1899-1975, 722 outbreaks of botulism were reported in the USA; 4.7% were due to home-processed acid foods and 0.1% to commercially-processed acid foods (the remainder being due to home- and commercially-processed low acid foods). Contamination of food with *C. botulinum*, effect of pH on *C. botulinum* and survival of spores in acid foods are considered, as are types of process failures during canning, and conditions necessary for *C. botulinum* growth in an acid food with a process failure. Presence of other viable microorganisms may cause the pH of an apparently safe food to

increase during storage.

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

From 1899 through 1963, 1,561 cases of botulism were reported in the United States. The decade of the 1930's had the greatest number of cases followed by the decade of the 1920's and the 1940's. Most of the botulism outbreaks from the 1920's and 1930's to the mid-1960's could be attributed to home canning, usually improperly or inadequately processed nonacid foods. From 1906 to 1963, 51 outbreaks involving commercially prepared foods were reported. Only 5 cases out of 44 from 1950-63 were attributable to commercial canned product.

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

154 incidents of food poisoning were associated with post-process leakage (PPL) between 1921 and 1979. These occurred mainly in UK (72.7%) and Canada (17.5%) from products exported from South America, Europe, Africa and Australia. Defects leading to leakage were identified as defective seams and perforations during processing; temporary microleaks during cooling; and case-cutter damage, punctures, corrosion and dents after processing. Organisms associated with the incidents were Staphylococcus aureus (100, 64.9%), Salmonella typhi (6, 3.9%) other Salmonella spp. (9, 5.8%), Clostridium botulinum (3, 2.0%), Clostridium perfringens (3, 2.0%), others and undetermined 33 (21.4%). Canned meat, fish and vegetable products were involved. In particular, corned beef contaminated with Staphylococcus or Salmonella caused 53 incidents; pork and ham products contaminated with the same organisms caused 16 incidents. Where information was available, it was found that the median amount of meat contaminated with Salmonella consumed by ill persons was 105 g. For Salmonella-contaminated fish the amount associated with illness was 40-320 g. Although many of the PPL incidents recorded occurred decades ago, significant outbreaks from this cause have appeared in the last few years. Appropriate action should be taken to reduce PPL at the manufacturing and retail level.

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

The chronology of events which occurred in February and March 1982 are reported in their order of occurrence. This related to the death in Belgium of a young man who had consumed Alaskan salmon from a tin with a tiny puncture which had permitted the entry and growth of botulinum spores. The salmon had been canned in July 1980, and the events led to the examination of the entire 1980 and 1981 output of the Alaskan salmon industry, and to the second largest group of food recalls in FDA history.

Product Spoilage in Thermally Processed, Commercially Sterile Food Products

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

This group of organisms, which are non-pathogenic, has been responsible for the type of spoilage known as 'hard swell'. It has been found in various canned products (especially vegetables), highly acid products such as fruit and tomatoes and in ingredients such as vegetables, sugar, dried milk, starch, flour, cereals, alimentary pastes and rendered meat. Characteristics are described of the type species, *Clostridium thermosaccharolyticum*. Recommended detection media, sporulation media and ingredient testing procedures are discussed. Survival of *C. thermosacharolyticum* spores in canned foods is of consequence only when cans are inadequately cooled and/or stored at greater than 35 degree C for extended periods.

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

Swelled cans of low-acid food were collected from supermarkets over a 17-month period. Microorganisms were recovered from 47% of the 790 containers tested. Calculations suggested that approx. another 47% of the swelled cans were the result of microbial contamination, although no microorganisms were recovered, while 6% were physically induced (nonmicrobiological) swells. Food type appeared to influence the recovery of microorganisms. Types and incidences of organisms recovered were: 91.6% typical leaker spoilage microorganisms, 0.5% thermophiles, and 7.9% pure cultures of sporeforming organisms traditionally associated with underprocessing.

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

In December, 1974, three cases of botulism occurred in a family; two were fatal. The first patient died after a 10-day illness without botulism being suspected. 4 days later, after a 2-day illness, the second patient was diagnosed as having botulism after a cardiorespiratory arrest; she died 3 days later. In the third patient, the only symptom was dysphagia. *Clostridium botulinum* type B was found in stool specimens from all three patients. Home-canned (bottled) mushrooms, which were found to contain *C. botulinum* type B and its toxin, were believed to be responsible for the outbreak; mushrooms were found at necropsy in the gastrointestinal tracts of both patients who died. Heat treatment of the mushrooms during canning had been inadequate.

Lake, D. E., R. R. Graves, R. S. Lesniewski, and J. E. Anderson. 1985. Post-processing spoilage

of low-acid canned foods by mesophilic anaerobic sporeformers. J. Food Prot. 48(3):221-226.

Over 4 yr, 770 low-acid canned food spoilage incidents were investigated to determine the cause of spoilage. In 27 of these, the cause was attributed to the growth of bacteria of the Clostridium genus that had entered the cans as a result of post-processing leakage. No correlations were found that might explain the occurrence of this mesophilic anaerobic type of spoilage. It appears to be a random event, probably linked to cannery insanitation. A variety of species was found, consisting of both proteolytic and non-proteolytic types. Clostridium botulinum was not isolated from any of the canned foods examined, nor were any of the samples found to contain botulinal toxin. Container leak test methodology and principles are discussed.

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

Commercially canned foods have had a remarkably good record over the last 45 yr with approx. 775 billion cans of commercially canned foods being consumed with only 4 known deaths until 1971. Since 1971, however, botulinal toxin and/or Clostridium botulinum has been found in commercially canned vichyssoise, chicken vegetable soup, peppers, marinated mushrooms, tuna, beef stew, and in 41 cans of mushrooms from 20 lots packed by 7 USA and 2 foreign producers. The typical cause of botulism in canned foods is underprocessing which may result from inadequate equipment, improper operating procedures, and thermal processes which are not appropriate for the actual operating conditions being used.

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

Pure cultures of causative organisms were successfully isolated from 290 (65%) of 445 samples of spoiled canned foods analyzed during 1968-1980. Pure cultures were hard to isolate from spoiled canned fruits and juices; only 24 of 71 such samples were analyzed successfully. Isolates from 24 of 194 swollen cans failed to produce gas in subculture, and non-spore-forming bacteria and yeasts were detected in 73 of 223 samples where container sealing was not suspect. Aerobic spore formers were isolated from 122 samples, obligate anaerobes from 76, non-spore-forming rods from 115, cocci from 12 and yeasts from 16. Causes of spoilage (%) were under-processing (49), not thermally processed (less than 1), post-process contamination (23), incipient spoilage (2), and exposure to unusually high temp. (2). [From En summ.]

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

In August 1977, 457 Manitoba households were surveyed on their canning practices. Many incorrect and potentially dangerous practices were found including incorrect processing methods, use of improper containers and lids, and inadequate cooking procedures prior to serving. Beans were the most popularly canned low-acid vegetable, yet only 17% of the people canning beans used the proper pressure canning method. Many people in the rural segment canned meat, fish, or poultry, even though this is not recommended by Agriculture Canada, and proper processing instructions are not readily available. In 75% of the cases where meat, fish, or poultry were canned, an incorrect method was used. Large numbers of respondents did not boil low-acid canned foods before eating to ensure destruction of botulism toxin.

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

The problem of botulism in canned acid foods is reviewed, analyzed and discussed. In the period 1899-1975, 722 outbreaks of botulism were reported in the USA; 4.7% were due to home-processed acid foods and 0.1% to commercially-processed acid foods (the remainder being due to home- and commercially-processed low acid foods). Contamination of food with C. botulinum, effect of pH on C. botulinum and survival of spores in acid foods are considered, as are types of process failures during canning, and conditions necessary for C. botulinum growth in an acid food with a process failure. Presence of other viable microorganisms may cause the pH of an apparently safe food to increase during storage.

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

Swelled cans were collected over a 17-month period from outlets of 2 supermarket food chains. Each swelled can was classified by product and the probable cause of the swelled condition. Using weekly sales volume data for each outlet, the incidence rate of swelled cans for each type of food was estimated. Incidence rates ranged from 2.1 to 78.4 swelled cans/100,000 units sold, depending on type of food. Of the 1104 swelled cans collected, 314 (28.4%) had major container defects which were assumed to have resulted in the swelled condition. Microbiological analyses were performed on the products in the remaining 790 cans; the following results were obtained: typical leaker spoilage, 86%; typical underprocessing spoilage, 7%; thermophilic spoilage, 1%; and nonmicrobial swells, 6%. Using vacuum testing and double seam measurements, causes of leakage were determined as follows: poor or questionable quality canner's end double seam, 51%; leaks at locations other than the double seam, 26%; and poor or questionable quality manufacturer's end double seam, 4%. It was concluded that examining swelled cans of low-acid foods at the retail level is a valid method for evaluating the canning operation of commercial food processing.

Rhodehamel, E. J., N. R. Reddy, and M. D. Pierson. 1992. Botulism: the causative agent and its

control in foods. Food Control 3(3):125-143.

Clostridium botulinum is the causative agent in 4 types of botulism: foodborne, infant, wound and those classified as undetermined. The types of C. botulinum and food products involved in various foodborne botulism outbreaks are discussed in this review. Most foodborne botulism outbreaks result from consumption of home-processed or home-canned foods; relatively few are caused by commercial products. Various physical and chemical treatments that can be used in foods either to destroy C. botulinum spores or control their outgrowth and toxin production are presented [aw and dehydration, pasteurization, thermal sterilization, irradiation, low temp. storage, salt, acidification, nitrite, ascorbate or isoascorbate, smoke and its components, extenders, binders and seasonings, polyphosphates, sugars and syrups, other preservatives, antioxidants and chemicals and interactive factors]. Concerns about potential foodborne botulism outbreaks from new generation foods are discussed.

Tsai, S.J., Y. C. Chang, J. D. Wang, and J. H. Chou. 1990. 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):43-8.

In late September 1986, we found 7 patients from a printing factory in Chang-Hwa city who developed an endemic disease manifested by general malaise, ptosis, double vision, dysarthria, dysphagia, and proximal limb weakness. After clinical, epidemiological, microbiological, and toxicological investigations, an outbreak of botulism was confirmed 2 weeks later, Commercially canned peanuts made by an unlicensed cannery were identified as the vehicle of botulinum toxin transmission. Antitoxin was given to 2 patients who needed ventilator support. One of the 7 victims died from medical complications and the remaining 6 patients recovered. Several administrative problems exposed in this outbreak were the poor governmental supervision of canned food, the inadequate quantities of "orphan drugs" stored in this country, the inefficient system for recalling the problem products, and the delayed broadcasting of warnings to the public. Since commercially processed food is increasingly popular with modernization, the possibility of future botulism outbreaks should not be overlooked.

United States of America, National Food Processors Association/Can Manufacturing Institute, Container Integrity Task Force. 1984. 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 Prot. 47(10):801-816.

This report focuses on the potential public health risks of Clostridium botulinum from post-process contamination of commercially produced foods in metal containers. This review examines the environmental sources of C. botulinum, the effect of sanitizers in cannery cooling water and the botulism incidents involving U.S. canned foods. There is no evidence that leaker spoilage due to container defects is increasing. The post-processing contamination of commercially produced foods in metal containers by C.

botulinum is a rare event which occurs randomly. Based on historical information, its probability of occurring is very small. This is a probability which compares well with the risk associated with the minimum acceptable thermal process of low-acid canned foods.

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

Advantages and drawbacks of 2- and 3-piece cans are discussed in the light of comments from can manufacturers and food processors. 2-piece cans eliminate side- and bottom-seams, thus reducing solder contact areas and lead (Pb) contamination, and improving can integrity. 3-piece cans with welded side seams also eliminate Pb contamination from this source, and are preferred for foods where both ends of the can are opened for serving. FDA figures are presented to show that levels of Pb in canned foods have declined since 1974, probably due to the advent of 2-piece cans and welded side seams.

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

Uptake of Pb by foods in cans with longitudinal seams soldered with Pb/Sn alloys is discussed, with reference to: possible health hazards; Pb concn. in canned foods; increases in Pb concn. during storage; use of Pb-free Sn solder; quality control; and developments in can-making technology reducing the risk of Pb contamination (e.g. use of 2-piece cans).

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

A total of 98 samples of canned foods (including tomato, meat, tuna, vegetable and fruit products), collected from retail sources over the period Jan. 1978-July 1979, was analysed for iron (Fe), Sn and Pb by AAS. A table of results is given. 27 of the 98 cans were in poor condition. Overall ranges of values were (p.p.m.): Pb traces-10.1; Sn 8.5-34.6; and Fe 2.8-1710. 37 samples had Pb concn. less than 1 p.p.m., 30 had Pb concn. of 1-2 p.p.m., 9 had Pb concn. of 2-3 p.p.m., and 22 had Pb concn. greater than 3 p.p.m. Similarly, 13 samples had Sn concn. less than 50 p.p.m., 35 had Sn concn. of 50-100 p.p.m., 30 had Sn concn. of 100-200 p.p.m., and 20 had Pb concn. greater than 200 p.p.m.; and 74 samples had Fe concn. less than 50 p.p.m., 6 had Fe concn. of 50-100 p.p.m., 8 had Fe concn. of 100-200 p.p.m. and 10 had Fe concn. greater than 200 p.p.m. Data are also given for 2 cans of anchovies in sauce purchased in May 1974 and analysed with the other samples; at the time of examination, the cans were in poor condition. Concn. of metals in the can contents were (p.p.m.): Pb 14 and 45; Sn 740 and 1840; and Fe 1048 and 5800. The potential

health hazard from canned foods with high Pb contents is discussed, with reference to

the desirability of legislation enforcing labelling of cans with the date of manufacture and/or the last recommended date for use.

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

Possible health hazards from presence of broken glass in beverage bottles are discussed; the most likely source is glass splinters from bottles bursting during filling. Recommendations to minimize this problem include: application of counterpressure to bottles as late as possible in the filling operation, so that the mouth of the following bottle is likely to be covered; fitting protective shields to isolate individual bottles within the section of the machine in which counterpressure is applied; installation of systems for washing of the filling heads after a bottle bursts; and frequent changing of the rubber seals on the filling heads (into which glass splinters may become embedded and subsequently released into bottles).

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

Contamination of foods is discussed with reference to: trends in incidence of food contamination; incidence of contamination of various foods with chemicals, glass and other materials; fraudulent claims of contamination; assessment of cases of claimed food contamination; and contamination of foods with compounds (e.g. chlorophenols used as fungicides) which adversely affect flavour.

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

The reduction in Pb and Sn contents of canned foods as a result of the change from soldered to welded cans is discussed. Swedish tolerances for Pb and Sn in canned foods have been reduced in accordance with this change in can construction. Dented cans show no increase in Pb or Sn uptake by the food; the contents of leaking cans should, however, not be consumed. Food should not be stored in opened cans, as exposure to air increases the rate of Pb and Sn uptake.

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

Pb was determined by AAS in 62 samples of canned foods from retail sources in Granada. Of 23 samples of canned vegetables, 10 exceeded the tolerance level of 1 p.p.m.; 4 had Pb concn. greater than or equal 2 p.p.m. Of 11 samples of canned fruit,

5 exceeded the tolerance level of 1 p.p.m.; 1 sample exceeded 2 p.p.m. Of 16 samples of prepared dishes, 4 exceeded the tolerance of 1 p.p.m.; 1 exceeded 2 p.p.m. Of 12

samples of meat or sea-food, none exceeded the tolerance level of 3 p.p.m.

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

Aspects discussed include: production and food/beverage use of metal cans in the USA; regulatory concern about Pb in foods; voluntary efforts by the food industry to reduce Pb levels; the relatively high potential for Pb contamination of evaporated milk in vent hole cans; measures to minimize dietary Pb intake by children; Pb in relation to the canmaking operation; contamination by visible solder pellets or sub-visual Pb dust; testing for Pb in cans and canned products; current Pb levels in canned foods; container-derived Pb in the diet; and alternatives to lead-soldered cans.

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

28 samples of (i) canned luncheon meat and 30 of (ii) canned liver pate, from 4 manufacturers, were analysed for residues of organochlorine pesticides. (i) samples from 2 manufacturers exceeded the tolerances for lindane and total DDT, average concn. being 0.956 mg/kg for lindane, 0.974 mg/kg for total DDT (approx. double the Yugoslav tolerance). The (i) samples from the other 2 manufacturers, and all (ii) samples, had organochlorine pesticide residue concn. well below the tolerance; residue concn. were higher in these (i) samples than in (ii).

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

Contamination of foods with glass is discussed with reference to: the inevitability that contamination with glass fragments will occasionally occur; the consequent need for efficient inspection; preventive measures; inspection of foods for glass fragments; optical inspection; X-ray detection; other detection methods (acoustic, microwave, metal detector, gamma-irradiation); diagnosis; and future possibilities.

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

Lead (Pb) and Copper (Cu) contents were determined by AAS in 328 canned foods. Results, shown graphically and in a table, revealed that Pb contamination was due mainly to the manufacturing process or the can, Cu mainly to the raw material. Values for Pb were mainly between 0 and 500 parts/billion (p.p.b.). Only 3.6% of the samples contained greater than 2 p.p.m. Pb, though 20% of canned vegetables contained greater than 1 p.p.m. 190 samples contained less than2 p.p.m. Cu, only 11 samples greater than 7 p.p.m. and only 1 sample greater than 12 p.p.m.

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

Possibilities of contamination of canned foods are discussed, together with measures taken to minimize this problem. Aspects considered include: dissolution of Sn and Fe from the tinplate; uptake of Pb from the solder; reduction of pesticide residue concn. in foods during preparation and processing; washing of cans before filling; rapid cooling of cans to minimize corrosion; and effects of nitrates and pesticide residues on the rate of dissolution of Sn from tinplate.

Yokomizo, Y. 1979. [Contamination of processed foods with pesticide residues.] Boletim do Instituto de Tecnologia de Alimentos, Brazil. 16(1):41-51.

Pesticide residues were determined by GLC in samples of canned sardines in oil, canned tuna in oil, canned Vienna sausages, tomato puree, liver pate, frozen conc. orange juice and passion fruit juice; 2 brands of each product except passion fruit juice were studied. Samples were collected at 6-month intervals, 2 in 1977, 1 in 1978. Tables of results are given, including data for concn. of alpha-BHC, gamma-BHC, aldrin, o,p-DDE, p,p-DDE, p,p-DDD, o,p-DDT, p,p-DDT, endrin, dieldrin and endosulfan. The orange and passion fruit juice samples were free from pesticide residues; only a few samples of tomato puree contained residues (DDT group and endrin). Most samples of meat and fish products contained residues of DDT + metabolites; the highest concn. were recorded in canned sausages. Residue concn. in the aqueous medium in which the sausages were canned were low; residue concn. in the oil in which the tuna and sardines were packed were commonly higher than in the fish itself. BHC, endrin, aldrin, dieldrin and endosulfan were present in some canned meat and fish samples. The potential health hazard presented by these residues (especially endrin, dieldrin and endosulfan) is discussed.

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Attachment 1

Examples of Questions to be Considered in a Hazard Analysis

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

A. Ingredients

1. Does the food contain any sensitive ingredients that may present biological hazards (e.g., *Salmonella*, *staphylococcus aureus*); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?

2. Is potable water used in formulating or in handling the food?

B. Intrinsic factors

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

1. Which intrinsic factors of the food must be controlled in order to assure food safety?

2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?

3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?

4. Are there other similar products in the market place? What has been the safety record for these products?

C. Procedures used for processing

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

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

D. Microbial content of the food

1. Is the food commercially sterile (e.g., low acid canned food)?

2. Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?

3. What is the normal microbial content of the food?

4. Does the microbial population change during the normal time the food is stored prior to consumption?

5. Does the subsequent change in microbial population alter the safety of the food pro or con?

E. Facility design

1. Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods if this is important to food safety?

2. Is positive air pressure maintained in product packaging areas? Is this essential for product safety?

3. Is the traffic pattern for people and moving equipment a significant source of contamination?

F. Equipment design

1. Will the equipment provide the time-temperature control that is necessary for safe food?

2. Is the equipment properly sized for the volume of food that will be processed?

3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?

4. Is the equipment reliable or is it prone to frequent breakdowns?

5. Is the equipment designed so that it can be cleaned and sanitized?

6. Is there a chance for product contamination with hazardous substances (e.g., glass)?

7. What product safety devices are used to enhance consumer safety?

- þ metal detectors
- þ magnets
- þ sifters
- þ filters
- þ screens
- þ thermometers
- þ deboners
- þ dud detectors

G. Packaging

1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?

2. Is the package clearly labeled "keep refrigerated" if this is required for safety?

3. Does the package include instructions for the safe handling and preparation of the food by the end user?

4. Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?

5. Are tamper-evident packaging features used?

6. Is each package and case legibly and accurately coded?

7. Does each package contain the proper label?

H. Sanitation

1. Can sanitation impact upon the safety of the food that is being processed?

2. Can the facility and equipment be cleaned and sanitized to permit the safe handling of food?

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

I. Employee health, hygiene, and education

1. Can employee health or personal hygiene practices impact upon the safety of the food being processed?

2. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?

3. Will the employees inform management of a problem which could impact upon safety of the food?

J. Conditions of storage between packaging and the end user

1. What is the likelihood that the food will be improperly stored at the wrong temperature?

2. Would an error in improper storage lead to a microbiologically unsafe food?

K. Intended use

1. Will the food be heated by the consumer?

2. Will there likely be leftovers?

L. Intended consumer

1. Is the food intended for the general public?

2. Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immunocompromised individuals)?