

## CHAPTER 18: Introduction of Pathogenic Bacteria After Pasteurization and Specialized Cooking Processes

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### UNDERSTAND THE POTENTIAL HAZARD.

The introduction of pathogenic bacteria after pasteurization and certain specialized cooking processes can cause consumer illness. The primary pathogens of concern are *Clostridium botulinum* (*C. botulinum*), *Listeria monocytogenes*, *Campylobacter jejuni*, pathogenic strains of *Escherichia coli*, *Salmonella spp.*, *Shigella spp.*, *Yersinia enterocolitica*, *Staphylococcus aureus* (*S. aureus*), *Vibrio cholerae*, *Vibrio vulnificus*, and *Vibrio parahaemolyticus*. See Appendix 7 for a description of the public health impacts of these pathogens.

- **Goal of pasteurization and specialized cooking processes**

Pasteurization is a heat treatment applied to eliminate the most resistant pathogenic bacteria of public health concern that is reasonably likely to be present in the food. With fishery products, pasteurization is usually performed after the product is placed in the hermetically sealed finished product container. It is applied to fishery products that are distributed either refrigerated or frozen. Examples of pasteurized fishery products follow: pasteurized crabmeat, pasteurized surimi-based analog products, and pasteurized lobster meat.

In addition to eliminating pathogenic bacteria, the pasteurization process also greatly reduces the number of spoilage bacteria present in the fishery product. Spoilage bacteria normally restrict the growth of pathogenic bacteria through

competition. Rapid growth of pathogenic bacteria that may be introduced after pasteurization is, therefore, a concern. This chapter covers control of recontamination after pasteurization.

For some products that are marketed refrigerated, cooking is performed immediately before reduced oxygen packaging (e.g., vacuum packaging, modified atmosphere packaging). For these products, the cooking process is targeted to eliminate the spores of *C. botulinum* type E and non-proteolytic types B and F, particularly when the product does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen (e.g., many refrigerated, vacuum packaged hot-filled soups, chowders, and sauces).

These specialized cooking processes, which are discussed in Chapter 16, have much in common with pasteurization processes, which are also discussed in Chapter 16. For example, control of recontamination after the product is placed in the finished product container is critical to the safety of these products. Additionally, because these products are cooked before they are packaged, they are at risk for recontamination between cooking and packaging. The risk of this recontamination may be minimized by filling directly from the cook kettle using a sanitary, automated, continuous-filling system (designed to minimize the risk of recontamination) while the product is still hot (i.e., hot filling). This control strategy may not be suitable for products such as crabmeat, lobster meat, or crayfish meat that are

handled between cooking and filling. Hot filling is covered in this chapter.

- **Control of pathogenic bacteria introduction after pasteurization and after specialized cooking processes**

There are three primary causes of recontamination after pasteurization and after cooking that is performed immediately before reduced oxygen packaging:

- Defective container closures;
- Contaminated container cooling water;
- Recontamination between cooking and reduced oxygen packaging.

Poorly formed or defective container closures can increase the risk of pathogens entering the container through container handling that occurs after pasteurization or after the cooked product is filled into the reduced oxygen package. This risk is a particular concern during container cooling performed in a water bath. Contaminated cooling water can enter through the container closure, especially when the closure is defective. Container closure can be controlled by adherence to seal guidelines that are provided by the container or sealing machine manufacturer. Control is accomplished through periodic seal inspection.

Contamination of cooling water can be controlled either by ensuring that a measurable residual of chlorine, or other approved water treatment chemical, is present in the cooling water or by ensuring that ultraviolet (UV) treatment systems for the cooling water are operating properly, particularly for systems in which the water is reused or recirculated.

Recontamination between cooking and reduced oxygen packaging in continuous filling systems, where the product is packaged directly from the kettle, can be controlled by hot filling at temperatures at or above 185°F (85°C). FDA is interested in information on the value of adding a time component (e.g., 3 minutes) to this hot filling temperature recommendation to

provide limited lethality for any non-proteolytic *C. botulinum* spores present on the packaging material.

It may also be prudent to use packaging that has been manufactured or treated to inactivate spores of *C. botulinum* type E and non-proteolytic types B and F (e.g., gamma irradiation and hot extrusion). FDA is also interested in comment on the utility of such measures.

- **Strategies for controlling pathogenic bacteria growth**

There are a number of strategies for the control of pathogenic bacteria in fish and fishery products. They include:

- Controlling the introduction of pathogenic bacteria after the pasteurization process and after the cooking process performed immediately before reduced oxygen packaging (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in Chapter 13);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the level of acidity (pH) in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by Chapter 13 for refrigerated acidified products);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 4);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16) or by retorting (covered by the Thermally

Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113, called the Low Acid Canned Foods regulation in this guidance document);

- Killing pathogens by processes that retain the raw product characteristics (covered in Chapter 17);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15).

## **DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.**

The following guidance will assist you in determining whether introduction of pathogenic bacteria after pasteurization is a significant hazard at a processing step:

1. Is it reasonably likely that pathogenic bacteria will be introduced at this processing step (consider post-pasteurization and post-cooking processing steps only)?

It is reasonable to assume that in the absence of controls, pathogens of various types may enter the finished product container after pasteurization or after filling the cooked product into the reduced oxygen package. This is a particular concern for products that are cooled in a water bath.

2. Can the introduction of pathogenic bacteria after pasteurization be eliminated or reduced to an acceptable level here?

Introduction of pathogenic bacteria after pasteurization should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. Preventive measures for introduction of

pathogenic bacteria after pasteurization can include:

- Controlling container sealing;
- Controlling the residual of chlorine, or other approved water treatment chemical, in container cooling water;
- Controlling UV light intensity of bulbs used for treating container cooling water and the flow rate of the cooling water moving through the UV treatment system;
- Hot filling the product into the final container in a continuous filling system.

- **Intended use**

It is unlikely that the intended use will affect the significance of this hazard.

## **IDENTIFY CRITICAL CONTROL POINTS.**

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for introduction of pathogenic bacteria after pasteurization.

If you identified the hazard as significant, you should identify the container sealing step, the water bath container cooling step, and the hot filling step (where applicable) as the CCPs for this hazard.

*Example:*

*A crabmeat processor that pasteurizes the finished product cans after filling and cools them in a water bath should set the CCPs for introduction of pathogenic bacteria after pasteurization at the can seaming and water bath can cooling steps.*

This control approach is a control strategy referred to in this chapter as “Control Strategy Example - Control of Recontamination.”

## DEVELOP A CONTROL STRATEGY.

The following guidance provides a strategy to control the introduction of pathogenic bacteria into the product after pasteurization. You may select a control strategy that is different from that which is suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following is an example of a control strategy included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Control of recontamination	✓	✓

- **CONTROL STRATEGY EXAMPLE - CONTROL OF RECONTAMINATION**

**Set Critical Limits.**

For container sealing:

- Container or sealing machine manufacturer's seal guidelines.

For container cooling:

- Measurable residual of chlorine, or other approved water treatment chemical, at the discharge point of the container cooling tank;
- OR
- Equipment manufacturer's UV light intensity and flow rate guidelines.

For hot filling:

- Product temperature of 185°F (85°C) or higher as the product enters the final container.

**Establish Monitoring Procedures.**

» **What Will Be Monitored?**

For container sealing:

- Container integrity.

For container cooling:

- For chemical treatment:
  - Residual chlorine, or other approved water treatment chemical, in the cooling water;

OR

- For UV treatment:
  - Intensity of UV light;
- AND
- Cooling water flow rate.

For hot filling:

- Product temperature as the product enters the final container.

» **How Will Monitoring Be Done?**

For container sealing:

Visual examination of containers (non-destructive):

- Recommendations for visual examinations that ensure a reliable hermetic seal should be obtained from the container or sealing machine manufacturer. They should include:
  - For double-seamed metal and plastic cans:
    - The external features of the double seam should be examined for gross closure defects, including: cutovers, seam sharpness, false seams, deadheading, droop, damage to the countersink wall indicating a broken chuck, cable cuts, and product overlapping the flange. In addition, visual examination should include examination of the entire container for product leakage or other obvious defects;

OR

- For pouches:
  - Visual examination should be sufficient to detect gross closure defects, including: cuts, fractures,

non-bonding, malformation, puncture, abrasion, blister, contaminated seal, delamination, seal creep, wrinkle, flex cracks, crushed package, or other obvious defects;

OR

- For glass containers:
  - Visual examination should be sufficient to detect gross closure and glass defects, including: cap tilt, cocked cap, crushed lug, stripped cap, cut through, and chipped and cracked glass finish;

AND

Detailed examination of containers (destructive):

- Recommendations for seal evaluation measurements that ensure a reliable hermetic seal should be obtained from the container or sealing machine manufacturer. They should include:
  - For double-seamed metal and plastic cans:
    - The examination should include a teardown examination of the can. If the micrometer method is used, three measurements, approximately 120° apart around the double seam, should be made. Measurements should include: cover hook, body hook, width, tightness, and thickness. If the optical method (seamscope or projector) is used, cuts should be made at at least two different locations, excluding the side seam juncture. Measurements should include body hook, overlap, tightness, and thickness;

OR

- For pouches:
  - The examination should include burst, vacuum or bubble testing. It may also include: drop testing, peel

testing (tensile strength), residual gas testing, electroconductivity testing, and dye testing;

OR

- For glass containers:
  - The examination should include cold water vacuum testing. Additional examinations may include: for lug-type caps, security values (lug-tension) and for lug-type, twist caps, pull-up (lug position).

For container cooling:

- For chemical treatment:
  - Measure residual of chlorine, or other approved water treatment chemical, at the discharge point of the container cooling tank;

OR

- For UV treatment:
    - Use a UV light meter;
- AND
- Use a flow rate meter.

For hot filling:

- Use a continuous temperature-measuring instrument (e.g., a recorder thermometer).

#### » How Often Will Monitoring Be Done (Frequency)?

For container sealing:

Visual examination of containers:

- At least one container from each sealing head at least every 30 minutes of sealing machine operation. At a minimum, visual examinations should include those made at the beginning of the production day, and immediately after a jam in the sealing machine, or after machine adjustment, repair, or prolonged shutdown;

AND

Detailed examination of containers:

- At least one container from each sealing head at least every 4 hours of sealing machine operation. At a minimum, visual examinations should include those made at the beginning of the production day, and immediately after a jam in the sealing machine, or after machine adjustment, repair, or prolonged shutdown.

For container cooling:

- For chemical treatment:
  - At least once every 4 hours of use;
- OR
- For UV treatment:
  - At least daily.

For hot filling:

- Continuous monitoring, with a visual check of the instrument at least once per batch of cooked product.

» **Who Will Do the Monitoring?**

For container sealing:

- Monitoring may be performed by any person who is trained and qualified to conduct container examinations.

For container cooling:

- Monitoring may be performed by any person who has an understanding of the nature of the controls.

For hot filling:

- For continuous temperature-measuring instruments:
  - Monitoring is performed by the equipment itself. The visual check of the data generated by the equipment, to ensure that the critical limits have consistently been met, may be performed by any person who has an understanding of the nature of the controls.

***Establish Corrective Action Procedures.***

Take the following corrective action to a product involved in a critical limit deviation:

For container sealing:

- Repack and recook or repasteurize the affected product;
- OR
- Segregate and hold the product to evaluate the seriousness of the defects, which may include, but is not limited to, 100% visual inspection of all affected containers to remove the defective containers. Any containers that are found to be unsafe should be destroyed, diverted to a non-food use, or repacked and recooked;
- OR
- Divert the product to a use in which the critical limit is not applicable (e.g., divert to a canning operation);
- OR
- Destroy the product;
- OR
- Divert the product to a non-food use.

For hot filling:

- Recook the product;
- OR
- Segregate and hold the product for a safety evaluation. If the product is found to be unsafe, it should be destroyed, diverted to a non-food use, or recooked;
- OR
- Divert the product to a use in which the critical limit is not applicable (e.g., divert to a canning operation);
- OR
- Destroy the product;
- OR
- Divert the product to a non-food use.

AND

Take one or more of the following corrective actions to regain control over the operation after a critical limit deviation:

For container sealing:

- Identify and correct the source of the defect.

For container cooling:

- If no measurable residual chlorine, or other approved water treatment chemical, is detected, add chlorine or adjust the chlorine-metering system and recheck for chlorine residual;

OR

- If UV intensity is inadequate, replace or clean the bulbs or shields;

OR

- If flow exceeds the critical limit, adjust or replace the pump.

For hot filling:

- Adjust the cooking equipment to increase the processing temperature;

OR

- Adjust the post-cook process to minimize time delays.

### ***Establish a Recordkeeping System.***

For container sealing:

- Record of visual examination of containers;
- AND
- Record of detailed examination of containers.

For container cooling:

- For chemical treatment:
  - Record of residual chlorine, or other approved water treatment chemical;

OR

- For UV treatment:
  - Record of UV intensity testing;

AND

- Record of flow rate testing.

For hot filling:

- Record of continuous temperature monitoring;

AND

- Record of visual checks of recorded data.

### ***Establish Verification Procedures.***

For container sealing:

- Obtain container seal guidelines from container or sealing machine manufacturer;

AND

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

For container cooling:

- Obtain UV light intensity and flow rate guidelines from the UV light manufacturer;

AND

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

For hot filling:

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:

This check can be accomplished by:

- Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point (note that the temperature should be adjusted to compensate for altitude, when necessary);

OR

- Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National

Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Devices subjected to high temperatures for extended periods of time may require more frequent calibration. Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND



TABLE 18-1

**CONTROL STRATEGY EXAMPLE - CONTROL OF RECONTAMINATION**

This table is an example of a portion of a Hazard Analysis Critical Control Point plan using "Control Strategy Example - Control of Recontamination." This example illustrates how a processor of pasteurized blue crabmeat, packed in steel cans, can control introduction of pathogenic bacteria after pasteurization. It is provided for illustrative purposes only.

Pathogenic bacteria recontamination after pasteurization may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides, pathogenic bacteria growth and toxin formation during processing, pathogenic bacteria survival through cooking and pasteurization, and metal fragments).

**Example Only  
See Text for Full Recommendations**

(1) CRITICAL CONTROL POINT	(2) SIGNIFICANT HAZARD(S)	(3) CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	(4) MONITORING			(7) WHO	(8) CORRECTIVE ACTION(S)	(9) RECORDS	(10) VERIFICATION
			(5) WHAT	(6) HOW	(6) FREQUENCY				
Container sealing	Pathogenic bacteria introduction	No visible cutovers, seam sharpness, false seams, deadheading, droop, damage to the countersink wall indicating a broken chuck, cable cuts, product overlapping the flange, product leakage, or other obvious defects	Container integrity	Visual seam examination	One can per seaming head every 30 minutes; at startup; and after jams, adjustments, repairs, and prolonged shutdowns	Seamer operator	Identify and correct the source of the defect  Evaluate the seriousness of the defect, and hold for further evaluation if necessary	Visual seam examination record	Obtain can seam guidelines from the can manufacturer  Review monitoring and corrective action records within 1 week of preparation
			Container integrity	Double seam teardown examination, using a micrometer at 3 points on the seam, 120° apart	One can per seaming head every 4 hours; at startup; and after jams, adjustments, repairs, and prolonged shutdowns	Seamer operator	Identify and correct the source of the defect  Evaluate the seriousness of the defect, and hold for further evaluation if necessary	Double seam teardown record	
Water bath container cooling	Pathogenic bacteria introduction	Measurable residual chlorine  Cover hook: .070 inch minimum; body hook: .072-.088 inch; width: .125 inch maximum; thickness .052-.058 inch; tightness 80%	Residual chlorine in water bath	Rapid test	Every batch	Pasteurizer operator	Add chlorine and recheck for residual	Residual chlorine record	

\* Note: The critical limits in this example are for illustrative purposes only and are not related to any recommended process

## **BIBLIOGRAPHY.**

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

- Gavin, A., and L. M. Weddig (ed.). 1995. Canned foods – principles of thermal process control, acidification, and container closure evaluation. National Food Processors Institute, Washington, DC.