IDENTIFICATION AND CONTROL OF FOOD SAFETY HAZARDS FOR COMMERCIALLY STERILE AND OTHER SHELF-STABLE MEAT AND POULTRY PRODUCTS

The purpose of this section is to:

- Review biological hazards of significance to commercially sterile meat and poultry products.
- Review biological hazards significant to shelf-stable meat and poultry products.
- Distinguish between biological hazards and spoilage organisms.
- Review chemical and physical hazards that are unique to commercially sterile and shelf-stable products.
- Discuss how hazards related to shelf-stable products may differ from those for non-shelf-stable products.
- Discuss the exemption provision for commercially sterile products and how it might be addressed in a HACCP plan.

In addition, you will put the knowledge you have gained to work as you:

1. Critique an example hazard analysis for a canned food product.
2. Critique an example hazard analysis for a shelf-stable product.

HACCP Overview

During the development and design of the HACCP plan, the official establishment determines if there are any biological, chemical, or physical hazards that are reasonably likely to occur before, during, or after entry into the establishment. This hazard analysis is a two-stage process: (1) hazard identification and (2) hazard evaluation. The hazard identification stage results in a comprehensive list of potential hazards to be considered during the hazard evaluation stage. When developing the list of potential hazards, the HACCP team will review, among other things, the raw materials and ingredients, activities conducted and equipment used at each processing step, storage and distribution methods, and the consumers and intended use of the product. Once a list of potential hazards is identified, each of these is evaluated to see which are reasonably likely to occur in the absence of controls to determine which must be addressed in the HACCP plan. Potential hazards that are not addressed in a HACCP plan are often addressed in SSOPs or some other prerequisite program. If the hazard is reasonably likely to occur, it must be addressed with a CCP in a HACCP plan.

Once the significant hazards have been determined, control measures are identified for each of these hazards. There can be many steps in a food processing system where the process (and biological, chemical, or physical hazards) can be controlled to some extent. These will be control points, and many of them will be found in prerequisite (or other) programs. However, there are only a few steps where a loss of control is likely to result in the production of a potentially unsafe food. A step at which control can be applied and at which control is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level is a Critical Control Point (CCP). Examples of control points may include storage temperature, sanitation and post-process handling. Pasteurization, retort processing and drying will be CCPs in many, but not all, operations. Metal detection may be a control point or a CCP, depending on the product and process. It is the establishment's hazard analysis that determines whether there is a hazard that needs to be controlled and the point essential to control that hazard. One reason to have a metal detector is to determine if metal is a hazard reasonably likely to occur.

It is easy to confuse control points (CPs) and CCPs. Let's look at an example with a product intended to be pasteurized. The HACCP team has identified the presence of a specific pathogen in an ingredient (e.g., Salmonella in raw poultry) as a hazard to be addressed in the HACCP plan. The following control measures were identified: temperature control during storage, maintenance of a sanitary environment and pasteurization of the product. While good temperature control and sanitation are important CPs, they alone cannot ensure that the finished product is free of the pathogen. Only the heating process is capable of doing so. Therefore the pasteurization step was identified as the CCP in this example.

The number and nature of CCPs are dependant on the product being produced, the ingredients used, the processing methods employed and the prerequisite programs implemented by the establishment, as addressed in the hazard analysis. These assessments can be complex and it's up to the HACCP team to use their experience and knowledge of the manufacturing process and existing control measures to determine what should and shouldn't be a CCP. That being said, there are certain hazards and CCPs that are likely to be identified by an establishment producing commercially sterile or shelf-stable products. If these are not present, an inspector or auditor would need to look carefully at the plant's justification for their HACCP plan to determine if all hazards are being controlled.

Regulatory Provision for Addressing Microbiological Hazards of Commercially Sterile Products

USDA FSIS states in 9 CFR 417.2 (b) (3) that "HACCP plans for thermally processed/ commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter" [9 CFR Chapter III]. Thus, even though microbiological hazards exist with these products, FSIS decided that these are eliminated by complying with the canning regulations for meat and poultry, which are based on HACCP concepts. Processors of canned meat and poultry products must still develop HACCP plans to address chemical and physical hazards that are reasonably likely to occur.

An example of how a processor of a canned product containing beef may address microbiological hazards in its hazard analysis is as follows.

Ingredient/ Process Step	Potential hazards introduced, controlled or enhanced at this step.	Does this potential hazard need to be addressed in HACCP plan? (Yes/No)	WHY? (Justification for decision made in previous column)	What measures can be applied to prevent, eliminate or reduce the hazards being addressed in your HACCP plan?	Is this step a critical control point (CCP)?
Receiving raw beef	B- vegetative pathogens such as *Salmonella* and *E. coli* O157:H7; sporeforming pathogens such as *C. botulinum* and *C. perfringens*	**No**	Final product is commercially sterile in compliance with 9 CFR 318 subpart G. 9 CFR 417.2 (b) (3) provides exemption for addressing microbiological hazards in the HACCP plan.		
Retort process	B- vegetative pathogens such as *Salmonella* and *E. coli* O157:H7; sporeforming pathogens such as *C. botulinum* and *C. perfringens*	**No**	Process complies with 9 CFR 318 subpart G		

Note: This is only part of the hazard analysis – not all steps are shown, nor are the potential chemical and physical hazards addressed here.

Establishments may also include a statement/letter with their hazard analyses to the effect that they are using the regulatory exemption.

Biological Hazards of Commercially Sterile Meat and Poultry Products

Biological hazards associated with meat and poultry products in general include sporeformers and nonsporefomers. The sporeformers include *Clostridium botulinum*, *Clostridium perfringens*, *Bacillus cereus*. Non-sporeformers (vegetative pathogens) may include, depending on the product, *Staphylococcus aureus*, *Salmonella* spp., *Campylobacter* spp., *Listeria monocytogenes*, and *Escherichia coli* O157:H7. In addition, parasites may be a hazard to be addressed, especially *Trichinella spiralis* in pork.

Clostridium botulinum is the hazard of greatest concern to canned (commercially sterile) products because (1) when it grows it can produce a deadly toxin or poison, (2) it can be isolated from soil or water practically everywhere in the world, (3) it is the pathogen with the greatest heat resistance due to the production of heat resistant spores, and (4) canning foods provides an anaerobic environment favorable to growth of the organism if it has not been destroyed by the process. When processing commercially sterile meat and poultry products, if an establishment controls *C. botulinum,* the other biological hazards in meat and poultry, as well as those in other added ingredients, will also be controlled. Thus, an establishment would be expected to identify *C. botulinum* as a hazard and implement controls for it when producing commercially sterile meat or poultry products. (There is, however, a regulatory provision that allows an establishment to not address controls for microbiological hazards such as *C. botulinum* in the HACCP plan that will be discussed later.)

In low acid foods, high heat must be applied to kill the spores of *C. botulinum*. Thus, these foods must be heat processed under pressure; the scheduled process established by a process authority would be a CCP (unless the establishment elects to use the regulatory exemption). In foods with low pH ($\leq$ 4.6), such as acidified meat and poultry products, the spores of *C. botulinum* cannot germinate and grow out. Controlling the pH is critical to address *C. botulinum*. These foods can be heated at lower temperatures not requiring pressure to destroy non-sporeformers such as *E. coli* O157:H7. Likewise in canned cured meat and poultry products in which outgrowth of *C. botulinum* spores is controlled by formulation (e.g., salt and nitrite), the thermal process will

not be designed to inactivate pathogenic sporeformers. In pH-controlled products and cured products, usually the formulation step is a CCP for *C. botulinum* (pH of product, amount of acid added, amount of nitrite and salt) and the heat step is a CCP (time and temperature) to control vegetative pathogens such as *E. coli* O157:H7 and *Salmonella* (unless the establishment elects to use the regulatory exemption). (If an acidified product is prepared with cooked meat, the establishment may determine that the hazard of vegetative cells of pathogens is not reasonably likely to occur.)

In order to make low acid, acidified and cured meat and poultry products commercially sterile (shelf-stable), processes are designed primarily to destroy heat resistant organisms that could spoil the product when it is held at room temperature rather than the pathogens of concern. These spoilage organisms include sporeformers such as *C. sporogenes* for low-acid and cured meat and poultry products and *C. butyricum* for acidified products. Product that has received an insufficient heat process may or may not be unsafe, depending on whether the underprocessing was sufficient to allow pathogens to survive. Also, it must be remembered that, by design, not all the lethality is included in most processes. Thus, in some underprocessing situations, the product will still be commercially sterile. It is important to have a processing authority that is familiar with the product involved in the design of the process and the evaluation of all deviations.

Because of the severity of the processes to provide a commercially sterile product, there is less concern about control at steps coming before the thermal process. For example, although establishments will implement programs to control the temperature of raw ingredients such as meat, even if there are problems with temperature control it is not likely that microbial growth will compromise the process (although it may compromise the quality of the product). Likewise, canning establishments are likely to have programs to control microorganisms in can cooling water; however, it is unlikely that low levels of chlorine in the water will result in unsafe product if water containing microorganisms should pass through the can seam during cooling. Thus, although these prerequisite programs address potential biological hazards, their primary impact is on product quality, not safety, and they are not considered CCPs.

Biological Hazards of Shelf-Stable Dried Meats

Biological hazards associated with meat and poultry products in general, as described for commercially sterile meat and poultry products, are the same for shelf-stable dried meats: *Clostridium botulinum*, *Clostridium perfringens*, *Bacillus cereus*, *Staphylococcus aureus*, *Salmonella* spp., *Campylobacter* spp., *Listeria monocytogenes*, and *Escherichia coli* O157:H7, and parasites such as *Trichinella*

spiralis in pork. Whether these potential hazards need to be addressed in a HACCP plan will depend on the specific product.

Although *Clostridium botulinum* is a hazard to be considered, because of the dried nature of these products vegetative pathogens– *Salmonella*, *E. coli* O157:H7, *S. aureus*, and *L. monocytogenes* - are more of a concern than with commercially sterile products. Control of biological hazards for shelf-stable dried meat products relies on multiple factors (the hurdle concept). The hurdles and the CCPs will vary, depending on the product and process, with pH and a_w of primary importance to the safety of these products. For fermented shelf-stable products CCPs are generally at the steps for fermentation (e.g., time to pH 5.3), heating (time and temperature), and, sometimes, drying (e.g., drying room temperature and time). For non-fermented salt-cured products, the salting step (e.g., amount of salt, penetration time) is critical and for dried products the drying step (e.g., drying temperature, time, humidity) is critical. For freeze-dried products and bacon bits, the cooking step (time and temperature) is usually critical.

The success of the CCPs for these products is more dependent on the proper conduct of other procedures that may be in prerequisite programs than with commercially sterile products. For example, proper handling of meats is important to ensure low levels of pathogens that can be controlled by fermentation, salting, drying, etc. With fermented meats, storage and handling of the starter culture is important to ensure proper fermentation takes place. Cell death of the culture due to temperature abuse can result in the rate of pH reduction not being adequate to prevent toxin formation by *S. aureus*. However, starter culture failure would be detected by monitoring the pH during fermentation (the CCP). Proper handling of starter cultures to prevent failure of the fermentation process is important to prevent economic loss.

Chemical Hazards

Chemical hazards for commercially sterile and shelf-stable meat products do not differ from those for other food products. Potential chemical hazards for shelf-stable products include nitrite, unlabeled allergens, antibiotic residues in meats, cleaners and sanitizers, etc. However, these are not unique to shelf-stable products. Establishments producing shelf-stable products would evaluate potential chemical hazards in the same manner as other establishments.

Physical Hazards

Physical hazards for commercially sterile and shelf-stable meat products do not differ from those for other food products. Potential physical hazards include metal, in ground meat products, and glass, if product is packed in glass containers. Again, these are not unique to shelf-stable products, and the establishment would use the same procedures to evaluate whether the identified potential physical hazards are reasonably likely to occur in its operations.

Hazards for Shelf-Stable Products Compared to Non-Shelf-Stable Products

The major difference in hazards for shelf-stable and non-stable products lies in the biological hazards that need to be addressed in the HACCP plan and how they are controlled. For comparison purposes, let's look at canned beef stew in comparison to frozen beef stew. As noted above, the biological hazard to be addressed for canned beef stew is *C. botulinum*. This hazard will be controlled by the thermal process given to the product in the can, which will include processing time and temperature, along with other critical factors specified by the process authority. However, with frozen beef stew, *C. botulinum* cannot grow since the product is frozen. The biological hazards likely to be addressed in the HACCP plan include *Salmonella* and *Escherichia coli* O157:H7 from the beef, *L. monocytogenes* in from the beef and the vegetables, and *C. perfringens* from the beef and spices. The vegetative cells of these pathogens will be killed in the cooking process for the stew; spores of *C. perfringens*, which will survive the cook, will be controlled by proper cooling. Recontamination with *L. monocytogenes* will probably be addressed with sanitation that is verified by environmental monitoring. Similarly, for luncheon meats, the hazard for commercially sterile pork luncheon meat is *C. botulinum*, which will be controlled by the curing salts (sodium chloride and nitrite) and the thermal process. For refrigerated luncheon meats, the hazards are likely to include *Salmonella*, trichinae, and *L. monocytogenes*, as well as *C. botulinum*. The curing salts (along with refrigeration) will control *C. botulinum* (and *C. perfringens*) and the heat treatment will kill *Salmonella*, trichinae and *L. monocytogenes*. *L. monocytogenes* recontamination must also be controlled using one of the three alternatives specified in 9 CFR 430.4 for ready-to-eat meat and poultry products; this may or may not be part of the HACCP plan.

Workshop: Canned Beef Stew

Directions

1st Read the Scenario for Canned Beef Stew
2nd Review the Flow Chart
3rd Review the Hazard Analysis
4th Answer the questions

Scenario

►**ABC Meat Canning Company** makes a beef stew that consists of beef and vegetable chunks in sauce. The company has been provided with a process letter by its processing authority, Thermal Process Authorities, Inc. (TPA). In establishing the process for the beef stew, the company contracted with TPA to have heat distribution tests run on the retort. In addition, they had heat penetration tests run on the product using 2-inch chunks of formed beef, which is larger than any of the chunks of meat or vegetables in the finished product. When the ABC HACCP team put together the hazard analysis for the product, they listed as biological hazards the vegetative pathogens that are commonly associated with beef – *Salmonella*, *E. coli* O157:H7 – as well as sporeformers such as *C. botulinum* and *C. perfringens*.

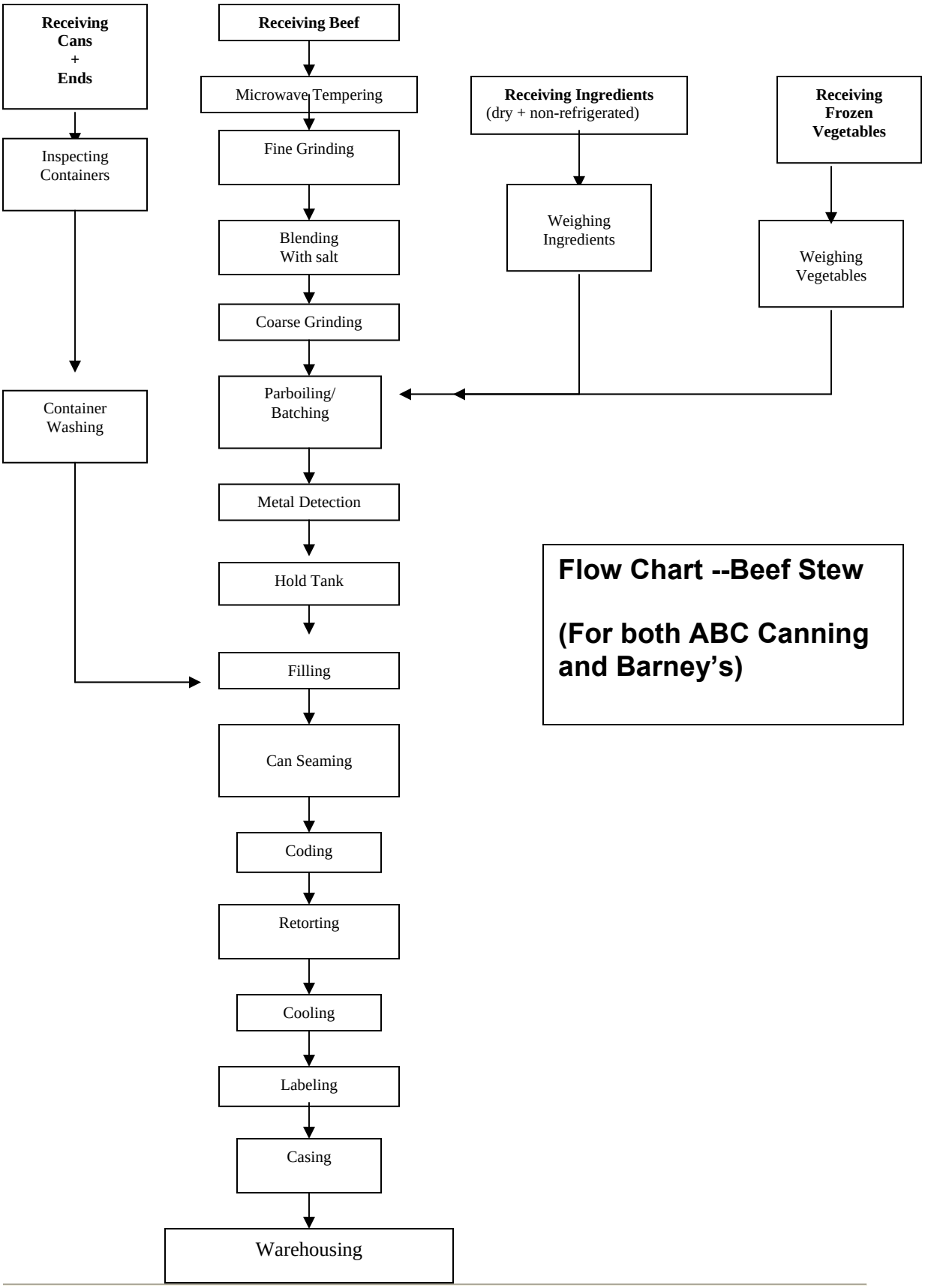
Chemical hazards such as antibiotic residues were considered not reasonably likely to occur, since the meat was obtained from a FSIS-inspected facility operating under HACCP. The team also decided that metal is not a significant hazard to address in their HACCP plan.

►**Barney's Beef Stew Inc.** also makes a beef stew using essentially the same ingredients and similar processing procedures as ABC Meat Canning Company. Barney's Beef Stew also had heat distribution/heat penetration tests conducted in the same manner as ABC. Since Barney's also uses TPA for their process authority, they have a process letter similar to ABC's. There are a couple of significant differences in the HACCP plans for the products produced by the two companies. In developing their HACCP plan, Barney's decided that metal is a significant hazard and established a metal detector as a CCP. Barney's does not address biological hazards in the HACCP plan, citing the exemption for canned products produced in accordance with the requirements of 9 CFR 318, subpart G.

Note: The flow chart for the beef stew is the same for both plants. ABC and Barney's have process letters that are essentially the same, so only one is provided.

Commercially Sterile Beef Stew

Product Description	Method of Distribution
Fully cooked beef stew in 401 x 411 metal doubled-seamed can with easy-open end.	Ambient Temperature Truck transport from warehouse to retail distribution facilities
Intended Use	**Target Consumer**
Ready – to – eat Reheat to warm the product before consuming	General Public (children, adults, elderly)
List of Ingredients	**Processing methods**
• Beef (85% lean and trimmings) • Dehydrated Frozen Potato Cubes • Frozen Carrot Cubes • Modified Corn Starch • Tomato Paste • Salt • Sugar • Seasonings • Caramel Coloring	• Receive ingredients and materials (frozen raw beef chunks, frozen vegetables, dry and non-refrigerated ingredients, metal cans and ends) • Grind and blend beef with salt • Grind beef and salt blend • Parboil formulated beef chunks in water • Batch meat blend, vegetables and remaining ingredients (heated) • Pump through in-line metal detector • Fill, seam and ink-jet code cans • Thermally process in batch retort and cool in cooling canal • Label • Case • Warehouse


Receiving Cans + Ends
Inspecting Containers
Container Washing
Receiving Beef
Microwave Tempering
Fine Grinding
Blending With salt
Coarse Grinding
Parboiling/ Batching
Metal Detection
Hold Tank
Filling
Can Seaming
Coding
Retorting
Cooling
Labeling
Casing
Warehousing
Receiving Ingredients (dry + non-refrigerated)
Weighing Ingredients
Receiving Frozen Vegetables
Weighing Vegetables
Flow Chart --Beef Stew
(For both ABC Canning and Barney's)

Questions

1. ABC does not include a CCP for metal in their HACCP plan, yet Barney's does for the same product. Did ABC miss identifying a hazard when they did their hazard analysis?

2. Barney's Beef Stew doesn't have CCPs for the thermal process in their HACCP plan. Should they? Do they have adequate control over biological hazards? Explain briefly.

3. *C. perfringens* has been known to cause illness yet it was not identified as a hazard in either plan. Would you expect these companies to address these organisms in their HACCP plan? Explain why or why not. What should the target organism be?

4. Review the attached **process letter**. ABC is monitoring time and temperature of the process. Based on the process letter, are they controlling all the right factors, or are there other factors that should be monitored?

5. On December 23, around the busy holidays, the retort temperature fell 4°F below the specified process temperature (245˚F). One of the alternate processes (240˚F) listed in the process letter was applied. Did a processing deviation occur? What if the temperature dropped to 235°F?

6. Barney's Beef Stew did not list a control for microbiological hazards and instead applied the option based on operating in accordance with 9 CFR 318 subpart G which requires them to process in accordance with a process schedule established by a process authority. You ask to see their process letter. What factors would you expect Barney's to be controlling?

7. At ABC Meat Canning there is a delay between seaming and the retort process. Should the company reassess their HACCP plan to address microbial hazards due to this delay prior to the retort step? Why or why not?

8. What are the major differences in the two hazard analyses? Are these differences justified?

7/20/2004

Dr. John Smith
Food Safety/Regulatory Compliance Senior Manager
ABC Meat Canning Company
1234 E. Canning Plant Road
Somewhere, ST 12345-1234

Dear John,

Based on the heat penetration data that we developed (see letter of 6/6/04), we would recommend the following thermal processes for your **BEST BEEF STEW** in 401X411 metal cans and processed in a still retort.

Product:: Best Beef Stew
Container: 401 x 411 can
Processing System: Still or Hydrostatic Retort
Least Sterilizing Value: $F_0 \geq 5.9$ minutes

Critical Factors

1. Maximum size of beef chunk 2 inches
2. Sauce Formulation (as tested)
3. Fill weight 20.4 oz

Recommended Thermal Process Schedule

	Process Time (minutes) at Retort Temperature (°F)				
Minimum Initial Temperature (°F)	**240**	**245**	**250**	**255**	**260**
100	141	131	125	121	118
120	140	130	124	120	117
140	139	129	123	119	116
160	137	127	121	117	115

These processes are designed to produce a commercially sterile product provided that all processing and packaging operations are completed satisfactorily. Please give us a call if you have any further questions.

Sincerely yours,

Kelly White
Senior Scientist, TPA, Inc.

Workshop: Pepperoni

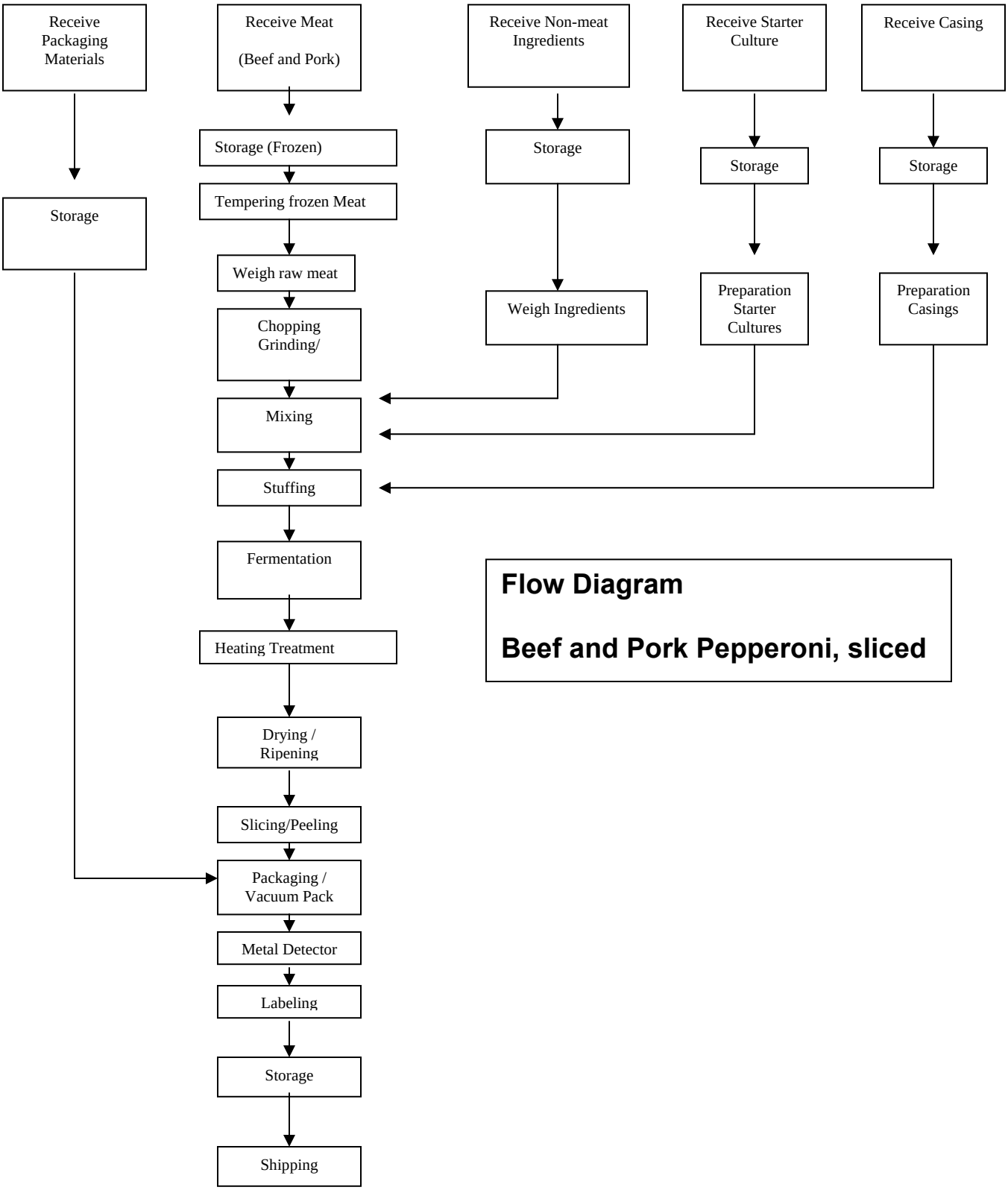
Directions

1st Read the Scenario for Pepperoni
2nd Review the Flow Chart
3rd Review the Hazard Analysis
4th Answer the questions

Tony's Specialty Meats, Inc., has been asked to produce a new product – a sliced beef and pork pepperoni. The company's first step in developing a HACCP plan for this product was to conduct a hazard analysis to determine which potential hazards present a significant health risk to consumers such that they must be addressed in the HACCP plan. You are reviewing the hazard analysis.

Beef and Pork Pepperoni, Sliced

Product Description	Method of Distribution
Beef and Pork Pepperoni Shelf-stable, in a resealable plastic package	Ambient Temperature Truck transport from warehouse to retail facilities
Intended Use	**Target Consumer**
Ready to Eat Used as a pizza topping to be reheated before serving	Retail Sales General Public (children, adults, elderly)
List of Ingredients	**Processing methods**
• Pork and Beef 50% Lean • Salt • Spices • Dextrose • Lactic acid starter culture • Oleoresin of paprika • Flavoring • Sodium ascorbate • Sodium nitrite • BHA, BHT, citric acid	Meat is ground, mixed with spices and other ingredients and a starter culture, stuffed into casings, fermented, dried, sliced, and packaged.


Receive Packaging Materials
Receive Meat (Beef and Pork)
Receive Non-meat Ingredients
Receive Starter Culture
Receive Casing
Storage (Frozen)
Storage
Storage
Storage
Tempering frozen Meat
Storage
Weigh raw meat
Weigh Ingredients
Preparation Starter Cultures
Preparation Casings
Chopping Grinding/
Mixing
Stuffing
Fermentation
Heating Treatment
Drying / Ripening
Slicing/Peeling
Packaging / Vacuum Pack
Metal Detector
Labeling
Storage
Shipping
Flow Diagram
Beef and Pork Pepperoni, sliced

Questions

1. Does the flow chart depict all the steps in the process? Does the hazard analysis depict all the steps in the process? If not, which steps are missing?

2. Did the establishment consider all three types of hazards (biological, chemical and physical) at each step listed in the hazard analysis? Did they list specific hazards? If not, where should they be more specific?

3. Does it appear that the establishment considered all relevant hazards? If not, what others should they consider?

4. Identify the potential pathogens that might be considered at the meat (beef and pork) receiving step.

5. List the hazards the plant has identified to be controlled in the HACCP plan and the CCPs for each of these hazards.

6. The team did not identify mold or mycotoxins in the hazard analysis. Should they be listed? Why or why not?

7. Some sausage processes include a heat treatment and others do not. Why is a heat treatment used? Why is it done after the fermentation process instead of heating the final product?

8. Is there appropriate justification for not including temperature control of raw meat during storage to prevent growth of pathogens as a CCP for this product? What supporting documentation would you be looking for?