CHAPTER 4: **Pathogens From the Harvest Area**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

UNDERSTAND THE POTENTIAL HAZARD

This chapter covers the control of pathogens from the harvest area for both molluscan shellfish and fish other than molluscan shellfish.

- **Strategies for control of pathogens**

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

- Controlling the source (i.e., harvest waters) of molluscan shellfish and the time from exposure to air (i.e., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (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 bacterial 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 introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18);
- 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 *Clostridium botulinum*, in Chapter 13; and for *Staphylococcus aureus* in hydrated batter mixes, in Chapter 15);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16) or retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation (hereinafter, the Low-Acid Canned Foods (LACF) Regulation), 21 CFR 113);
- Killing pathogenic bacteria by processes that retain raw product characteristics (covered in Chapter 17).

- **Molluscan shellfish**

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. For the purposes of this guidance, molluscan shellfish include:

(1) oysters; (2) clams; (3) mussels; and (4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria (e.g., *Vibrio spp., Salmonella spp., Shigella spp.,* and *Campylobacter jejuni* (*C. jejuni*)) and viruses (e.g., hepatitis A virus and norovirus). See Appendix 7 for a description of the public health impacts of these pathogens.

Pathogens from the harvest area are of particular concern in molluscan shellfish because (1) environments in which molluscan shellfish grow are commonly subject to contamination from

sewage, which may contain pathogens, and contamination from naturally occurring bacteria, which may also be pathogens; (2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and (3) molluscan shellfish are often consumed whole, either raw or partially cooked.

Certain pathogens generally originate from human or animal fecal sources (e.g., *Vibrio cholerae* (*V. cholerae*) O1 and O139, *Salmonella spp., Shigella spp., C. jejuni, Yersinia enterocolitica* (*Y. enterocolitica*), hepatitis A virus, and norovirus). Other pathogens are naturally occurring in certain waters (e.g., *Vibrio vulnificus* (*V. vulnificus*), *Vibrio parahaemolyticus* (*V. parahaemolyticus*), and *V. cholerae* non-O1 and non-O139), and their presence is not associated with human or animal fecal sources.

See Appendix 7 for a description of the public health impacts of these pathogens.

Control of pathogens of human or animal origin

To minimize the risk of molluscan shellfish containing pathogens of human or animal fecal origin (e.g., *V. cholerae* O1 and O139, *Salmonella spp., Shigella spp., C. jejuni,* hepatitis A virus, and norovirus), Federal, state, tribal, territorial and foreign government agencies, called shellfish control authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain conditions from others. Shellfish control authorities exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been determined to be safe.

Other significant elements of shellfish control authorities' efforts to control the safety of molluscan shellfish include requirements that (1) containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, the harvester, the harvest location, and the date of harvest (21 CFR 123.28(c)); (2) molluscan shellfish harvesters be licensed (note that licensing may not be required in all jurisdictions); (3) processors that ship, reship, shuck, or repack molluscan shellfish be certified; and (4) containers of shucked molluscan shellfish bear a label with the processor's name, address, and certification number.

The controls listed above serve to minimize the risk of molluscan shellfish containing pathogens of human or animal origin, but do not fully eliminate the risk. As a result, consumption of raw or undercooked molluscan shellfish may not be safe for individuals with certain health conditions, such as liver disease; chronic alcohol abuse; diabetes; and stomach, blood, and immune disorders. For this reason, shellfish control authorities require that shellstock intended for raw consumption bear a tag that instructs retailers to inform their customers that consuming raw or undercooked shellfish may increase the risk of foodborne illness, especially for individuals with certain medical conditions.

You can also eliminate the hazard of pathogens from the harvest area by properly cooking, pasteurizing, or retorting the product. Guidance on cooking and pasteurizing to control pathogenic bacteria is provided in Chapter 16. Mandatory retorting controls are described in the LACF Regulation (21 CFR 113). It should be noted that neither cooking, nor pasteurizing, nor retorting will eliminate the hazards of natural toxins or environmental chemical contaminants and pesticides that also may be associated with molluscan shellfish. Appropriate control strategies for these hazards are provided in Chapters 6 and 9. Additionally, the laws and regulations of states that participate in the National Shellfish Sanitation Program administered by FDA require that all molluscan shellfish be harvested from waters authorized for harvesting by the shellfish control authority, regardless of how it will be processed.

Control of naturally occurring pathogens

To minimize the risk of illness from the consumption of molluscan shellfish containing

naturally occurring pathogens such as *V. vulnificus, V. parahaemolyticus,* and *V. cholerae* non-O1 and non-O139, shellfish control authorities place certain controls on the harvest of molluscan shellfish.

Naturally occurring pathogens may be present in relatively low numbers at the time that molluscan shellfish are harvested but may increase to more hazardous levels if they are exposed to time and temperature abuse. To minimize the risk of growth of *Vibrio spp.*, shellfish control authorities place limits on the time from exposure to air (i.e., by harvest or receding tide) to refrigeration. The length of time is dependent upon the Average Monthly Maximum Air Temperature (AMMAT) or the Average Monthly Maximum Water Temperature (AMMWT) at the time of harvest, which is determined by the shellfish control authority.

In addition to the above, control for *V. parahaemolyticus* in oysters involves (1) a risk evaluation by the shellfish control authority to determine whether the risk of *V. parahaemolyticus* illness from the consumption of oysters harvested from a growing area(s) in a state is reasonably likely to occur; and (2) a determination by shellfish control authorities about whether a growing area(s) in a state has average monthly daytime water temperatures that exceed 60°F for waters bordering the Pacific Ocean or 81°F for waters bordering the Gulf of Mexico and the Atlantic Ocean (New Jersey and south) at times during which harvesting occurs. If either of these conditions is met, the shellfish control authority develops and implements a *V. parahaemolyticus* control plan intended to reduce the incidence of *V. parahaemolyticus* illnesses. As part of the plan, shellfish control authorities may (1) temporarily close some waters to the harvesting of oysters; (2) limit the time from exposure to air (i.e., by harvest or receding tide) to refrigeration; (3) temporarily permit harvesting of oysters for products that will be labeled "For Shucking Only" from some waters; or (4) temporarily permit harvesting of oysters for processes that retain raw product characteristics (covered in Chapter 17) only from some waters.

As with pathogens of sewage origin, the above controls for naturally occurring pathogens help minimize the risk from these pathogens in molluscan shellfish but do not fully eliminate the risk. For this same reason, shellfish control authorities require that shellstock intended for raw consumption bear a tag containing an advisory relative to raw and undercooked consumption (described above).

The controls for *Vibrio spp.* discussed in this chapter apply only to molluscan shellfish if they are intended for raw consumption. For example, they would not be applied to oyster shellstock if tags on the containers of shellstock indicate that they must be shucked before consumption. *Vibrio spp.* can be eliminated or reduced to non-detectable levels by cooking, pasteurizing, and retorting. These control mechanisms are widely used in the processing of fishery products for the control of pathogens. Guidance for these control mechanisms can be found in Chapter 16 (cooking and pasteurization to control pathogenic bacteria) and the LACF Regulation, 21 CFR 113 (retorting). Other mechanisms for control of *Vibrio spp.* include processes that are designed to retain the raw characteristics of the food, including individual quick freezing (IQF) with extended storage, mild heat, high hydrostatic pressure, and irradiation. These control mechanisms are covered in Chapter 17.

Appropriate controls to prevent further growth of these pathogenic bacteria during processing, storage, and transportation between processors are discussed in Chapter 12.

- **Fish other than molluscan shellfish**

Pathogens from the harvest area may also be a potential hazard for fish other than molluscan shellfish. Pathogens may be found on raw fish as a result of near-shore harvest water contamination, poor sanitary practices on the harvest vessel, and poor aquacultural practices. The pathogens of concern include those described above for molluscan shellfish, but also include *Listeria monocytogenes* and *Escherichia coli*. See Appendix 7 for a description of the public health impacts of these pathogens.

Control of pathogens

The processor can control pathogens by proper cooking, pasteurizing, or retorting. Guidance for these control mechanisms can be found in Chapter 16 (cooking and pasteurizing to kill pathogenic bacteria) and the LACF Regulation, 21 CFR 113 (retorting).

For many products (e.g., raw fish fillets), there is no cooking, pasteurizing, or retorting step performed by the processor. For most of these products, cooking is performed by the consumer or end user before consumption. FDA is not aware of any Hazard Analysis Critical Control Point (HACCP) controls that exist internationally for the control of pathogens in fish and fishery products that are customarily fully cooked by the consumer or end user before consumption other than a rigorous sanitation regime as part of a prerequisite program or as part of HACCP itself. The Fish and Fishery Products regulation (21 CFR 123.11, "Sanitation control procedures") requires such a regime. The proper application of sanitation controls is essential because of the likelihood that pathogens in seafood products can be introduced through poor handling practices by the aquaculture producer, the harvester, or the processor.

For some products (e.g., raw fish intended for sushi), there is no cooking performed by either the processor, or the consumer, or the end user. When the processor has knowledge or has reason to know that the product will be consumed without a process sufficient to kill pathogens of public health concern or where the processor represents, labels, or intends for the product to be so consumed, the processor should control time and temperature exposure of the product to prevent growth of bacterial pathogens and formation of toxins by any bacterial pathogens that may be present in the product. Guidance for these controls can be found in Chapter 12 and in Chapter 13 (for those products where the packaging technique creates a reduced oxygen environment).

Note: The guidance contained in the remainder of this chapter applies to receiving controls for molluscan shellfish only.

DETERMINE WHETHER THIS POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether pathogens from the harvest area are a significant hazard at a processing step:

1. Is it reasonably likely that an unsafe level of pathogens from the harvest area will be introduced at this processing step (e.g., are pathogens present in the raw material at an unsafe level)?

   Under ordinary circumstances, it would be reasonably likely that pathogens of human or animal origin from the harvest area could enter the process at an unsafe level at the receiving step for the following types of fish:

   - Raw oysters;
   - Raw clams;
   - Raw mussels;
   - Raw scallops (see information provided under "Intended use").

   In addition:

   - Under ordinary circumstances, it would be reasonably likely that an unsafe level of *V. vulnificus* (a naturally occurring pathogen) could enter the process from oysters harvested from areas 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:
     - 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 growing area has been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past 3 years.

2. Can an unsafe level of pathogens from the harvest area that was introduced at the receiving step be eliminated or reduced to an acceptable level at this processing step?

Pathogens from the harvest area should also be considered a significant hazard at any processing step where a measure is or can be used to eliminate the pathogens that had been introduced at a previous step or is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. Measures to eliminate pathogens or to reduce the likelihood of occurrence of the hazard from the harvest area include:

- Checking incoming molluscan shellfish to ensure that they are properly tagged or labeled;
- Making sure that incoming molluscan shellfish are supplied by a licensed harvester (where licensing is required by law) or by a certified dealer;
- Killing pathogenic bacteria by cooking or pasteurizing (covered in Chapter 16) or retorting (covered by the LACF Regulation, 21 CFR 113). It should be noted that neither cooking nor retorting will eliminate the hazards of natural toxins or chemical contamination that also may be associated with molluscan shellfish;
- Killing *Vibrio spp.* by IQF with extended storage, mild heat, irradiation, or high hydrostatic pressure (covered in Chapter 17);
- Minimizing the growth of *V. cholerae*, *V. parahaemolyticus*, and *V. vulnificus* by limiting the time from exposure to air (i.e., by harvesting or receding tide) to refrigeration;
- Including an advisory on tags on containers of molluscan shellstock intended for raw consumption or on containers of shucked molluscan shellfish that instructs retailers to inform their customers that consuming raw or undercooked shellfish may increase the risk of foodborne illness, especially for individuals with certain medical conditions.

- **Intended use**

For most raw molluscan shellfish products, you should assume that the product will be consumed raw. You should, therefore, identify the hazard as significant if it meets the criteria in the previous section.

Where the product consists of scallop adductor muscle only, it may be reasonable to assume that the product will be cooked before consumption. In this case, you would not need to identify pathogens from the harvest area as a significant hazard. However, if you have knowledge, or have

reason to know, that the scallop adductor muscle will be consumed without a process sufficient to kill pathogens of public health concern or where the processor represents, labels, or intends for the product to be so consumed, you should control time and temperature exposure of the product to prevent growth of bacterial pathogens and formation of toxins by any bacterial pathogens that may be present in the product. Guidance for these controls can be found in Chapter 12 and in Chapter 13 (for those products where the packaging technique creates a reduced oxygen environment).

The controls for *V. vulnificus* and *V. parahaemolyticus* that are discussed in this chapter do not need to be applied to molluscan shellfish that are not marketed for raw consumption. For example, they need not be applied to oyster shellstock from the Gulf of Mexico 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 pathogens from the harvest area:

1. Will the product be cooked, pasteurized, or retorted sufficiently to kill all bacterial pathogens of public health concern during processing in your facility?

    a. If it will be, you should identify the cook step, pasteurization step, or retorting step as the CCP. In this case, you would not need to identify the receiving step as a CCP for the hazard of pathogens from the harvest area. However, note that neither cooking, nor pasteurizing, nor retorting will eliminate the hazards of natural toxins or environmental chemical contaminants and pesticides that also may be associated with molluscan shellfish. Chapters 6 and 9 provide appropriate control strategies for these hazards. Additionally, the laws and regulations of states that participate in the National Shellfish Sanitation Program require that all molluscan shellfish be harvested from waters authorized for harvesting by the shellfish control authority, regardless of how it will be processed.

    Example:

    A canned clam chowder processor should set the CCP for pathogens from the harvest area at the retorting step, and would not identify the receiving step as a CCP for this hazard.

    b. If the product will not be cooked, pasteurized, or retorted sufficiently to kill bacterial pathogens during processing in your facility, you should identify the receiving step as a CCP where you can exercise control over the source of the molluscan shellfish and the time from exposure to air (i.e., by harvest or receding tide) to refrigeration in order to control pathogens from the harvest area. If the finished product is shellstock intended for raw consumption, you should also identify the labeling step or the label (tag) receiving step as a CCP, because you can ensure that the raw consumption advisory is on the tag.

    Example:

    A processor that shucks raw oysters and ships a raw product should check the tags of incoming shellstock (in-shell oysters), the license of the harvesters that supply the shellstock, and the length of time between exposure to air (i.e., by harvest or receding tide) and refrigeration. The processor should identify the receiving step as the CCP for this hazard.

Example:

A processor that ships oyster shellstock should check the tags of incoming shellstock, the license of the harvesters that supply the shellstock, the harvest location, and the length of time between exposure to air (i.e., by harvest or receding tide) and refrigeration. The processor should identify the receiving step as a CCP for this hazard. The processor should also identify the labeling step as a CCP for this hazard and would check for the presence of the raw consumption advisory on the label or tag.

This control approach includes two control strategies referred to in this chapter as "Control Strategy Example 1 - Source Control" and "Control Strategy Example 2 - Shellstock Temperature Control." Refer to Control Strategy Example 2 - Shellstock Temperature Control" when controls for *V. vulnificus* or *V. parahaemolyticus* are needed." Conditions that warrant control for these pathogens are described below.

2. If the finished product is raw oyster shellstock intended for raw consumption and is harvested from a state that has been confirmed as the original source of oysters associated with two or more V. vulnificus illnesses (e.g., the Gulf of Mexico), will it be subjected in your plant to a process that is designed to retain raw product characteristics (e.g., mild heat processing, IQF with extended storage, high hydrostatic pressure processing, or irradiation) and is sufficient to kill V. vulnificus during processing in your facility (i.e., reduced to a non-detectable level of less than 30 Most Probable Number per gram (herein referred to as 30 MPN/gram), as defined in the "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision")?

   a. If the finished product will be subjected to such a process in your facility, you should identify the processing step that is designed to retain raw product characteristics as the CCP for control of *V. vulnificus*. In this case, you would not need to identify the receiving step as a CCP for the control of *V. vulnificus*.

      Example:

      A Gulf of Mexico oyster processor should set the CCP for V. vulnificus at the mild heat processing step and would not identify the receiving step as a CCP for that pathogen.

      If you choose to follow this approach, you should refer to Chapter 17 for further guidance.

   b. If the finished product will not be subjected to a process that is designed to retain raw product characteristics and is sufficient to kill *V. vulnificus* during processing in your facility, you should identify the receiving step as a CCP, because you can exercise control over the time from exposure to air (i.e., by harvest or receding tide) to refrigeration in order to control *V. vulnificus*.

      Example:

      A Gulf of Mexico oyster processor should set the CCP for V. vulnificus at the receiving step.

      This control strategy is referred to as "Control Strategy Example 2 - Shellstock Temperature Control" Refer to "Control Strategy Example 2 - Shellstock Temperature Control" when controls for *V. vulnificus* are needed." These controls should be considered in addition to the controls contained in "Control Strategy Example 1 - Source Control." If your shellfish control authority has developed a *V. vulnificus* control plan, you should develop a HACCP plan that is based on the requirements of that plan. Elements of the control strategy example provided in this chapter and in Chapter 17 may be useful for development of such a plan.

3. If the finished product is raw oyster shellstock intended for raw consumption and is harvested from an area where: (1) 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; (2) 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); or (3) 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, will it be subjected in your facility to a process that is designed to retain raw product characteristics (e.g., mild heat processing, IQF with extended storage, high hydrostatic pressure processing, or irradiation) and is sufficient to kill V. parahaemolyticus (i.e., reduced to a non-detectable level of less than 30 MPN/gram, as defined in the "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision")?

   a. If the finished product will be subjected to such a process in your facility, you should identify the processing step designed to retain raw product characteristics as the CCP for the control of *V. parahaemolyticus*. In this case, you would not need to identify the receiving step as a CCP for the control of *V. parahaemolyticus*.

      Example:

      An oyster processor should set the CCP for V. parahaemolyticus at the mild heat processing step and would not identify the receiving step as a CCP for that pathogen.

      If you choose to follow this approach, you should refer to Chapter 17 for further guidance.

   b. If the finished product will not be subjected in your facility to a process that is designed to retain raw product characteristics and is sufficient to kill *V. parahaemolyticus* during processing, you should identify the receiving step as a CCP, because you can exercise control over the time from exposure to air (i.e., by harvest or receding tide) to refrigeration in order to control *V. parahaemolyticus* or exercise other controls as determined by your state's *V. parahaemolyticus* control plan.

      Example:

      An oyster processor should set the CCP for V. parahaemolyticus at the receiving step.

      This control strategy is referred to as "Control Strategy Example 2 - Shellstock Temperature Control." Refer to "Control Strategy Example 2 - Shellstock Temperature Control" when controls for *V. parahaemolyticus* are needed." These controls should be considered in addition to the controls contained in "Control Strategy Example 1 - Source Control." If your shellfish control authority has developed a *V. parahaemolyticus* control plan, you should develop a HACCP plan that is based on the requirements of that plan. Elements of the control strategy examples provided in this chapter and in Chapter 17 may be useful for development of such a plan.

Only the primary processor (the processor who takes possession of the molluscan shellfish from the harvester) should apply the time-to-refrigeration controls for *Vibrio spp.* that are discussed in this chapter, because this processor is in the best position to control the time from exposure to air (i.e., by harvest or receding tide) to refrigeration.

DEVELOP A CONTROL STRATEGY.

The following guidance provides three examples of control strategies for pathogens from the harvest area. 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, except that some parts of "Control Strategy Example 1 - Source Control" are specifically required by the Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products regulation, 21 CFR 123 (called the Seafood HACCP Regulation in this guidance document).

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

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Source control	✓	✓
Shellstock temperature control	✓	

- **CONTROL STRATEGY EXAMPLE 1- SOURCE CONTROL**

Note: The following controls should be considered in addition to those in "Control Strategy Example 2 - Shellstock Temperature Control."

Set Critical Limits.

- All containers of shellstock (in-shell molluscan shellfish) received from a harvester must bear a tag that discloses the date and place they were harvested (by state and site), type and quantity of shellfish, and information on the harvester or the harvester's vessel (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable, or if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). For bulk shipments of shellstock where the shellstock is not containerized, the shellstock must be accompanied by a bill of lading or similar shipping document that contains the same information;

Note: The source controls listed in this critical limit are required under 21 CFR 123.28(c).

OR

- All containers of shellstock received from a processor must bear a tag that discloses the date and place they were harvested (by state and site), the type and quantity of shellfish, and the certification number of the processor;

OR

- All containers of shucked molluscan shellfish must bear a label that identifies the name, address, and certification number of the packer or repacker of the product;

AND

- All molluscan shellfish must have been harvested from waters authorized for harvesting by a shellfish control authority. For U.S. federal waters, no molluscan shellfish may be harvested from waters that are closed to harvesting by an agency of the federal government;

AND

- All molluscan shellfish must be from a harvester that is licensed as required (note that licensing may not be required in all jurisdictions) or from a processor that is certified by a shellfish control authority;

AND

- All finished product shellstock intended for raw consumption must bear a tag that instructs retailers to inform their customers that consuming raw or undercooked shellfish may increase the risk of foodborne illness, especially for individuals with certain medical conditions.

Note: Only the primary processor, the processor that takes possession of the molluscan shellfish from the harvester, needs to apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Information contained on tags on containers of incoming shellstock or on the bill of lading or similar shipping document accompanying bulk shipments of shellstock;

AND

- Information on whether the harvest area is authorized for harvest by a shellfish control authority or information on whether federal harvest waters are closed to harvesting by an agency of the federal government;

  OR

- Information contained on labels on containers of incoming shucked molluscan shellfish;

AND

- The harvester's license, where applicable;

AND

- The raw consumption advisory on tags on containers of finished product shellstock intended for raw consumption or the raw consumption advisory on labels on containers of shucked molluscan shellfish.

» **How Will Monitoring Be Done?**

- Perform visual checks;

  AND

- Ask the shellfish control authority of the state in which your shellstock are harvested whether the harvest area is authorized for harvest.

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

- For checking incoming tags:
  - Every container;

  OR

- For checking the bill of lading or similar shipping document:
  - Every delivery;

  OR

- For checking incoming labels:
  - At least three containers randomly selected from every lot;

  AND

- For checking licenses:
  - Every delivery;

  AND

- For checking the raw consumption advisory on finished product tags or labels:
  - Each container of finished product shellstock intended for raw consumption or at least three containers randomly selected from every lot of shucked molluscan shellfish.

» **Who Will Do the 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:

- Reject the lot;

  OR

- Relabel finished product shellstock intended for raw consumption that does not bear a tag that contains the raw consumption advisory or relabel shucked molluscan shellfish that does not bear a label that contains the raw consumption advisory;

  OR

- Reject any incoming tags to be used on finished product shellstock intended for raw consumption that do not contain the raw consumption advisory or reject any incoming labels to be used on shucked molluscan shellfish that do not contain the raw consumption advisory.

AND

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

- Discontinue use of the supplier until evidence is obtained that harvesting, tagging, and/or label manufacturing practices have changed;

  OR
- Modify labeling practices.

Establish a Recordkeeping System.

For shellstock:

- Receiving record that documents:
  - Date of harvest;

    AND
  - Location of harvest by state and site;

    AND
  - Quantity and type of shellfish;

    AND
  - Name of the harvester, name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority (for shellstock received directly from the harvester only);

    AND
  - Number and date of expiration of the harvester's license, where applicable;

    AND
  - Certification number of the shipper, where applicable;

    AND
  - For shellstock intended for raw consumption, the presence of the raw consumption advisory, when received from a certified dealer.

For shucked molluscan shellfish:

- Receiving record that documents:
  - Date of receipt;

    AND
  - Quantity and type of shellfish;

    AND
  - Name and certification number of the packer or repacker;

    AND
  - Presence of the raw consumption advisory.

Establish Verification Procedures.

- 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.

TABLE 4-1

CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Source Control." This example illustrates how a primary processor (processor that takes possession of the oysters from the harvester) of shellstock oysters, that is, the shellstock shipper, can control pathogens from the harvest area. It is provided for illustrative purposes only. This control strategy should be considered in addition to "Control Strategy Example 2 - Shellstock Temperature Control."

Pathogens from the harvest area 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., natural toxins, environmental chemical contaminants and pesticides, and pathogens during processing).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving shellstock	Pathogens from the harvest area	All incoming shellstock must be tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of the harvester's vessel	Information on incoming shellstock tags	Visual checks	Every sack	Receiving employee	Reject the lot Discontinue use of the supplier until evidence is obtained that tagging practices have changed	Receiving record	Review monitoring and corrective action records within 1 week of preparation
		All shellstock must be from waters approved by the state shellfish control authority	Harvest site on tags Ask the shellfish control authority of the state in which the shellstock are harvested whether the area is authorized for harvest	Visual checks	Every lot	Receiving employee	Reject lots from unapproved waters Discontinue use of the supplier until evidence is obtained that harvesting practices have changed	Receiving record	
		All shellstock must be from a licensed harvester	Harvester's license	Visual checks	Every delivery	Receiving employee	Reject lots from unlicensed harvesters Discontinue use of the supplier until evidence is obtained that the harvester has secured a license	Receiving record	

- **CONTROL STRATEGY EXAMPLE 2 - SHELLSTOCK TEMPERATURE CONTROL**

Note: The following controls should be considered in addition to those in "Control Strategy Example 1 - Source Control."

Set Critical Limits.

- When controls for neither *V. vulnificus* nor *V. parahaemolyticus* are needed:
  - For AMMAT of less than 66°F (less than 19°C): 36 hours;

    OR
  - For AMMAT of 66 to 80°F (19 to 27°C): 24 hours;

    OR
  - For AMMAT of greater than 80°F (greater than 27°C): 20 hours;

Note: AMMAT is determined by the shellfish control authority.

OR

- When controls for *V. vulnificus* are needed:
  - For AMMWT of less than 65°F (less than 18°C): 36 hours;

    OR
  - For AMMWT of 65 to 74°F (18 to 23°C): 14 hours;

    OR
  - For AMMWT of greater than 74 to 84°F (greater than 23 to 29°C): 12 hours;

    OR
  - For AMMWT of greater than 84°F (greater than 29°C): 10 hours;

Note: AMMWT is determined by the shellfish control authority. The shellfish control authority may implement time to temperature controls that are more stringent than those described here. Processors should consult with their shellfish control authority for current requirements.

OR

- When controls for *V. parahaemolyticus* are needed:
  - For AMMAT of less than 66°F (less than 19°C): 36 hours;

    OR
  - For AMMAT of 66 to 80°F (19 to 27°C): 12 hours;

    OR
  - For AMMAT of greater than 80°F (greater than 27°C): 10 hours.

Note: AMMAT is determined by the shellfish control authority. The shellfish control authority may implement time to temperature controls that are more stringent than those described here. Processors should consult with their shellfish control authority for current requirements.

Note: Only the primary processor, the processor that takes possession of the molluscan shellfish from the harvester, should apply controls for the time from exposure to air (i.e., by harvest or receding tide) to refrigeration.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The time shellfish was exposed to air (i.e., by harvest or receding tide);

  AND
- The time shellstock was placed under refrigeration;

» **How Will Monitoring Be Done?**

- For the time from exposure to air (i.e., by harvest or receding tide) to refrigeration:
  - Obtain information from the shellfish control authority;

    OR
  - Check the harvester's log or tags;

    OR
  - Note the time of departure from and return to dock;

    OR
  - Ask the harvester.

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

- Every delivery.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls may perform the monitoring.

Establish Corrective Action Procedures.

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

- Reject lots that do not meet the critical limit;

  OR

- Subject the shellstock to a cooking, pasteurization, retorting, or other process that reduces pathogens of public health concern to acceptable levels. See Chapters 16 and 17 and LACF Regulation (21 CFR 113) for further guidance;

  OR

- Destroy the product;

  OR

- Divert the product to a non-food use.

AND

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

- Discontinue use of the supplier until evidence is obtained that harvesting practices have changed.

Establish a Recordkeeping System.

- Receiving record that documents:
  - Time shellstock is exposed to air (i.e., by harvest or receding tide);

    AND

  - Time shellstock was placed under refrigeration;

    AND

  - AMMWT.

Establish Verification Procedures.

- 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.

TABLE 4-2

CONTROL STRATEGY EXAMPLE 2 - SHELLSTOCK TEMPERATURE CONTROL
(V. VULNIFICUS MODEL)

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Shellstock Temperature Control." This example illustrates how a primary processor (one that takes possession of the oysters from the harvester) of shellstock oysters, that is, the shellstock shipper, can control the pathogen from the harvest area, V. vulnificus. It is provided for illustrative purposes only. This control strategy should be considered in addition to "Control Strategy Example 1 - Source Control."

Pathogens from the harvest area 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., natural toxins, environmental chemical contaminants and pesticides, and pathogens during processing).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving shellstock	Pathogens from the harvest area	Maximum time from harvest to refrigeration: AMMWT < 65°F: 36 hours AMMWT 65 to 74°F: 14 hours AMMWT >74 to 84°F: 12 hours; AMMWT >84°F: 10 hours	Time of harvest	Harvester's log	Every delivery	Receiving employee	Reject lot Discontinue use of the supplier until evidence is obtained that harvesting practices have changed	Receiving record	Review monitoring and corrective action records within 1 week of preparation
			Time placed in refrigeration	Visual checks	Every delivery	Receiving employee			

AMMWT = Average Monthly Maximum Water Temperature

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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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