CHAPTER 12: **Pathogenic Bacteria Growth and Toxin Formation (Other Than Clostridium botulinum) as a Result of Time and Temperature Abuse**

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UNDERSTAND THE POTENTIAL HAZARD.

Pathogenic bacteria growth and toxin formation as a result of time and temperature abuse of fish and fishery products can cause consumer illness. This hazard is limited to bacterial pathogens since viral pathogens (viruses) are not able to grow in food. Of particular concern in seafood are the pathogenic forms of *Listeria monocytogenes* (*L. monocytogenes*), *Vibrio vulnificus* (*V. vulnificus*), *Vibrio parahaemolyticus* (*V. parahaemolyticus*), *Vibrio cholera* (*V. cholera*), *Escherichia coli* (*E. coli*), *Salmonella spp.*, *Shigella spp.*, *Staphylococcus aureus* (*S. aureus*), *Clostridium perfringens* (*C. perfringens*), *Bacillus cereus* (*B. cereus*), *Campylobacter jejuni* (*C. jejuni*), and *Yersinia enterocolitica* (*Y. enterocolitica*). See Appendix 7 for a description of the public health impacts of these pathogens.

Pathogenic bacteria can enter the process on raw materials. They can also be introduced into foods during processing from the air, unclean hands, insanitary utensils and equipment, contaminated water, or sewage and through cross-contamination between raw and cooked product. The primary method for control is to reduce levels through cooking or other treatments, when feasible, minimize the potential for recontamination and to maintain products at temperatures that do not support growth of pathogenic bacteria.

Time and temperature abuse occurs when a product is allowed to remain at temperatures favorable to pathogenic bacteria growth for sufficient time to result in unsafe levels of pathogenic bacteria or their toxins in the product. Therefore, management of time and temperature of product exposure is important to producing a safe product. Table A-1 (Appendix 4) provides guidance concerning the conditions under which certain pathogenic bacteria can grow. The bacteria listed are those of greatest concern in fish and fishery products.

Managing time and temperature of exposure

Time and temperature management relies on identification of time and temperature combinations that ensure the safety of your product. The following factors should be considered:

- The types of pathogenic bacteria that are reasonably likely to be present;
- Whether those pathogens can grow in the food;
- The infective dose of the pathogenic bacteria;
- The expected initial level of the pathogenic bacteria in the food.

Presence of pathogenic bacteria

It is reasonable to assume that pathogenic bacteria of various types that are not associated with specific food sources, including those listed in Table A-1 (Appendix 4), will be present on raw fish

and fishery products and non-fishery ingredients. They might be present only at low levels or only sporadically, but even such occurrences warrant consideration because of the potential for growth and toxin production under temperature abuse conditions. However, certain pathogenic bacteria are associated with specific food sources, and it may not be necessary to assume that they will be present in other foods unless introduced from a contaminated source. For example, *V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae* non-O1 and non-O139 are generally associated with marine and estuarine species of fish and not with freshwater species or non-fishery ingredients.

Pathogenic bacteria can also be introduced during processing, even after cooking. Well-designed sanitation programs will minimize their introduction. However, in most cases, it is not reasonable to assume that sanitation programs will fully prevent the introduction of pathogenic bacteria. For this reason, controls should be in place to minimize the risk of pathogenic bacteria growth.

Pathogenic bacteria growth

Fish and fishery products generally provide sufficient nutrients for pathogenic bacteria growth. However, chemical and physical characteristics of the product and its packaging could limit or enhance pathogenic bacteria growth and toxin formation. Furthermore, these characteristics could restrict competing microorganism growth and provide conditions favorable to pathogenic bacteria growth.

Consider:

- The moisture available to support pathogenic bacteria growth in the product (i.e., water activity);
- The amount of salt and preservatives in the product (e.g., water phase salt and nitrates);
- The acidity of the product (i.e., pH);
- The availability of oxygen in the product (i.e., aerobic or anaerobic conditions);
- The presence of competing spoilage organisms in the food.

Table A-1 (Appendix 4) provides guidance on some conditions that limit the growth of those pathogenic bacteria that are most relevant to fish and fishery products. Table A-1 provides minimum and maximum values of pathogenic bacteria growth. This table can help you to decide whether particular pathogenic bacteria will grow in your food if it is time and temperature-abused.

Certain pathogenic bacteria grow well in time and temperature-abused raw fish and fishery products (e.g., raw molluscan shellfish), and others do not. Those that grow well in time and temperature-abused raw fish include: *V. vulnificus*, *V. parahaemolyticus, V. cholerae*, and *L. monocytogenes*. Others may grow if the natural condition of the raw fish is changed, such as through salting or reduced oxygen packaging. Those that ordinarily do not grow well, because they compete poorly with the normal spoilage bacteria, include: *C. jejuni,* pathogenic strains of *E. coli, Salmonella spp., Shigella spp., S. aureus*, *C. perfringens*, *B. cereus,* and *Y. enterocolitica*.

Most pathogenic bacteria will grow well in temperature-abused cooked fish if their growth is not controlled by means such as drying, salting, or acidification, because competing bacteria are destroyed by the cooking process.

Infective dose

The infective dose or toxic dose is the total number of a pathogen, or the total amount of a toxin, that is necessary to produce human illness. The dose often varies considerably for a single pathogen based on the health of the consumer and the virulence (infective capacity) of the particular strain of the pathogen.

The typical infectious dose is known or suspected to be very low (i.e., one to several hundred organisms can cause illness) for many of the pathogenic bacteria listed in Table A-1 (Appendix 4). These include *C. jejuni, E. coli, Salmonella spp., Shigella spp.,* and *Y. enterocolitica*. The typical infectious dose for other pathogenic bacteria is considered to be

somewhat higher (i.e., several thousand to less than 100,000). These include *V. vulnificus* and *V. parahaemolyticus*. In the case of both of these categories of pathogens, it is advisable to prevent any significant growth so that the typical infective dose is not exceeded. In other words, product temperatures should be maintained below the minimum growth temperature for the pathogen or should not be allowed to exceed that temperature for longer than the lag growth phase (i.e., the slow growth phase during which a pathogenic bacteria acclimates to its environment before proceeding to rapid growth) of the pathogenic bacteria at the exposure temperature.

Still other pathogenic bacteria require large numbers in order to cause disease. The typical infectious dose of *V. cholerae* is suspected to be 1,000,000 cells. *S. aureus* and *B. cereus* toxin do not normally produce sufficient toxin to cause illness until numbers of the pathogen reach 100,000 to 1,000,000/gram.

C. perfringens typically does not produce toxin in the human gut unless at least 100,000,000 bacteria are consumed. Limited growth of these pathogens might not compromise the safety of the product. However, time and temperature controls must be adequate to prevent growth before the infectious or toxic dose is reached.

Levels of pathogenic bacteria

The levels of a pathogen that are likely to be present in a fish or fishery product is dependent on factors such as the quality of the harvest water, how the raw material was handled before it was delivered to your plant, and the effectiveness of your sanitation control program.

As a practical matter, the initial number of low-to-moderate infectious dose pathogenic bacteria in a food is usually of limited importance when you develop a time and temperature management strategy because these pathogens should be controlled by a time and temperature strategy that does not permit their growth to pass the lag phase. On the other hand, when controlling pathogenic bacteria that have a relatively high infective dose, the initial number of pathogenic bacteria may be a significant consideration.

Practical considerations for unrefrigerated processing

Consider the above described factors to identify the pathogen(s) that presents the greatest challenge with respect to managing time and temperature exposure in your product. This then becomes the target pathogen(s) for time and temperature control. Table A-2 (Appendix 4) can then be used to establish safe exposure times for the target pathogen(s) at the temperatures at which you expect your product to be exposed.

As an alternative, you can use predictive microbiology models, such as the U.S. Department of Agriculture Pathogen Modeling Program (*http://ars.usda.gov/Services/docs.htm?docid=6786*) or ComBase (*http://www.combase.cc/default.html*) for product-specific time and temperature exposure calculations. However, you should validate the reliability of predictions from such models for your food.

Growth rates of pathogens are highly temperature dependent. Ordinarily, pathogenic bacteria growth is relatively slow at temperatures below 70°F (21.1°C). In most cases, growth is very slow below 50°F (10°C), and 40°F (4.4°C) is below the minimum growth temperature of most pathogenic bacteria, although there are some exceptions. On the other hand, pathogenic bacteria grow relatively fast at temperatures above 70°F (21.1°C). Product temperatures should be maintained below the minimum growth temperature for the pathogen or should not be allowed to exceed that temperature for longer than the lag growth phase of the pathogen growth cycle.

Consider the following recommendations when developing a product monitoring program. Product surface temperature or ambient temperature generally should be monitored when the ambient temperature (e.g., air) is warmer than the product internal temperature. Internal temperature in the

center of the thickest part of the product should be monitored when the ambient temperature (e.g., air, ice, and brine) is cooler than the product internal temperature. Similarly, when selecting a product for temperature measurement, consider the location of the product selected in relation to the environment and select the likely worse case product. For example, a product in the center of a pile of products will take longer to cool than a product at the surface.

- **Strategies for control of pathogenic bacteria**

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

- Managing the amount of time that food is exposed to temperatures that are favorable for pathogen growth and toxin production (covered generally in this chapter; for *Clostridium botulinum* (*C. botulinum*), in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15);
- 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 (hereinafter, the Low-Acid Canned Foods (LACF) Regulation);
- Killing pathogenic bacteria by processes that retain the raw product characteristics (covered in Chapter 17);
- Controlling the amount of moisture that is available for pathogen growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the amount of moisture that is available for pathogen 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);
- 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).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether pathogenic bacteria growth and toxin formation as a result of time and temperature abuse 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 come in with the raw material or will the process introduce them)?

   It is reasonable to assume that pathogenic bacteria of various types that are not associated with specific food sources, including those listed in Table A-1 (Appendix 4), will be present on raw fish and fishery products and non-fishery ingredients. However, certain pathogenic bacteria are associated with specific food sources, and it may not be necessary to assume that they will be present in other foods unless they have been cross-contaminated. For example, V. vulnificus, V. parahaemolyticus, and V. cholerae non-O1 and non-O139 are generally associated with marine and estuarine species of fish and not with freshwater species or non-fishery ingredients.

   Pathogenic bacteria also could be introduced during processing, even after cooking. Well-designed sanitation programs (prerequisite programs) will minimize the introduction of pathogenic bacteria. However, in most cases

it is not reasonable to assume that they will fully prevent the introduction of pathogenic bacteria. Additional information on this topic is presented in the previous section, "Understand the Potential Hazard."

2. Is it reasonably likely that pathogenic bacteria will grow to unsafe levels and/or produce toxin at this processing step?

   In order to answer this question, you must first determine which of those pathogenic bacteria that are reasonably likely to be present in your product would be able to grow under time and temperature abuse conditions. Information on this topic is presented in the previous section, "Understand the Potential Hazard."

   Time and temperature abuse at one step alone might not result in an unsafe product. However, time and temperature abuse that occurs at successive processing steps (including storage steps) might be sufficient to result in unsafe levels of pathogenic bacteria or toxins. For this reason, you should consider the cumulative effect of time and temperature abuse during the entire process. Table A-2 (Appendix 4) provides guidance about the kinds of time and temperature abuse that might cause a product to be unsafe. A study may need to be conducted to determine time and temperature exposure of your seafood to temperature abuse for each process step.

   Remember that you should consider the potential for time and temperature abuse in the absence of controls. You might already have controls in your process that minimize the potential for time and temperature abuse that could result in unsafe levels of pathogenic bacteria or toxins. This section and subsequent sections will help you determine whether those or other controls should be included in your Hazard Analysis Critical Control Point (HACCP) plan.

   In summary, under ordinary circumstances (e.g., without data to the contrary), you should consider that it is reasonably likely that a pathogenic bacteria in Table A-1 (Appendix 4) will grow to an unsafe level or produce toxin in your product at a particular processing step if all of the following conditions are met:

   - It is reasonably likely to be present;
   - Its growth is not prevented by a condition of the food;
   - It is reasonably likely that, in the absence of controls, cumulative time and temperature abuse conditions such as those described in Table A-2 (Appendix 4) could occur during processing of the product, and the processing step could contribute significantly to that cumulative abuse.

3. Can unsafe levels of pathogenic bacteria and/or toxin production that are reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Pathogenic bacteria growth and toxin formation due to time and temperature abuse should 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 measures that can be applied for pathogenic bacteria growth and toxin formation due to time and temperature abuse include:

   - Refrigeration of the product and controlling refrigeration temperatures;
   - Proper icing of the product;
   - Controlling the amount of time that the product is exposed to temperatures that would permit pathogenic bacteria growth or toxin production;
   - Rapid cooling of the product;

- Ensuring that incoming fish were handled properly during refrigerated transportation from the previous processor, including:
    - Controlling refrigeration temperatures during transit;
    - Proper icing during transit.

- **Intended use**

  Except as noted, it is unlikely that the intended use will affect the significance of the hazard.

  FDA is not aware of any HACCP controls that exist internationally for the control of pathogenic bacteria 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 (called the Seafood HACCP Regulation in this guidance document) requires such a regime. The proper application of sanitation controls is essential because of the likelihood that pathogenic bacteria can be introduced into fish and fishery products through poor handling practices by the aquaculture producer, the fisherman, or the processor.

  FDA is interested in information regarding any HACCP controls beyond sanitation that could be necessary and practical for the control of pathogenic bacteria in fish and fishery products that are customarily fully cooked by the consumer or end user. However, the agency makes no recommendations in this guidance document and has no specific expectations with regard to such controls in processors' HACCP plans. The agency plans to develop Good Manufacturing Practice guidelines for harvest vessels and for aquaculture in an effort to minimize the likelihood that these operations will contribute pathogens to fish and fishery products.

  Some products are partially cooked by the processor for culinary purposes (e.g., setting the batter or breading, or stabilizing the product shape), and are customarily fully cooked by the consumer or end user. Examples include: fish balls, shrimp egg rolls, shrimp and cheese stuffed ravioli, crab cakes, and breaded fish portions. Although the exterior of these products may appear cooked, the interior fish protein is not coagulated, and the products are not ready-to-eat.

  Other products contain a combination of raw or partially cooked, and fully cooked ingredients (e.g., seafood mixture of raw oysters, cooked shrimp, and raw or cooked octopus). Although the protein of some of the fishery ingredients is coagulated, some is not. As a result, many of these products are not ready-to-eat. However, these combination products should be considered ready-to-eat if the raw or partially cooked ingredients are customarily eaten without cooking by the consumer or end user.

  Note that the toxin produced by *S. aureus* is not destroyed by cooking or retorting. Its formation should, therefore, be prevented in all fish and fishery products. However, as previously mentioned, *S. aureus* does not grow well in raw fish, unless the growth of competing spoilage organisms is inhibited (e.g., by salting or vacuum packaging). *B. cereus* also produces a heat-stable toxin and forms heat-resistant spores that can survive cooking.

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 growth and toxin formation as a result of time and temperature abuse:

1. If there is a cook step, pasteurization step, or retorting step later in your manufacturing process, you should, in most cases, identify that step as the CCP. You would not usually need to identify processing steps prior to cooking, pasteurization, or retorting as CCPs for this hazard.

   Example:

   A cooked shrimp processor should set the critical control point for pathogenic bacteria growth and toxin formation as a result of time and temperature abuse at the cook step. The processor would not need to identify each of the processing steps prior to cooking as CCPs.

   Guidance for this pathogen control strategy is contained in Chapter 16 (for cooking and pasteurization) and the LACF Regulation, 21 CFR 113 (for retorting).

   However, there are two important limitations to this strategy:

   - The cooking, pasteurizing, or retorting process must be sufficient to eliminate the most resistant pathogenic bacteria of public health concern that are reasonably likely to be present;
   - Certain toxins (e.g., *S. aureus* and *B. cereus* toxins) are heat stable. Heat treatment, including retorting, might not eliminate the toxin once it is formed.

   In either case, time and temperature control would be necessary at the processing steps at which growth and toxin formation could occur.

2. If there is no cook step, pasteurization step, or retorting step later in the process, you should identify as a CCP each processing step at which you have identified this hazard as significant. You should control cumulative exposure of the product to time and temperatures that will permit growth or toxin formation at these steps.

   Example:

   A crabmeat processor identifies a series of post-cook processing and storage steps (e.g., backing, picking, packing, and refrigerated storage) as presenting a reasonable likelihood of pathogenic bacteria growth and toxin formation. The processor does not subject the product to a final pasteurization process and recognizes that it might be consumed without further cooking. The processor controls the temperature during refrigerated storage and the time of exposure to unrefrigerated conditions during the processing steps. The processor should identify each of the post-cook processing and storage steps as CCPs for this hazard.

This chapter provides the following four control approaches, or control strategies, each relating to a separate potential CCP or a set of CCPs:

- "Control Strategy Example 1 - Transit Control." This control strategy should be applied to the control of transit at receipt of chilled (i.e., refrigerated, iced, or held under chemical cooling media, such as gel packs, and not frozen) ready-to-eat fishery products;
- "Control Strategy Example 2 - Refrigerated Storage and Refrigerated Processing Control." This control strategy should be applied to chilled (i.e., refrigerated, iced, and not frozen) storage and refrigerated (i.e., ≤40°F (4.4°C)) processing;
- "Control Strategy Example 3 - Cooling After Cooking Control." This control strategy should be applied to a cooling

step when there is no significant handling during the cooling and there is a need to control spore-forming pathogenic bacteria;

- "Control Strategy Example 4 - Unrefrigerated Processing Control." This control strategy should be applied to unrefrigerated (i.e., ≥40ºF (4.4ºC)) processing.

Following is further guidance that may help you determine whether these processing steps should be identified as CCPs for this hazard. The guidance is divided into two types of finished products: cooked ready-to-eat and raw ready-to-eat.

- **Cooked, ready-to-eat products**

  These products may be cooked by the processor, received by the processor already cooked, or assembled by the processor from ready-to-eat components. They may appear to the consumer or end user to be ready-to-eat products and may, therefore, be eaten without further cooking. Examples include: cooked crabmeat, lobster meat, and crayfish meat; surimi-based analog products; seafood salads; and hot-smoked fish. Note that smoked fish is also covered in Chapter 13, and cooking and pasteurization are covered in Chapter 16.

  Cooked, ready-to-eat products, especially assembled products, might develop pathogen hazards as a result of cross-contamination and growth. Contributing factors to this risk are manual handling steps, multiple ingredients, unrefrigerated processing, and multiple cooling steps. Cumulative exposure to time and temperature abuse after the cook step should be taken into consideration when establishing CCPs based on time and temperature.

  In some cases, refrigerated cooked, ready-to-eat foods (e.g., lobster meat, pasteurized crabmeat, smoked fish, and surimi-based analog products) are received by a secondary processor and held for sale without further handling. In other cases, these products are received by a secondary processor and used as ingredients in a ready-to-eat product that will not be cooked or pasteurized by that processor (e.g., seafood salad). In these cases, the receiving and storage steps by the secondary processor should be designated as CCPs to control the hazard of pathogenic bacteria growth. On the other hand, if these ready-to-eat foods are received by the secondary processor to be used in a product that will be cooked or pasteurized by that processor, the receiving and storage steps before the cooking or pasteurization step might not need to be designated as CCPs, unless *S. aureus* or *B. cereus* toxin formation is a significant hazard. Remember that these toxins are not likely to be inactivated by heat.

  In still other cases, ready-to-eat foods are received by a secondary processor and used as ingredients in a non-ready-to-eat product (e.g., cooked octopus used by the processor as an ingredient in a seafood mix that is customarily eaten after cooking by the consumer or end user). Again, the receiving and storage steps might not need to be designated as CCPs, unless *S. aureus* or *B. cereus* toxin formation is a significant hazard.

  The need to establish a CCP at cooling after cooking or pasteurization depends on:

  - The severity of the cooking (including hot smoking) or pasteurization step;
  - The extent to which the product is handled between the end of the cooking or pasteurization step and the end of the cooling step.

  Spore-forming pathogenic bacteria may survive cooking or pasteurization processes that target vegetative pathogenic bacteria.

For example, in foods that contain meat or rice, spores of *C. perfringens* and *B. cereus* could be present, could survive the cooking process, and could grow and produce toxin in the product during cooling and subsequent handling. In fact, the heat from the cooking process might initiate growth of the surviving spores. In this case, a CCP may be needed at product cooling. However, some cooking processes might be adequate to kill even the spores of *C. perfringens* and *B. cereus*. In this case, a CCP at product cooling may not be necessary.

When significant handling occurs after cooking or pasteurization, there is a risk that the product might be recontaminated with pathogenic bacteria. Because many of the normally occurring spoilage organisms may have been eliminated by the cooking or pasteurization process and are no longer present to compete with the pathogenic bacteria, rapid growth and toxin formation by the pathogenic bacteria are possible. It is advisable to fully cool a product before it is further handled, in order to minimize pathogenic bacteria growth and toxin formation. When significant handling occurs after the heating process but before the completion of the cooling process or when the cooked product comes into contact with equipment that was not heated along with the product, time and temperature exposure controls may need to start at that point. In some processes, cooling is performed (1) before any significant handling of the cooked product; and (2) in the same container in which the product was cooked. Under these conditions, cooling after cooking may not need to be identified as a CCP for this hazard. However, such a determination is dependent upon strict adherence to good sanitation practices to further minimize the risk of recontamination with pathogenic bacteria.

Time and temperature controls may be needed at the following steps (CCPs):

- Receiving;
- Thawing;
- Cooling after cooking;
- Processing after cooking:
    - Slicing hot-smoked salmon;
    - Mixing seafood salad;
    - Picking crabmeat;
- Packaging;
- In-process and finished product refrigerated (not frozen) storage.

Time and temperature controls will usually not be needed at processing steps that meet the following conditions:

- Continuous, mechanical processing steps that are brief:
    - Mechanical size grading of cooked shrimp;
    - Mechanical forming of surimi-based analog products;
    - Individual quick freezing;
- Processing steps that are brief and unlikely to contribute significantly to the cumulative time and temperature exposure to unrefrigerated conditions:
    - Date code stamping;
    - Case packing;
- Processing steps where the product is held in a frozen state:
    - Glazing;
    - Assembly of orders for distribution;
    - Frozen product storage;
- Processing steps where the product is held at temperatures above 135°F (57.2°C):
    - Initial stage of cooling;
    - Hot holding.

- **Raw, ready-to-eat products**

  These products are not heated during processing to a temperature that destroys pathogenic bacteria. They are often consumed without cooking. Examples include: cold-smoked fish, raw oysters, clams and mussels, and raw finfish (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).

  Like cooked, ready-to-eat products, raw ready-to-eat products may contain pathogenic bacteria as a result of near-shore harvest water contamination, poor aquaculture practices, or poor sanitary practices during harvesting, transportation, or processing. For example, oysters, especially those harvested during the warm weather months, might contain *V. vulnificus* or *V. parahaemolyticus*. Raw finfish might contain *V. parahaemolyticus*, *Salmonella spp.,* or *L. monocytogenes*. Some of these pathogenic bacteria (e.g., *V. vulnificus, V. parahaemolyticus*, and *L. monocytogenes*) are capable of growth in raw fish.

  Time and temperature controls may be needed at the following processing steps (CCPs):

  - Receiving;
  - Processing:
    - Thawing;
    - Shucking;
    - Portioning;
  - Packaging;
  - Raw material, in-process product, and finished product refrigerated (not frozen) storage.

  Time and temperature controls will usually not be needed at processing steps that meet the following conditions:

  - Continuous, mechanical processing steps that are brief:
    - Mechanical filleting;
  - Processing steps that are brief and unlikely to contribute significantly to the cumulative time and temperature exposure to unrefrigerated conditions:
    - Date code stamping;
    - Case packing;
  - Processing steps where the product is held in a frozen state:
    - Assembly of orders for distribution;
    - Frozen storage.

- **Time and temperature profile**

  Preparing a diagram that depicts the maximum times and temperatures at which your product will be exposed at each processing step may help you determine cumulative product exposure, especially if your product is cooked, ready-to-eat. This diagram can help you identify CCPs, as well as critical limits, as will be discussed later. Figures 12-1 and 12-2 are examples of time and temperature profiles for two different crabmeat processes. Although the figures show similar time and temperature profiles, they demonstrate how differences in processing operations, especially with respect to when significant handling occurs, can have an impact on the location of CCPs and on the critical limits at those CCPs.

  Figure 12-1 shows a time and temperature profile for a cooked crabmeat processor that significantly handles product before it is cooled to 50°F (10°C). As a result, a CCP is likely to be needed at backing, picking, and packing.

Figure 12-2 shows a time and temperature profile for a cooked crabmeat processor that does not significantly handle product before it is cooled to 50°F (10°C). As a result, a CCP is not needed until the picking operation, which is the first point at which significant handling occurs. A more restrictive set of critical limits is also likely for the product depicted by Figure 12-1 than for that depicted by Figure 12-2, because the former product is handled while still warm.

FIGURE 12-1: Internal Temperature Profile — Blue Crabmeat Processing
Partial Cooling Only After Cook With Significant Handling Before Full Cooling

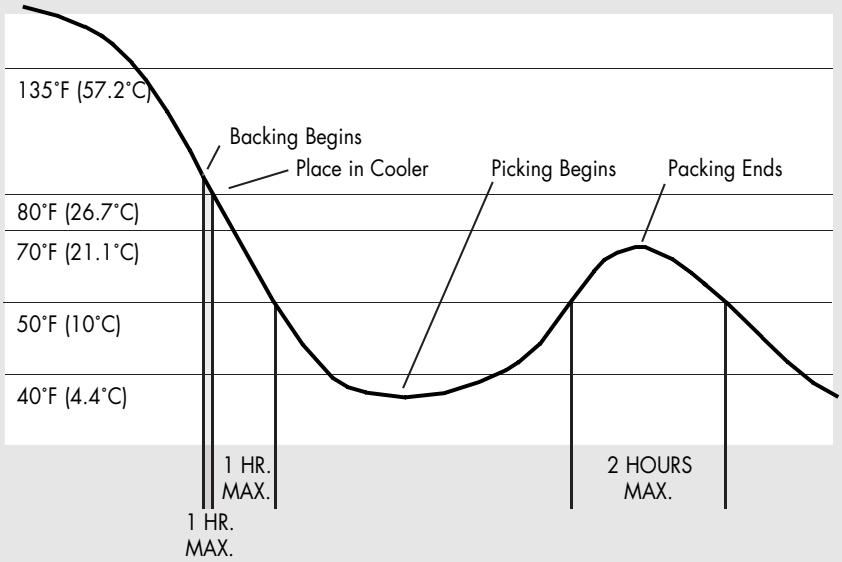
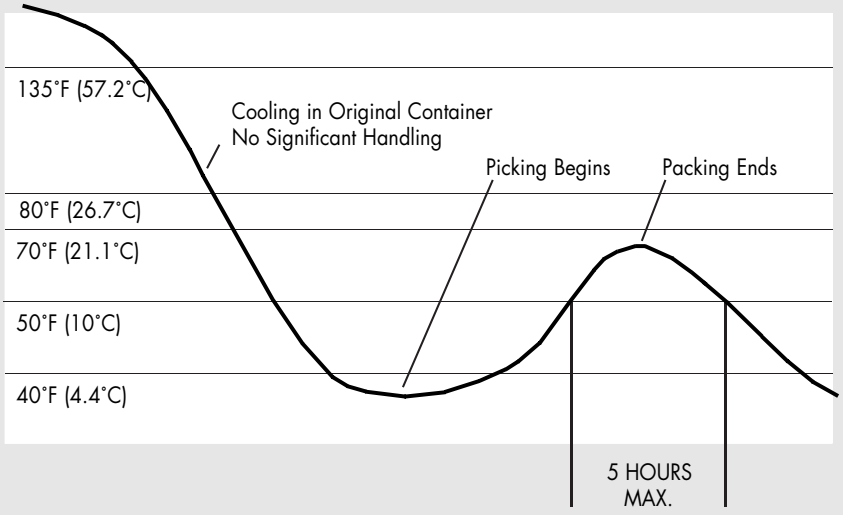


FIGURE 12-2: Internal Temperature Profile — Blue Crabmeat Processing
Cooling After Cook in Original Container With No Significant Handling During Cooling



DEVELOP A CONTROL STRATEGY.

The following guidance provides examples of four control strategies for pathogenic bacteria growth and toxin formation. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation. 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
Transit control		✓
Refrigerated storage and refrigerated processing control	✓	✓
Cooling after cooking control	✓	✓
Unrefrigerated processing control	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - TRANSIT CONTROL (FOR REFRIGERATED (NOT FROZEN) COOKED, READY-TO-EAT OR RAW, READY-TO-EAT FISHERY PRODUCTS TO BE STORED OR PROCESSED WITHOUT FURTHER COOKING)**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

- For fish or fishery products delivered refrigerated (not frozen):
  - All lots received are accompanied by transportation records that show that the product was held at or below an ambient or internal temperature of 40°F (4.4°C) throughout transit. Note that allowance for routine refrigeration defrost cycles may be necessary;

  OR
- For products delivered under ice:
  - Product is completely surrounded by ice at the time of delivery;

  OR
- For products delivered under chemical cooling media, such as gel packs:
  - There is an adequate quantity of cooling media that remain frozen to have maintained the product at an internal temperature of 40°F (4.4°C) or below throughout transit;

    AND
  - The internal temperature of the product at the time of delivery is 40°F (4.4°C) or below;

  OR
- For products delivered refrigerated (not frozen) with a transit time (including all time outside a controlled temperature environment) of 4 hours or less (optional control strategy):
  - Time of transit does not exceed 4 hours;

    AND
  - Internal temperature of the product at the time of delivery does not exceed 40°F (4.4°C).

Note: Processors receiving product with transit times of 4 hours or less may elect to use one of the controls described for longer transit times instead.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For products delivered refrigerated (not frozen):
  - The internal temperature of the product throughout transportation;

    OR
  - The ambient temperature within the truck or other carrier throughout transportation;

OR

- For products delivered under ice:
  - The adequacy of ice surrounding the product at the time of delivery;

  OR
- For products held under chemical cooling media, such as gel packs:
  - The quantity and frozen status of cooling media at the time of delivery;

    AND
  - The internal temperature of a representative number of product units at time of delivery;

  OR
- For products delivered refrigerated (not frozen) with a transit time of 4 hours or less:
  - The date and time product was removed from a controlled temperature environment before shipment and the date and time delivered;

    AND
  - The internal temperature of a representative number of product containers (e.g., cartons and totes) at the time of delivery.

» **How Will Monitoring Be Done?**

- For products delivered refrigerated (not frozen):
  - Use a continuous temperature-recording device (e.g., a recording thermometer) for internal product temperature or ambient air temperature monitoring during transit;

  OR
- For products delivered under ice:
  - Make visual observations of the adequacy of ice in a representative number of containers (e.g., cartons and totes) from throughout the shipment at delivery;

  OR
- For products delivered under chemical cooling media, such as gel packs:
  - Make visual observations of the adequacy and frozen state of the cooling media in a representative number of containers (e.g., cartons and totes) from throughout the shipment at delivery;

    AND
  - Use a temperature-indicating device (e.g., a thermometer) to determine internal product temperatures in a representative number of product containers from throughout the shipment at delivery;

  OR
- For products delivered refrigerated (not frozen) with a transit time of 4 hours or less:
  - Review carrier records to determine the date and time product was removed from a controlled temperature environment before shipment and the date and time delivered;

    AND
  - Use a temperature-indicating device (e.g., a thermometer) to determine internal product temperatures in a representative number of product containers (e.g., cartons and totes) randomly selected from throughout the shipment, at delivery. Measure a minimum of 12 product containers, unless there are fewer than 12 products in a lot, in which case measure all of the containers. Lots that show a high level of temperature variability may require a larger sample size.

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

- Every lot received.

» **Who Will Do the Monitoring?**

- For continuous 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;

OR

- 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:

- Chill and hold the affected product until an evaluation of the total time and temperature exposure is performed (a product with cumulative exposures that exceed the critical limits recommended in "Control Strategy Example 4 - Processing Controls" should be cooked or diverted to a use in which the critical limit is not applicable (e.g., divert crabmeat to a stuffed flounder operation), after giving consideration to the fact that any *S. aureus* or *B. cereus* toxin that may be present may not be inactivated by heat, or destroyed or diverted to a non-food use);

OR

- Cook the product, after giving consideration to the fact that any *S. aureus* or *B. cereus* toxin that may be present may not be inactivated by heat;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g., divert crabmeat to a stuffed flounder operation), after giving consideration to the fact that any *S. aureus* or *B. cereus* toxin that may be present may not be inactivated by heat;

OR

- Reject the lot.

AND

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

- Discontinue use of the supplier or carrier until evidence is obtained that the identified transportation- handling practices have been improved.

Establish a Recordkeeping System.

- Receiving records showing:
  - The results of continuous temperature monitoring, including:
    - Printouts, charts, or readings from temperature-recording devices;

    AND

    - Visual check of recorded data;

    OR
  - The results of ice checks, including:
    - The number of containers (e.g., cartons and totes) examined and the sufficiency of ice for each;

    AND

    - The number of containers (e.g., cartons and totes) in the lot;

    OR
  - The results of chemical media checks, including:
    - The number of containers (e.g., cartons and totes) examined and the frozen status of the media for each;

    AND

    - The number of units in the lot;

    AND/OR
  - The results of internal product temperature monitoring, including:
    - The number of containers (e.g., cartons and totes) examined and the internal temperatures observed for each;

AND

- The number of containers (e.g., cartons and totes) in the lot;

AND

- Date and time product was initially removed from a controlled temperature environment and date and time product was delivered, when applicable.

Establish Verification Procedures.

- 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
    - Comparing the temperature reading on the device to the reading on a known accurate reference device (e.g., a thermometer traceable to standards of the National Institute of Standards and Technology (NIST)) 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. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and if 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
- Calibrate the temperature-indicating 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). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

  AND
- Check the accuracy of temperature-recording devices that are used for monitoring transit conditions upon receipt of each lot. The accuracy of the device can be checked by comparing the temperature reading on 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) within the temperature range at which it will be used;

  AND
- When visual checks of ice or cooling media are used, periodically measure internal temperatures of fish to ensure that the ice or cooling media are sufficient to maintain product temperatures at 40°F (4.4°C) or less;

  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 12-1

CONTROL STRATEGY EXAMPLE 1 - TRANSIT CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Transit Control." This example illustrates how a processor receiving pasteurized crabmeat can control pathogenic bacteria growth and toxin formation as a result of time and temperature abuse during transit. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation 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, pathogen survival through cooking and pasteurization, and metal fragments).

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 pasteurized crabmeat	Pathogenic bacteria growth and toxin formation	All lots received are accompanied by truck records that show temperature was maintained at or below 40°F	Temperature of truck refrigerated compartment	Digital time and temperature data logger	Continuous, with visual review and evaluation of temperature monitoring records for each shipment	Receiving employee	Reject the shipment Discontinue use of the supplier or carrier until evidence is obtained that the identified transportation-handling practices have been improved	Data logger printout	Check accuracy of the temperature data logger upon receipt of each lot Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - REFRIGERATED STORAGE AND REFRIGERATED PROCESSING CONTROL**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

- For refrigerated (not frozen) storage or processing of the raw material, in-process product, or finished product:
    - The product is held at a cooler ambient air temperature of 40°F (4.4°C) or below. Note that allowance for routine refrigeration defrost cycles may be necessary. On the other hand, minor variations in cooler temperature measurements can be avoided by submerging the sensor for the temperature-recording device (e.g., a recording thermometer) in a liquid that mimics the characteristics of the product. Also note that critical limits during refrigerated storage and refrigerated processing that specify a cumulative time and temperature of exposure to temperatures above 40°F (4.4°C) are not ordinarily suitable to control the hazard because of the difficulty in tracking the specific products and the specific cumulative temperature exposures that those products experience. The cumulative exposure for each product would need to be determined prior to shipping. If you chose this approach, the critical limit for cumulative exposure to temperatures above 40°F (4.4°C) should include time during transit, refrigerated storage, and refrigerated and unrefrigerated processing;

OR

- For raw material, in-process product, or finished product stored under ice:
    - The product is completely and continuously surrounded by ice throughout the storage time.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For refrigerated storage or processing:
    - The ambient air temperature of the cooler or refrigerated processing room;

OR

- For storage under ice:
    - The adequacy of ice surrounding the product.

» **How Will Monitoring Be Done?**

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

OR

- For storage under ice:
    - Make visual observations of the adequacy of ice in a representative number of containers (e.g., cartons and totes) from throughout the cooler.

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

- For continuous temperature recording devices:
    - Continuous monitoring by the device itself, with a visual check of the recorded data at least once per day;

OR

- For storage under ice:
    - Sufficient frequency to ensure the critical limit is met.

» **Who Will Do the Monitoring?**

- For continuous 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;

  OR
- 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:

- Chill and hold the affected product until an evaluation of the total time and temperature exposure is performed. A product with cumulative exposures that exceed the critical limits recommended in "Control Strategy Example 4 - Unrefrigerated Processing Controls," should be cooked or diverted to a use in which the critical limit is not applicable (e.g., divert crabmeat to a stuffed flounder operation), after giving consideration to the fact that any *S. aureus* or *B. cereus* toxin that may be present may not be inactivated by heat, or destroyed or diverted to a non-food use;

  OR
- Cook the product, after giving consideration to the fact that any *S. aureus* or *B. cereus* toxin that may be present may not be inactivated by heat;

  OR
- Divert the product to a use in which the critical limit is not applicable (e.g., divert crabmeat to a stuffed flounder operation), after giving consideration to the fact that any *S. aureus* or *B. cereus* toxin that may be present may not be inactivated by heat;

  OR
- Destroy the product;

  OR
- Divert the product to a non-food use.

AND

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

- Prevent further deterioration of the product:
  - Add ice to the product;

    OR
  - Move some or all of the product in the malfunctioning cooler to another cooler;

    OR
  - Freeze the product;

  AND
- Address the root cause:
  - Make repairs or adjustments to the malfunctioning cooler;

    OR
  - Make adjustments to the ice application operations.

Establish a Recordkeeping System.

- For refrigerated storage:
  - Printouts, charts, or readings from continuous temperature-recording devices;

    AND
  - Record of visual checks of recorded data;

  OR
- For storage under ice:
  - The results of ice checks:
    - The number of containers (e.g., cartons and totes) examined and the sufficiency of ice for each;

      AND
    - The approximate number of containers (e.g., cartons and totes) in the cooler.

Establish Verification Procedures.

- 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:
    - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

      OR
    - Comparing the temperature reading on 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) within the temperature range at which it will be used;

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

  AND
- When visual checks of ice are used, periodically measure internal temperatures of fish to ensure that the ice is sufficient to maintain product temperatures at 40°F (4°C) or less;

  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 12-2

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATED STORAGE AND REFRIGERATED PROCESSING CONTROL (ICING MODEL)

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigerated Storage and Refrigerated Processing Control (Icing Model)." This example illustrates how a blue crabmeat processor can control pathogenic bacteria growth and toxin formation as a result of time and temperature abuse during icing. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation 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, pathogen survival through cooking and pasteurization, and metal fragments).

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			
Finished product cooler	Pathogenic bacteria growth and toxin formation	Finished product containers completely surrounded with ice	Adequacy of ice	Visual observation	Each case immediately before shipping	Production employee	Re-ice the product Hold and evaluate based on total time and temperature exposure	Ice storage record	Check internal temperature of iced crabmeat weekly Review monitoring, corrective action, and verification records within 1 week of preparation

TABLE 12-3

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATED STORAGE AND REFRIGERATED PROCESSING CONTROL (REFRIGERATION MODEL)

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigerated Storage and Refrigerated Processing Control (Refrigeration Model)." This example illustrates how a blue crabmeat processor can control pathogenic bacteria growth and toxin formation as a result of time and temperature abuse during refrigerated storage. It is provided for illustrative purposes only.

Pathogenic bacteria growth and toxin formation 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, pathogen survival through cooking and pasteurization, and metal fragments).

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			
Finished product cooler	Pathogenic bacteria growth and toxin formation	Cooler maintained at or below 40°F	Cooler temperature	Digital time and temperature data logger	Continuous, with visual check of recorded data once per day	Production employee	Move to alternate cooler and/or add ice Hold and evaluate based on total time and temperature exposure	Data logger printout Record or visual checks	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

- **CONTROL STRATEGY EXAMPLE 3 - COOLING AFTER COOKING CONTROL**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

- The product is cooled from 135°F (57.2°C) to 70°F (21.1°C) within 2 hours;

  AND

- The product is further cooled from 135°F (57.2°C) to 40°F (4.4°C) within an additional 4 hours;

  OR

- The minimum or maximum values for the critical factors of the process that affect the rate of cooling, as established by a cooling rate study (e.g., product internal temperature at the start of cooling, cooler temperature, quantity of ice, quantity or size of the product being cooled, product formulation, configuration of the product in the cooler).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The length of the cooling cycle and the internal temperature of the product;

  OR

- The critical factors of the process that affect the rate of cooling, as established by a cooling rate study.

» **How Will Monitoring Be Done?**

- Clock;

  AND

- Use a temperature-indicating device (e.g., a thermometer) and visual check on time of cooling;

  OR

- Use a continuous temperature-recording device (e.g., time and temperature data logger);

  OR

- Use appropriate instruments (e.g., a temperature-indicating device, such as a thermometer, a continuous temperature-recording device, such as a time and temperature data logger, a scale) and/or visual observations as necessary to measure the critical factors of the process that affect the rate of cooling, as established by a cooling rate study.

Example:

A crayfish processor identifies cooling after the cook step as a CCP for pathogenic bacteria growth and toxin formation. The processor establishes a cooling critical limit of no more than 2 hours from 135°F (57.2°C) to 70°F (21.1°C) and no more than 4 more hours from 70°F (21.1°C) to 40°F (4.4°C). The processor uses marked batches of cooked product to monitor the cooling process. The time that the marked batch is removed from the cooker is monitored visually, and the internal temperature of the product in that batch 2 hours after cooking and 4 more hours after cooking is monitored with a dial thermometer.

Example:

Another crayfish processor has similarly identified cooling after cooking as a CCP and has established the same critical limit. The processor uses a digital time and temperature data logger to monitor the cooling rate of the cooked product.

Example:

Another crayfish processor has similarly identified cooling after cooking as a CCP. This processor has performed a cooling rate study that determined that a cooling rate of no more than 2 hours from 135°F (57.2°C) to 70°F (21.1°C) and no more than 4 more hours from 70°F (21.1°C) to 40°F (4.4°C) can be achieved as long as

certain conditions are met in the cooling process. The study determined that the following critical limits must be met: a cooler temperature of no more than 60°F (15.6°C) during the first 2 hours of cooling and no more than 40°F (4.4°C) during the remainder of cooling; and no more than 1,000 pounds of crayfish in the cooler. The processor monitors the cooler temperature with a recording thermometer and monitors the weight of the product at receiving with a scale.

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

- For temperature-indicating devices:
  - At least every 2 hours;

  OR
- For temperature-recording devices:
  - At least every 2 hours a device is placed in the product. It provides continuous monitoring, which is visually checked at the end of the cooling period;

  OR
- For critical aspects of the cooling process:
  - As often as necessary to ensure control of the process.

» **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;

  OR
- 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:

- Recook the product, after giving consideration to the fact that any *S. aureus* toxin that may be present may not be inactivated by heat;

  OR
- Divert the product to a use in which the critical limit is not applicable (e.g., divert crabmeat to a stuffed flounder operation), after giving consideration to the fact that any *B. cereus* toxin that may be present may not be inactivated by heat;

  OR
- Destroy the product;

  OR
- Divert the product to a non-food use.

AND

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

- Prevent further deterioration of the product:
  - Add ice to the product;

  AND
- Address the root cause:
  - Make repairs or adjustments to the malfunctioning cooler;

  OR
- Make adjustments to the ice application operation.

Establish a Recordkeeping System.

- For temperature-indicating devices:
  - Cooling records showing the internal temperature of the product, and the length of time between the end of the cooking (or the time that the product internal temperature falls below 135°F (57.2°C)), and the time that the measurement was made;

OR

- For temperature-recording devices:
  - Record of continuous temperature monitoring;

    AND
  - Record of visual checks of recorded data;

  OR
- For the critical factors of the process that affect the rate of cooling, as established by a cooling rate study:
  - Appropriate records (e.g., processing record showing the results of the time and temperature checks and/or volume of product in cooler).

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) or temperature- recording device (e.g., a time and temperature data logger) 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 reading on 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., 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. 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
- 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 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
- 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 12-4

CONTROL STRATEGY EXAMPLE 3 - COOLING AFTER COOKING CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3 - Cooling After Cooking Control." This example illustrates how a dungeness crabmeat processor can control pathogenic bacteria growth and toxin formation as a result of time and temperature abuse during cooling after cooking. In this case, the product is fully cooled, i.e., to 40°F (4.4°C), after cooking before significant handling. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation 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, pathogen survival through cooking and pasteurization, and metal fragments).

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			
Cooked crab cooler	Pathogenic bacteria growth and toxin formation	Crabs cooled from 135°F to 70°F in 2 hours and 70°F to 40°F in 4 more hours	Length of cooling cycle	Clock	Start marked batch Approximately every 2 hours during cooking	Production supervisor	Destroy product Make adjustment or repairs to cooler	Production record	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
			Cooked crab internal temperature	Dial thermometer in marked batches of cooked crabs					

Note: Control during unrefrigerated processing is covered under "Control Strategy Example 4 - Unrefrigerated Processing Control."
Note: Control is necessary at this step because the processor has not established that the cook step is adequate to kill the spores of C. perfringens or B. cereus

- **CONTROL STRATEGY EXAMPLE 4 - UNREFRIGERATED PROCESSING CONTROL**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

The following recommended critical limits are intended to keep the pathogenic bacteria of greatest concern in fish and fishery products from reaching the rapid growth phase (i.e., keep them in the lag phase) as a result of time and temperature exposure during processing. You may also wish to reference Table A-2 (Appendix 4), which provides cumulative time and temperature combinations for the pathogenic bacteria individually.

For raw, ready-to-eat products:

- **CRITICAL LIMIT 1:**
  - If at any time the product is held at internal temperatures above 70°F (21.1°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 2 hours (3 hours if *S. aureus* is the only pathogen of concern),

    OR
  - Alternatively, exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 4 hours, as long as no more than 2 of those hours are between 70°F (21.1°C) and 135ºF (57.2ºC);

  OR

- **CRITICAL LIMIT 2:**
  - If at any time the product is held at internal temperatures above 50°F (10°C) but never above 70°F (21.1°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 5 hours (12 hours if *S. aureus* is the only pathogen of concern);

    OR

- **CRITICAL LIMIT 3:**
  - The product is held at internal temperatures below 50°F (10°C) throughout processing,

    OR
  - Alternatively, the product is held at ambient air temperatures below 50°F (10°C) throughout processing.

For cooked, ready-to-eat products:

Note: The critical limits for cooked, ready-to-eat products are intended to begin at the completion of cooling or at the time that the product is first significantly handled after cooking, whichever occurs first.

- **CRITICAL LIMIT 1:**
  - If at any time the product is held at internal temperatures above 80°F (26.7°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 1 hour (3 hours if *S. aureus* is the only pathogen of concern),

    OR
  - Alternatively, if at any time the product is held at internal temperatures above 80°F (26.7°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 4 hours, as long as no more than 1 of those hours is above 70°F (21.1°C);

  OR

- **CRITICAL LIMIT 2:**
  - If at any time the product is held at internal temperatures above 70°F (21.1°C) but never above 80°F (26.7°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 2 hours (3 hours if *S. aureus* is the only pathogen of concern),

OR

- Alternatively, if the product is never held at internal temperatures above 80°F (26.7°C), exposure times at internal temperatures above 50°F (10°C) should be limited to 4 hours, as long as no more than 2 of those hours are above 70°F (21.1°C);

OR

- **CRITICAL LIMIT 3:**
  - If at any time the product is held at internal temperatures above 50°F (10°C) but never above 70°F (21.1°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 5 hours (12 hours if *S. aureus* is the only pathogen of concern);

OR

- **CRITICAL LIMIT 4:**
  - The product is held at internal temperatures below 50°F (10°C) throughout processing,

OR

  - Alternatively, the product is held at ambient air temperatures below 50°F (10°C) throughout processing.

Note: The preceding recommended critical limits do not address internal product temperatures between 40°F (4.4°C), the recommended maximum storage temperature for refrigerated fish and fishery products, and 50°F (10°C). The recommended critical limits do not address such temperatures because growth of foodborne pathogenic bacteria is very slow at these temperatures and the time necessary for significant growth is longer than would be reasonably likely to occur in most fish and fishery product processing steps. However, if you have processing steps that occur at these temperatures that approach the maximum cumulative exposure times listed in Table A-2 (Appendix 4) for the pathogenic bacteria of concern in your product, you should consider development of a critical limit for control at these temperatures. The cumulative time and temperature critical limits above (other than the last critical limit for raw, ready-to-eat and cooked, ready-to-eat fish and fishery products) are depicted in table format below:

Example:

A crabmeat processor using a retort process identifies a series of post-cook processing steps (e.g., backing, picking, and packing) as CCPs for pathogenic bacteria growth and toxin formation. Initial cooling takes place in the cooking crates and then the product is first handled at temperatures of around 120°F (48.9°C). The processor sets a critical limit of maximum cumulative time of exposure of 4 hours at product internal temperatures above 50°F (10°C), no more than 1 of which is above 70°F (21.1°). This critical limit is selected because the crabs are handled while still warm (e.g., above 80°F (26.7°C)). Cooling that takes place after the product is handled is included in the limit.

Example:

Another crabmeat processor using a retort process also identifies a series of post-cook processing steps (e.g., backing, picking, and packing) as CCPs. However, this product is cooled fully before handling, and ice is used on the product during processing to control time and temperature abuse. The processor sets a critical limit of a maximum product internal temperature of 50°F (10°C) at all times. Specifying a time of exposure is not necessary in this case, because it is not reasonably likely that the product would be held long enough that significant pathogen growth could occur at this temperature (e.g., 2 to 21 days, depending upon the pathogen).

TABLE 12-5

CUMULATIVE TIME AND TEMPERATURE CRITICAL LIMITS

WHEN THE PRODUCT INTERNAL TEMPERATURE RANGE IN °F (°C) IS…	THEN THE CUMULATIVE EXPOSURE TIME AT INTERNAL TEMPERATURES ABOVE 50°F (10°C) IN HOURS IS[1]…				
	1	2	3	5	12
RAW, READY TO EAT					
>50[3] (>10)		X	X[2]		
Alternatively, >50 to ≤ 70 (>10 to ≤ 21.1)			X		
Plus >70 (>21.1)	X				
Alternatively, >50 to ≤ 70 (>10 to ≤ 21.1)		X			
Plus >70 (>21.1)		X			
>50 to ≤ 70 (>10 to ≤21.1)				X	X[2]
COOKED, READY TO EAT					
>50[4] (>10)	X		X[2]		
Alternatively, >50 to ≤ 70 (>10 to ≤ 21.1)			X		
Plus >70[4] (>21.1)	X				
>50 to ≤ 80 (>10 to ≤ 26.7)		X	X[2]		
Alternatively, >50 to ≤ 70 (>10 to ≤ 21.1)			X		
Plus >70 to <80 (>21.1 to <26.7)	X				
Alternatively, >50 to ≤ 70 (>10 to ≤ 21.1)		X			
Plus >70 to <80 (>21.1 to <26.7)		X			
>50 to ≤ 70 (>10 to ≤ 21.1)				X	X[2]

1. Time at temperatures of 135°F (57.2°C) and above is not counted.
2. Where S. aureus is the only pathogen of public health significance.
3. Temperature may exceed 70°F (21.1°C).
4. Temperature may exceed 80°F (26.7°C).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The length of time of product exposure to unrefrigerated conditions (i.e., above 40°F (4.4°C));
  - The product internal temperature during the exposure period;

    OR
  - The ambient temperature of the processing area;

  OR
- The length of time only of product exposure to unrefrigerated conditions (i.e., >40°F (4.4°C)), for critical limit 1 (raw, ready-to-eat and cooked, ready-to-eat);

  OR
- The internal temperature only of the product, when internal temperatures are held below 50°F (10°C) or above 135°F (57.2°C) throughout processing for critical limit 3 for raw, ready-to-eat or critical limit 4 for cooked, ready-to-eat;

  OR
- The ambient air temperature only, when ambient air temperature is held below 50°F (10°C) throughout processing for critical limit 3 for raw, ready-to-eat or critical limit 4 for cooked, ready-to-eat.

» **How Will Monitoring Be Done?**

- For product internal temperature or ambient air temperature:
  - Use a temperature-indicating device (e.g., a thermometer);

  OR
- For ambient air temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

  AND/OR
- Make visual observations of length of exposure to unrefrigerated conditions (i.e., >40°F (4.4°C)) using a clock.

Example:

A crabmeat processor identifies a series of processing steps (e.g., backing, picking, and packing) as CCPs for pathogenic bacteria growth. The processor establishes a critical limit of no more than 1 cumulative hour of exposure to unrefrigerated temperature during these processing steps (Critical Limit 1). The processor uses marked product containers to monitor the progress of the product through the three processing steps. The time that the marked container is removed from and returned to refrigeration is monitored using a clock.

Example:

Another crabmeat processor with identical CCPs establishes a more complex set of critical limits: no more than 4 cumulative hours with product internal temperatures above 50°F (10°C), with no more than 1 of those hours above 70°F (21.1°C) (Critical Limit 1 Alternative). This processor also uses marked containers to monitor the progress of the product through the process. However, in addition to monitoring time using a clock, the processor also monitors product internal temperature for the marked containers using a thermometer. This monitoring technique provides the processor more flexibility in processing but requires more monitoring effort.

Example:

A lobster meat processor identifies the meat removal process as a CCP for pathogenic bacteria growth. The operation is performed under near-refrigeration conditions (<50°F (10°C)) (Critical Limit 4 Alternative). The processor monitors ambient air temperature with a digital data logger.

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

- For continuous temperature-recording devices:
  - Continuous monitoring during processing is accomplished by the device itself, with a visual check of the recorded data at least once per day;

  OR
- For temperature-indicating devices and clocks:
  - At least every 2 hours;

    OR
  - Every batch.

» **Who Will Do the Monitoring?**

- For continuous 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;

  OR
- For temperature-indicating devices and clocks:
  - 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:

- Chill and hold the affected product until an evaluation of the total time and temperature exposure is performed;

  OR
- Cook the product, after giving consideration to the fact that any *S. aureus* or *B. cereus* toxin that may be present may not be inactivated by heat;

  OR
- Divert the product to a use in which the critical limit is not applicable (e.g., divert crabmeat to a stuffed flounder operation), after giving consideration to the fact that any *S. aureus* or *B. cereus* toxin that may be present may not be inactivated by heat;

  OR
- Destroy the product;

  OR
- Divert the product to a non-food use.

AND

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

- Add ice to the product;

  OR
- Return the affected product to the cooler;

  AND
- Modify the process as needed to reduce the time and temperature exposure.

Establish a Recordkeeping System.

- Processing records showing the results of time and/or temperature exposure measurements.

Establish Verification Procedures.

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

AND

- Where appropriate to the critical limit, by using a study that establishes the relationship between exposure time and product temperature;

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 12-6

CONTROL STRATEGY EXAMPLE 4 - UNREFRIGERATED PROCESSING CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4 - Unrefrigerated Processing Control." This example illustrates how a blue crabmeat processor that handles the crabs at the beginning of backing while still hot can control pathogenic bacteria growth and toxin formation as a result of time and temperature abuse during unrefrigerated processing. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation 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, pathogen survival through cooking and pasteurization, and metal fragments).

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			
Backing, in-process cooler, picking, and packing	Pathogenic bacteria growth and toxin formation	Exposure time (i.e., time at internal temperatures above 50°F but below 135°F) during backing, in-process cooler, picking, and packing should be limited to 4 hours, as long as no more than 1 of those hours is above 70°F	The length of time of product exposure to unrefrigerated conditions (i.e., above 40°F)	Visual observation of marked containers using a clock	Start marked container approximately every 2 hours during backing, in-process cooler, picking, and packing	Production supervisor	Immediately ice product or move to cooler Hold and evaluate based on total time and temperature exposure	Production record	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, verification, and corrective action records within 1 week of preparation
			The product internal temperature during the exposure period	Dial thermometer					

Note: Control during refrigerated storage is covered under "Control Strategy Example 2 - Refrigerated Storage and Refrigerated Processing Control.
Note: This critical limit is necessary because the crabs are handled at internal temperatures above 80°F during backing

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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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NOTES: