

## CHAPTER 17: Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics

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### UNDERSTAND THE POTENTIAL HAZARD.

The survival of pathogenic bacteria through processes designed to retain raw product characteristics can cause consumer illness. The primary pathogens of concern are *Vibrio vulnificus* (*V. vulnificus*) and *Vibrio parahaemolyticus* (*V. parahaemolyticus*). See Appendix 7 for a description of the public health impacts of these pathogens.

- **Goal of processes designed to retain raw product characteristics**

Some processes are designed to reduce specific pathogens to acceptable levels while retaining the sensory qualities (appearance, taste, and texture) of the raw product. These processes are particularly useful in addressing the hazard associated with the target pathogen in raw products such as raw molluscan shellfish (i.e., oysters, clams, mussels, and whole and roe-on scallops) that are intended for the raw ready-to-eat market. Because these processes do not eliminate all pathogens of public health concern, they are not considered cooking or pasteurization processes. Finished products in which the raw sensory qualities are not maintained are covered in Chapter 16, "Pathogenic Bacteria Survival Through Cooking and Pasteurization."

Examples of processes designed to retain raw product characteristics include:

- High hydrostatic pressure processing (HPP);
- Individual quick freezing (IQF) with extended frozen storage;

- Mild heat processing;
- Irradiation.

HPP, IQF with extended frozen storage, mild heat processing, and irradiation are processes currently used for the treatment of raw molluscan shellfish to reduce the presence of *V. vulnificus* and *V. parahaemolyticus* to non-detectable levels. *V. vulnificus* and *V. parahaemolyticus* are naturally occurring pathogens (i.e., not associated with human or animal sources) that may be present in fish and fishery products, and in particular, raw molluscan shellfish. Non-detectable for these pathogens is defined under the National Shellfish Sanitation Program (NSSP) as less than 30 (MPN)/gram. MPN means most probable number and it is an approximation of the bacterial population in analyzed product. Shellfish that are processed in a manner that achieves a non-detectable level for one or both of these pathogens may bear "added safety" labeling. Additionally, they need not meet the time from exposure to air (e.g., by harvest or receding tide) to refrigeration recommendations specific to *V. vulnificus* and *V. parahaemolyticus* described in Chapter 4.

These processes also may have application to pathogens other than *Vibrio spp.* and to products other than raw molluscan shellfish, but such applications are not presently in commercial use in the U.S. fish and fishery products industry.

Control of pathogenic bacteria growth and toxin formation during storage of these products may be important to their safety because:

- Pathogens that are more resistant than the target pathogen(s) may survive the process;

- These processes may reduce the number of spoilage bacteria in the food, reducing competition for any surviving pathogenic bacteria.

Strategies for controlling pathogenic bacteria growth and toxin formation are included in Chapter 12 (for pathogens other than *Clostridium botulinum* (*C. botulinum*)) and Chapter 13 (for *C. botulinum*).

- **High Hydrostatic Pressure Processing (HPP)**

HPP is the application of hydrostatic compression in the range of 14,500 to 145,000 pound per square inch (100 to 1,000 megapascal (MPa)). These pressures are capable of inactivating pressure-sensitive pathogens, especially vegetative forms. Some pathogens are more sensitive to pressure than are others. For example, *V. parabaemolyticus* and *V. vulnificus* are particularly sensitive. However, HPP appears to have limited effect against bacterial spores like *C. botulinum* unless combined with other treatments, such as heat and acidity (pH).

The effectiveness of the process is dependent upon the amount of pressure applied, the process temperature, and the duration of the process. However other organoleptic changes, such as texture, viscous liquor and a “plumper” appearance have been reported. Additionally, the pressure facilitates oyster adductor muscle changes; hence, HPP may result in a shucked oyster.

- **Individual quick freezing (IQF) with extended frozen storage**

IQF involves the use of cryogenic or blast freezing technology to rapidly lower the product temperature below freezing. This process results in a reduction in the number of freeze-sensitive pathogens. Some pathogens are more sensitive to freezing than are others. For example, *V. parabaemolyticus* and *V. vulnificus* are especially sensitive. To reduce *V. parabaemolyticus* and/or *V. vulnificus* to non-detectable levels, the IQF process is followed by a period of frozen storage, which may vary depending on organism.

- **Mild heat processing**

Mild heat processing involves submerging the product first in a hot water bath for a prescribed time period followed by dipping it in an ice water bath. This process results in a reduction in the number of heat-sensitive pathogens. Some pathogens are more sensitive to heat than are others. *V. parabaemolyticus* and *V. vulnificus* are especially sensitive.

- **Irradiation**

Ionizing radiation (i.e., irradiation) is used to eliminate or reduce the numbers of bacterial pathogens, parasites, and insects in food. It can also be used to delay physiological processes (e.g., ripening) in fruit and vegetables. Acceptable sources of ionizing radiation in the United States include: gamma rays from sealed units of the radionuclides cobalt-60 and cesium-137; electrons generated by machine sources (at energies not exceeding 10 million electron volts); and, x-rays generated by machine sources (at energies not exceeding 5 or 7.5 million electron volts, depending on the target material as set forth in 21 CFR 179.26 (a)).

FDA has approved the use of ionizing radiation for the control of *V. parabaemolyticus* and *V. vulnificus* and other foodborne pathogens in fresh or frozen molluscan shellfish. Mandatory irradiation controls are described in the Irradiation in the Production, Processing and Handling of Food regulation (21 CFR 179). Irradiation of fresh and frozen molluscan shellfish may not exceed an absorbed dose of 5.5 kilograys (kGy) (21 CFR 179.26(b)).

Some pathogens are more sensitive to ionizing radiation than are others. *V. parabaemolyticus* and *V. vulnificus* are highly sensitive, whereas *Salmonella spp.* and *Listeria monocytogenes* (*L. monocytogenes*) are more resistant. Bacterial spores (e.g., *C. botulinum*) are more resistant to ionizing radiation than are bacterial vegetative cells (e.g., *L. monocytogenes*).

The effectiveness of the process is determined by the amount of the ionizing radiation absorbed

by the food. The amount of ionizing radiation absorbed depends on factors associated with the irradiator itself, for example, activity (energy output) of the source (e.g., x-ray intensity and electron or photon energy spectrum), source geometry (configuration or relationship between the product and the source), source-to-product distance, process path through the irradiator, and beam characteristics. The amount of absorption also depends on factors associated with the specific process, for example, length of time irradiated, conveyor speed, environmental temperature, product temperature, product composition and density, packaging size, shape and composition, and configuration of the load of product in the irradiator. It is important that every part of the product receive the prescribed absorbed dose within a specified range. Dosimetry mapping is used to document the distribution of absorbed dose throughout a process load for a particular set of irradiator parameters. All factors listed above should be considered in the establishment of the process and its verification. The parameters that could affect the absorbed dose should be monitored. A suitable dosimetry system should be used to verify the range of absorbed dose delivered to each lot of product.

- **Control of processes intended to retain raw product characteristics**

Controlling pathogenic bacteria survival through processes intended to retain raw product characteristics is accomplished by:

- Scientifically establishing and validating a process that will reduce the target pathogen(s) to an acceptable level (the scientific study may be conducted by the processor or obtained from scientific literature);
- Designing and operating the processing equipment so that every unit of the product receives at least the established minimum process;
- Continuously monitoring the critical process parameters to verify achievement of a scientifically established process.

If “added safety” labeling is to be used on the product or if the process is used as a substitute for the time from exposure to air (e.g., by harvest or receding tide) to refrigeration recommendations specific to *V. vulnificus* and *V. parahaemolyticus* described in Chapter 4, the ability of a process to reliably achieve the appropriate reduction of the target pathogen should be validated by a scientific study approved by the shellfish control authority with concurrence from FDA. A scientific study is conducted to initially validate the efficacy of the process and to revalidate it when there has been a change in the process. Additional guidance on the conduct of a validation study can be found in the “National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision.”

- **Strategies for control of pathogens**

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

- Killing pathogenic bacteria by processes that retain the raw product characteristics (covered in this chapter);
- Killing pathogenic bacteria by cooking or pasteurizing (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);
- 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 *Staphylococcus aureus* in hydrated batter mixes, in Chapter 15);
- 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 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 time from exposure to air (e.g., by harvest or receding tide) to refrigeration in order to control pathogens from the harvest area (covered in Chapter 4);
- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18).
- The shellfish control authority has conducted a risk evaluation and determined that the risk of *V. parahaemolyticus* illness from the consumption of oysters harvested from that growing area is reasonably likely to occur. Specific guidance for determining risk can be found in the “National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision”;
- The shellfish control authority has determined that harvesting occurs in the growing area at a time when average monthly daytime water temperatures exceed 60°F for waters bordering the Pacific Ocean and 81°F for waters bordering the Gulf of Mexico and the Atlantic Ocean (New Jersey and south), except where a more rigorous risk evaluation has led the shellfish control authority to conclude that the risk of *V. parahaemolyticus* illness from the consumption of oysters harvested from that growing area is not reasonably likely to occur;
- The waters of the state have been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past 3 years.

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

The following guidance will assist you in determining whether pathogenic bacteria survival through processes designed to retain raw product characteristics is a significant hazard at a processing step:

1. Is it reasonably likely that unsafe levels of pathogenic bacteria will be introduced at this processing step (do unsafe levels of pathogenic bacteria come in with the raw material or will the process introduce unsafe levels of pathogens)?

Under ordinary circumstances, it would be reasonably likely that an unsafe level of *V. vulnificus* could enter the process from oysters harvested from states that have been confirmed as the original source of oysters associated with two or more *V. vulnificus* illnesses (e.g., states bordering the Gulf of Mexico).

Under ordinary circumstances, it would be reasonably likely that an unsafe level of *V. parahaemolyticus* could enter the process from oysters harvested from an area that meets any one of the following conditions:

2. Can unsafe levels of pathogenic bacteria that were introduced at an earlier processing step be eliminated or reduced to an acceptable level at this processing step?

Pathogenic bacteria survival through processes designed to retain raw product characteristics 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. The preventive measure that can be applied for pathogenic



bacteria survival through processes designed to retain raw product characteristics is proper design and control of the process.

- **Intended use**

The controls for *V. vulnificus* and *V. parahaemolyticus* that are discussed in this chapter are only intended to be applied to oysters if they are intended for raw consumption. You should assume that most oysters will be consumed raw. However, controls need not be applied to oyster shellstock if tags on the containers of shellstock indicate that they must be shucked before consumption.

## IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for pathogenic bacteria survival through processes designed to retain raw product characteristics:

1. If the finished product is raw oyster shellstock intended for raw consumption, will it be subjected to a process in your facility that is designed to retain raw product characteristics (e.g., mild heat processed, IQF with extended frozen storage, high hydrostatic pressure processed, or irradiated) and is sufficient to reduce *V. vulnificus* or *V. parahaemolyticus* to acceptable levels (i.e., reduced to a non-detectable level, less than 30 MPN/gram)?
  - a. If the finished product will be subjected to a process designed to retain raw product characteristics, you should identify that processing step as the CCP for the target pathogen. In this case, you would not need to identify the receiving step as a CCP for the control of the target pathogen. However, you may need to identify the receiving step as a CCP for control of other non-target pathogens (e.g., *Salmonella spp.* and norovirus), as described in Chapter 4.

This control approach includes two control strategies referred to in this chapter as “Control Strategy Example 1 - High Hydrostatic Pressure Processing,” or “Control Strategy Example 2 - IQF With Extended Frozen Storage.” For guidance on controls for mild heat processing, see “Control Strategy Example 1 - Cooking and Pasteurization,” in Chapter 16; however, guidance on process validation for mild heat processing is more appropriately obtained from “Control Strategy Example 1 - High Hydrostatic Pressure Processing,” in this chapter. No specific guidance is given on control of irradiation.

- b. If the product will not be subjected to a process in your facility that is designed to retain raw product characteristics and is sufficient to reduce *V. vulnificus* or *V. parahaemolyticus* to acceptable levels, you should identify the receiving step as the CCP for *V. vulnificus* and/or *V. parahaemolyticus*, as appropriate. Guidance for development of this control strategy is provided in Chapter 4.

## DEVELOP A CONTROL STRATEGY.

The following guidance provides two control strategies for pathogenic bacteria survival through processes designed to retain raw product characteristics. You may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following are examples of control strategies included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
High hydrostatic pressure processing	✓	✓
IQF with extended frozen storage	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - HIGH HYDROSTATIC PRESSURE PROCESSING**

**Set Critical Limits.**

- The minimum or maximum values for the critical factors established by conducting a scientific study to validate the process (e.g., minimum pressure, minimum hold time at pressure, and minimum initial temperature of the product).

**Establish Monitoring Procedures.**

» **What Will Be Monitored?**

- Pressure;  
AND
- Hold time at pressure;  
AND
- Initial temperature of the product;  
AND
- Other critical factors that affect the effectiveness of the process, as specified by the study (e.g., pressurization time (step-up time), decompression time (step-down time), and treatment temperature).

» **How Will Monitoring Be Done?**

- For time and pressure:
  - Use a continuous pressure-recording device (e.g., a pressure recorder);  
AND
- For initial temperature of the product:
  - Use a temperature-indicating device (e.g., a thermometer);  
AND
- For other critical limits:
  - Use equipment appropriate to the critical limit.

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

- For time and pressure:
  - Continuous monitoring, with a visual check of the recorded data at least once per batch;

AND

- For initial temperature of the product:
  - Each batch;

AND

- For other critical factors:
  - With sufficient frequency to achieve control.

» **Who Will Do the Monitoring?**

- For continuous-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, 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;

AND

- For other checks:
  - 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:

- Reprocess the product;  
OR
- Chill and hold the product for an evaluation of the adequacy of the high hydrostatic pressure process. If the product has not received an adequate high hydrostatic pressure process, the product should be destroyed, diverted to a non-food use, or reprocessed;

OR

- Divert the product to a use in which the

critical limit is not applicable (e.g., divert the improperly processed product to a canning operation);

OR

- Destroy the product;

OR

- Divert the product to a non-food use or a use without the “added safety” labeling.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Adjust or repair the processing equipment;

AND/OR

- Extend the high hydrostatic pressure process to compensate for a pressure drop, using a process established by a scientific study.

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

- Record of continuous pressure monitoring;

AND

- Record of visual checks of recorded data;

AND

- Record of visual observations of initial temperature of product;

AND

- Records that are appropriate for other critical limit monitoring.

### **Establish Verification Procedures.**

- Process validation study:
  - The adequacy of the high hydrostatic pressure treatment should be validated by conducting a scientific study. It should be designed to ensure an appropriate reduction in the number of the target pathogen(s). In the case of *V. vulnificus* or *V. parahaemolyticus*, it should be designed to reduce the presence of these pathogens to non-detectable levels. Non-detectable for these pathogens is defined under the

NSSP as less than 30 MPN/gram. If “added safety” labeling is to be used on the product or if the process is used as a substitute for the time from exposure to air (e.g., by harvest or receding tide) to refrigeration limitations described in Chapter 4, the ability of a post-harvest process to reliably achieve the appropriate reduction of the target pathogen should be validated by a study approved by the shellfish control authority with concurrence from FDA. A study is used to initially validate the efficacy of the process and to revalidate it when there has been a change in the process. Additional guidance on conducting a validation study can be found in the “National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision” (<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm046353.htm>).

Expert knowledge of high hydrostatic pressure process calculations may be required to validate a high hydrostatic pressure process. Such knowledge can be obtained by education or experience, or both. Validating high hydrostatic pressure processes may require access to suitable facilities and the application of recognized methods. The equipment should be designed, operated, and maintained to deliver the established process to every unit of the product. In some instances, inoculated pack studies may be necessary to validate the minimum process. In other instances, existing literature or federal, state, or local regulations that establish minimum processes or adequacy of equipment may be available. Characteristics of the process, product, and/or equipment that affect the adequacy of the

established minimum high hydrostatic pressure process should be taken into consideration in the validation of the process. A record of process validation studies should be maintained;

AND

- Before a temperature-indicating device (e.g., a 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:
    - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;
- OR
- 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
- Doing a combination of the above if the device will be used at or near room temperature;
- OR
- Comparing the temperature indicated by 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;

AND

- Once in service, check the temperature-indicating device daily before the beginning of operations. 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

- Calibrate the temperature-indicating 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). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Check and calibrate other monitoring instruments as necessary to ensure their accuracy;

AND

- 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.



TABLE 17-1

**CONTROL STRATEGY EXAMPLE 1 - HIGH HYDROSTATIC PRESSURE PROCESSING**

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - High Hydrostatic Pressure Processing." This example illustrates how a raw oyster processor using a high hydrostatic pressure processor can control pathogen survival through processes designed to retain raw product characteristics. It is provided for illustrative purposes only.

Pathogen survival through processes designed to retain raw product characteristics 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., pathogens from the harvest area, environmental chemical contaminants, natural toxins, pathogenic bacteria growth and toxin formation during processing, food and color additives, and metal fragments).

**Example Only  
See Text for Full Recommendations**

(1)	(2)	(3)	(4)				(7)	(8)	(9)	(10)
			WHAT	HOW	FREQUENCY	WHO				
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				RECORDS	VERIFICATION		
High hydrostatic pressure processing	V. vulnificus survival	Minimum hold time: 250 seconds	Hold time at pressure	Pressure-recording device	Continuous, with visual check of the recorded data once per batch	Pressure equipment operator	Chill and hold for evaluation Adjust or repair equipment as needed	Pressure-recording device printout	Process validation Check the dial thermometer for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year  Review monitoring, corrective action, and verification records within 1 week of preparation	
			Pressure during the holding period	Pressure-recording device	Continuous, with visual check of the recorded data once per batch	Pressure equipment operator		Pressure-recording device printout		
			Initial temperature of product	Dial thermometer	Each batch	Pressure equipment operator		Initial temperature log		

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

- **CONTROL STRATEGY EXAMPLE 2 - IQF WITH EXTENDED FROZEN STORAGE**

**Set Critical Limits.**

- There are minimum or maximum values for the critical factors established by conducting a scientific study to validate the process (e.g., amount of time to reach frozen state, maximum frozen storage temperature and minimum time)

**Establish Monitoring Procedures.**

» **What Will Be Monitored?**

- IQF freezer and product parameters critical to ensure that the product internal temperature is achieved within the time established by the scientific study. These variables may include, but are not limited to: initial product temperature, tunnel air temperature, time in tunnel, air velocity, belt speed, product moisture, product size, and loading pattern;

AND

- Frozen storage temperature;

AND

- Length of frozen storage.

» **How Will Monitoring Be Done?**

- For the IQF freezer:
  - Use equipment appropriate to the critical limit (e.g., initial temperature with a temperature-indicating device (e.g., a thermometer));

AND

- For frozen storage temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

AND

- For length of frozen storage:
  - Use a clock.

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

- For the IQF freezer:
  - With sufficient frequency to achieve control;

AND

- For frozen storage temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once per lot;

AND

- For length of frozen storage:
  - Each lot, at the beginning and end of a batch.

» **Who Will Do the Monitoring?**

- For temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, 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;

AND

- For other monitoring:
  - 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:

- Refreeze the product;
- OR
- Hold the product for an evaluation of the adequacy of the freezing process. If the product has not received an adequate process, it should be destroyed, diverted to a non-food use or other appropriate use, or refrozen;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g., divert an improperly frozen product to a cooking or canning operation);

OR

- Destroy the product;
- OR
- Divert the product to a non-food use or a use without the “added safety” labeling.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Make repairs or adjustments to the IQF freezing equipment;
- OR
- Make repairs or adjustments to the frozen storage freezer;

OR

- Move some or all of the product in the frozen storage freezer to a properly functioning freezer.

AND/OR

- Extend the freezing cycle or frozen storage time period to compensate for a rise in temperature, using a process developed by a process authority;

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

- For the IQF freezer:
  - Records that are appropriate to the monitoring;

AND

- For frozen storage temperature:
  - Record of continuous temperature monitoring;

AND

- For length of frozen storage:
  - Freezing log with notation of the start and end of frozen storage periods.

### **Establish Verification Procedures.**

- Process validation study:
  - The adequacy of the IQF with extended frozen storage process should be validated by conducting a scientific study. It should be designed to ensure an appropriate reduction in the number of the target pathogen(s). In the case of *V. vulnificus* or *V. parahaemolyticus*, it should be designed to reduce the presence of these pathogens to non-detectable levels. Non-detectable for these pathogens is defined under the NSSP as less than 30 MPN/gram. If “added safety” labeling is to be used on the product or if the process is used as a substitute for the time from harvest to refrigeration limitations described in Chapter 4, the ability of a post-harvest process to reliably achieve the appropriate reduction of the target pathogen should be validated by a study approved by the shellfish control authority with concurrence from FDA. A study is performed to initially validate the efficacy of the process and to revalidate it when there has been a change in the process. Process verification may also be required at predetermined intervals. Additional guidance on conducting a validation study can be found in the “National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision.”

Validating an IQF with extended frozen storage process may require access to suitable facilities and the application of recognized methods. The equipment should be designed, operated, and maintained to deliver the established process to every unit of the product. In some instances, inoculated pack studies may be necessary to establish the minimum process. In other instances, existing literature or federal, state, or local regulations that establish minimum processes or adequacy of equipment

may be available. Characteristics of the process, product, and/or equipment that affect the adequacy of the established minimum IQF with extended frozen storage process should be taken into consideration in the validation of the process. A record of the process validation studies should be maintained;

AND

- Before a temperature-indicating device (e.g., a thermometer) or 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:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;
- OR
- 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
- Doing a combination of the above if the device will be used at or near room temperature;
- OR
- Comparing the temperature indicated by the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature, product internal temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-indicating device or temperature-recording device daily before the beginning of operations. 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 has, where applicable, sufficient ink and paper;

AND

- Calibrate the temperature-indicating device or temperature-recording device against a known accurate reference device (e.g., a 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 used to determine the core temperature of frozen fish or fishery products 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

- 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.

TABLE 17-2

**CONTROL STRATEGY EXAMPLE 2 - IQF WITH EXTENDED STORAGE**

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 2 - IQF With Extended Storage." This example illustrates how a raw oyster processor using a continuous cryogenic freezer can control pathogen survival through processes designed to retain raw product characteristics. It is provided for illustrative purposes only.

Pathogen survival through processes designed to retain raw product characteristics 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., pathogens from the harvest area, environmental chemical contaminants and pesticides, natural toxins, pathogenic bacteria growth and toxin formation during processing, food and color additives, and metal fragments)

**Example Only  
See Text for Full Recommendations**

(1)	(2)	(3)	(4)				(7)	(8)	(9)	(10)
			WHAT	HOW	FREQUENCY	WHO				
IQF freezer	V. vulnificus survival	The minimum or maximum values for the critical factors established by a scientific validation study*	Critical factors that affect the effectiveness of the process, as specified by the study*	Use equipment appropriate to the critical limit*	With sufficient frequency to achieve control*	IQF equipment operator	Segregate and hold the product for evaluation Adjust or repair equipment as needed	IQF record	Process validation Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year  Review monitoring, corrective action, and verification records within 1 week of preparation	
			Length of frozen storage	Clock	Beginning and end of each lot	Frozen storage operator		Frozen storage record		
			Temperature of frozen storage	Digital time/temperature data logger	Continuous, with visual check of recorded data once per lot	Frozen storage operator		Data logger printout		

\* Note: This plan is for illustrative purposes only. An actual plan should specify the actual critical limits for the IQF freezer, actual minimum frozen storage temperature, and actual minimum length of frozen storage. Additionally, an actual plan should specify the actual critical factors that will be monitored, the way in which they will be monitored, and the frequency of monitoring.



## 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.

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