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Fish & Fisheries Products Hazards & Controls Guidance: *Third Edition*

June 2001

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Seafood

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Status

This is the third edition of the Food and Drug Administrations's (FDA) "Fish and Fishery Products Hazards and Controls Guidance." This Guide relates to FDA's final regulations (21 CFR 123) that require processors of fish and fishery products to develop and implement Hazard Analysis Critical Control Point (HACCP) systems for their operations. Those final regulations were published in the *Federal Register* on December 18, 1995 and became effective on December 18, 1997. The codified portion of the regulations is included in Appendix 8.

FDA intends to revise and reissue this guidance every two to three years as the state of knowledge advances relative to fish and fishery products hazards and controls. The agency will accept public comment on this third edition of the guidance for consideration in drafting the fourth edition. Comments should be submitted to:

U.S. Food and Drug Administration
Dockets Management Branch (HFA-305)
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Comments should be identified with Docket Number 93N-0195.

This guidance is being issued as a companion document to "HACCP: Hazard Analysis Critical Control Point Training Curriculum," which was developed by the Seafood HACCP Alliance for Training and Education. The Alliance is an organization of federal and state regulators, including FDA, academia, and the seafood industry. FDA encourages processors of fish and fishery products to use the two documents together in the development of a HACCP system. Copies of the training document may be obtained from:

Florida Sea Grant
IFAS - Extension Bookstore
University of Florida
P.O. Box 110011
Gainesville, FL 32611-0011
1-800-226-1764

Purpose

The primary purpose of this guidance is to assist processors of fish and fishery products in the development of their HACCP plans. Processors of fish and fishery products will find information in this guidance that will help them identify hazards that are associated with their products, and help them formulate control strategies.

Another purpose of this guidance is to help consumers and the public generally to understand commercial seafood safety in terms of hazards and their controls. This guidance does not specifically address safe handling practices by consumers or by retail establishments, although many of the concepts contained in this guidance are applicable to both.

This guidance is also intended to serve as a tool to be used by federal and State regulatory officials in the evaluation of HACCP plans for fish and fishery products.

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Scope & Limitations

The controls and practices provided in this guidance are recommendations and guidance to the fish and fishery products industry. This guidance provides information that would likely result in a HACCP plan that is acceptable to FDA. However, it is not a binding set of requirements. Processors may choose to use other control measures, as long as they provide an equivalent level of assurance of safety for the product. However, processors that chose to use other control measures (e.g. critical limits) are responsible for scientifically establishing their adequacy.

The information contained in the tables in Chapter 3 and in Steps #10 and 11 in Chapters 4-21 provide guidance for determining which hazards are "reasonably likely to occur" in particular fish and fishery products under ordinary circumstances. The tables should not be used separately for this purpose. The tables list potential hazards for specific species and finished product types. This information must be combined with the information in the subsequent chapters to determine the likelihood of occurrence.

This guidance is not a substitute for the performance of a Hazard Analysis by a processor of fish and fishery products, as required by FDA's regulations. Hazards not covered by this guidance may be relevant to certain products under certain circumstances. In particular, processors should be alert to new or emerging problems (e.g., the occurrence of natural toxins in fish not previously associated with that toxin).

This guidance covers safety hazards associated with fish and fishery products only. It does not cover most hazards associated with non-fishery ingredients (e.g., *Salmonella enteritidis* in raw eggs). However, where such hazards are presented by a fishery product that contains non-fishery ingredients, control must be included in the HACCP plan. Processors may use the principles included in this guide for assistance in developing appropriate controls for these hazards. For example, the hazard of food allergens and food intolerance substances that are part of or directly added to the food can be controlled using the principles described in Chapter #19. As a further assistance in this regard, Appendix 6 provides a list of the most common food allergens that can pose a health risk to certain sensitive individuals.

This guidance does not cover the hazard associated with the formation of *Clostridium botulinum* toxin in low acid canned foods (LACF) or shelf-stable acidified foods. Mandatory controls for this hazard are contained in the LACF regulation (21 CFR 113) and the acidified foods regulation (21 CFR 114). Such controls need not be included in HACCP plans for these products.

This guidance does not cover the sanitation controls required by the Seafood HACCP regulation. However, the maintenance of a sanitation monitoring program is an essential prerequisite to the development of a HACCP program. If necessary sanitation controls are not included in a prerequisite sanitation monitoring program, they must be included in the HACCP plan. It is the agency's intent to provide guidance on the development of sanitation standard operating processes and sanitation monitoring programs in the future.

This guidance does not describe corrective action or verification records, because these records are not required to be listed in the HACCP plan. Nonetheless, such records must be maintained, where applicable. Likewise, it does not recount the specific requirements for the content of records that are set out in § 123.9(a).

This guidance does not cover verification activities such as reassessment of the HACCP plan and/or the hazard analysis and review of consumer complaints, that are mandated by § 123.8.

The guidance also does not provide specific guidance to importers of fish and fishery products for the development of required importer verification procedures. However, the information contained in the text, and, in particular, in Appendix 5, should prove useful for this purpose. Additionally, it is the agency's intent to provide more specific guidance for importers, either in future editions of this guidance, or in a separate guidance document.

Changes in this Edition

Following is a summary of the most significant changes in this edition of the guidance.

The information contained in Table 3-1 (Potential Vertebrate Species Related Hazards) is modified as follows:

- Dace (*Rhinichthys* spp.) is now listed as having a potential pesticides and environmental contaminants hazard;
- Alewife or river herring (*Alosa pseudoharengus*) is now listed as having a potential scombrotoxin (histamine) hazard;
- Wild-caught freshwater salmon (*Oncorhynchus* spp., *Salmo salar*) is no longer listed as having a potential aquaculture drug hazard, an error in the Second Edition;
- Mackerel (*Scomber scombrus*) is no longer listed as having a potential natural toxin (PSP) hazard.

The information contained in Table 3-3 (Potential Process Related Hazards) is modified as follows:

- Smoked fish is now listed as having a potential *C. botulinum* hazard only when it is reduced oxygen packaged and distributed or stored refrigerated;
- A number of products are now listed in Table 3-3 as having potential glass inclusion hazards;
- Dried fish is now listed as having a potential *C. botulinum* hazard;
- Fully cooked prepared foods are now listed as having potential pathogen survival through pasteurization and pathogen contamination after pasteurization hazards.

The recommendations in Chapter 4 for the control of pathogens from the harvest area are changed as follows for consistency with 1998 and 1999 Interstate Shellfish Sanitation Conference actions:

- Raw consumption warnings on tags of molluscan shellfish shellstock containers are now recommended only if the shellstock is intended for raw consumption and the recommended language has been modified;
- Additional information is included about the control of *Vibrio parahaemolyticus* in shellstock intended for raw consumption, including information about water sampling for *Vibrio parahaemolyticus* performed by Shellfish Control Authorities under certain conditions;
- Specific controls are now recommended for the control of *Vibrio parahaemolyticus* in oyster shellstock intended for raw consumption if the oysters are harvested in an area which has been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past three years. The new control strategy example relies on the following critical limits for the time from harvest to refrigeration, and is based on the Average Monthly Maximum Air Temperature (AMMAT):
  - For AMMAT of less than 66˚F (less than 19˚C): 36 hours
  - For AMMAT of 66˚F to 80˚F (19˚C to 27˚C): 12 hours
  - For AMMAT greater than 80˚F (greater than 27˚C): 10 hours;
- For the control of *Vibrio vulnificus*, the critical limits recommended for the time from harvest to refrigeration for shellstock intended for raw consumption, based on Average Monthly Maximum Water Temperature (AMMWT), are now:
  - For AMMWT of less than 65˚F (less than18˚C): 36 hours
  - For AMMWT of 65 to 74°F (18 to 23°C): 14 hours;
  - For AMMWT of greater than 74 to 84°F (greater than 23 to 28°C): 12 hours;
  - For AMMWT of greater than 84°F (greater than 28°C): 10 hours;
- For the control of pathogens other than *Vibrio parahaemolyticus* and *Vibrio vulnificus*, the critical limits recommended for the time from harvest to refrigeration for shellstock intended for raw consumption are now:
  - For AMMAT of less than 66°F (less than 19°C): 36 hours;
  - For AMMAT of 66 to 80°F (19 to 27°C): 24 hours;
  - For AMMAT of greater than 80°F (greater than 27°C): 20 hours.

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The recommendations in Chapter 4 for the control of pathogens from the harvest area are additionally changed as follows:

- The information on pathogens in molluscan shellfish is now more clearly divided into two categories:
  - The control of pathogens of human or animal origin;
  - The control of naturally occurring pathogens;
- The recommended goal of pasteurization for the control of *Vibrio vulnificus* is now more clearly defined as the reduction of the pathogen to nondetectable levels [i.e., less than 3 MPN/gram, as defined by the National Shellfish Sanitation Program (NSSP)].

The recommendations in Chapter 5 for the control of parasites are changed as follows:

- The results of a survey of U.S. gastroenterologists on U.S. seafood-borne parasitic infections are now cited;
- The recommended freezing times/temperatures are now:
  - Freezing and storing at -4˚F (-20˚C) or below for 7 days (total time); or
  - Freezing at -31˚F (-35˚C) or below until solid and storing at -31˚F (-35˚C) or below for 15 hours; or
  - Freezing at -31˚F (-35˚C) or below until solid and storing at -4˚F (-20˚C) or below for 24 hours;
- Because of the changes in the recommended critical limits, the recommended control strategies now refer only to external temperatures during freezing and to the length of time that the fish is held at the appropriate freezer temperature or the length of time that the fish is held after it is solid frozen, whichever is appropriate;
- The parasite hazard is no longer considered reasonably likely to occur if the finished product is fish eggs that have been removed from the skein and rinsed.

The recommendations in Chapter 6 for the control of natural toxins are changed as follows:

- PSP in lobster is no longer considered a significant hazard because the levels found in lobster tomale are not likely to pose a health hazard unless large quantities are eaten from a heavily contaminated area.

The recommendations in Chapter 7 for the control of scombrotoxin formation are changed as follows:

- Information is now provided about the salt-tolerant and facultative anaerobic nature of some of the histamine-forming bacteria, raising concern for scombrotoxin formation in some salted and smoked fishery products and in fishery products packed in reduced oxygen environments (e.g. vacuum packaging);
- The on-board chilling recommendations are significantly modified as follows:
  - Generally, fish should be placed in ice or in refrigerated seawater or brine at 40˚F (4.4˚C) or less within 12 hours of death, or placed in refrigerated seawater or brine at 50˚F (10˚C) or less within 9 hours of death;
  - Fish exposed to air or water temperatures above 83˚F (28.3˚C), or large tuna (i.e., above 20 lbs.) that are eviscerated before on-board chilling, should be placed in ice (including packing the belly cavity of large tuna with ice) or in refrigerated seawater or brine at 40˚F (4.4˚C) or less within 6 hours of death;
  - Large tuna (i.e., above 20 lbs.) that are not eviscerated before on-board chilling should be chilled to an internal temperature of 50˚F (10˚C) or less within 6 hours of death;
- It is now recommended that, when refrigerated brine or seawater is used for chilling fish on the harvest vessel, the temperature of the cooling media be monitored and recorded (harvest vessel control strategy only);
- It is now recommended that the critical limits at receiving from the harvest vessel include a requirement that the chilling of fish on the harvest vessel be continued to bring the internal temperature of the fish to 40˚F (4.4˚C) or less (harvest vessel control strategy only);
- It is now recognized that certain data previously expected to be recorded by the harvester on harvest vessel records may, under certain circumstances, be more efficiently recorded by the primary (first) processor on receiving records (harvest vessel control strategy only), such as:
  - Method of capture;
  - Air and water temperature;
  - Method of onboard cooling;
  - Estimated date and time of death;

• It is now recognized that, as an alternative to the primary processor receiving harvest vessel records that are maintained by the vessel operator, certain harvest operations may lend themselves to monitoring and record keeping entirely by the primary processor. This arrangement is suitable only if the primary processor has direct knowledge about those aspects of the harvesting practices that must be controlled to ensure that the appropriate critical limits are met. For example, if the harvest vessel leaves from the processor's facility and returns with the iced or refrigerated catch to the processor's facility within the appropriate time limits for on board icing or refrigeration of the catch, under certain circumstances it may be possible for the processor to perform all of the monitoring and record keeping functions ordinarily performed by the harvester;

• It is now recommended that the critical limits at receiving from the harvest vessel include a requirement that fish delivered in less than 12 hours after death should exhibit evidence that chilling began on the harvest vessel (e.g. at receipt the internal temperature of the fish is below ambient air and water temperature);

• It is now recommended that the date and time of off-loading be recorded on receiving records maintained by the primary processor;

• It is no longer recommended that primary (first) processors check for the adequacy of ice, refrigerated seawater, refrigerated brine, or other cooling media at receipt from the harvest vessel;

• It is no longer recommended that secondary processors check the internal temperature of fish received from other processors. However, it is now recommended that the checks for the adequacy of ice or other cooling media at receiving be verified periodically by measuring the internal temperature of the fish to ensure that it is at or below 40˚F (4.4˚C);

• It is now recommended that the accuracy of time/temperature data loggers or recorder thermometers on vehicles delivering fish to secondary processors be checked on all new suppliers' vehicles and at least quarterly thereafter;

• The table of approximate safe shelf-life for scombrotoxin-forming species which was previously present is replaced with more generalized guidance because the values contained in the table were apparently being misused as binding limits;

• The recommended critical limits for storage and processing are significantly modified as follows:

- For fish that have not been previously frozen: the fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 4 hours, cumulatively, if any portion of that time is at temperatures above 70˚F (21˚C); or the fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 8 hours, cumulatively, as long as no portion of that time is at temperatures above 70˚F (21˚C);
- For fish that have been previously frozen: the fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 12 hours, cumulatively, if any portion of that time is at temperatures above 70˚F (21˚C); or the fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 24 hours, cumulatively, as long as no portion of that time is at temperatures above 70˚F (21˚C);

• There is no longer a minimum length of frozen storage in the definition of "previously frozen product;"

• It is now recommended that ambient air temperature be monitored at the processing and packaging critical control points;

• A new concept is introduced to assist in the assessment of whether the hazard is significant at receiving by the primary (first) processor: the hazard may not be significant if the worst case environmental conditions (i.e. air and water temperatures) during the harvest season in a particular region would not permit the formation of histamine during the time necessary to harvest and transport the fish to the primary processor;

• The recommendations previously provided for refrigerated storage are now also recommended for refrigerated processing;

• For purposes of selecting fish for histamine analysis and sensory examination it is now recommended that lots be identified that contain only one species;

• It is now recommended that the number of fish tested for internal temperature at receipt by the primary (first) processor be one per ton for lots of 10 tons or more, and one per 1000 lbs. for lots of under 10 tons, as long as at least 12 fish per lot are examined;

• It is now recommended that no less than 18 fish per lot be analyzed for histamine at receipt by the primary (first) processor except where the lot is smaller than 18 fish (histamine testing control strategy only). The fish

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collected for analysis may be composited for analysis if the critical limit is reduced accordingly;
• A sample size of 60 fish and a reject level of any fish at or above 50 ppm histamine is now recommended as one option for corrective action when the processing critical limits have been violated;
• Another option is now provided for corrective action when the sensory critical limit has been violated (primary processor):
  - Perform histamine analysis on the lot (i.e. fish of common origin) by analyzing 60 fish (or the entire lot for lots smaller than 60 fish) and rejecting the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found. The fish collected for analysis may be composited for analysis if the critical limit is reduced accordingly;

AND

  - Perform a sensory examination of all fish in the lot;

• It is now recognized that when refrigerated fish are transported only short distances (4 hours or less) from processor to processor, a suitable alternative to requiring continuous monitoring during transit may be for the secondary processor to check the internal temperature of the fish upon receipt;
• It is no longer recommended that maximum indicating thermometers be used to monitor ambient air temperature in storage coolers;
• It is now recommended that high temperature alarms used to monitor ambient air temperature in storage coolers be connected to a 24-hour monitoring service.

The recommendations in Chapter 11 for the control of aquaculture drugs are changed as follows:

• Additional information is now provided about the labeling of approved conditions of use on aquaculture drugs;
• Information is now included about the newly approved drug, chorionic gonadotropin;
• Information is now included about additional approved uses for formalin solution;
• An additional approved manufacturer of tricaine methansolfonate is now listed;
• Thiamine hydrochloride is now listed as a low regulatory priority drug for treatment of thiamine deficiency in salmonids;
• Discontinued use of the supplier until corrections are made is now recommended as a corrective action for all control strategy examples in which aquacultured fish are received from the producer.

The recommendations in Chapter 12 for the control of pathogen growth and toxin formation (other than *Clostridium botulinum*) as a result of time/temperature abuse are changed as follows:

• A third set of recommended critical limits is now provided for control during processing steps: If the product is held at internal temperatures both above and below 70˚F (21.1˚C), exposure times above 50˚F (10˚C) should ordinarily be limited to 4 hours, as long as no more than 2 of those hours are above 70˚F (21.1˚C);
• Additional information and guidance is now provided to assist in the development of critical limits during processing and storage, including:
  - Examples of product time/temperature profiles;
  - A recommendation that most microbiologically sensitive products be stored at or below 40˚F (4.4˚C), except where control of nonproteolytic *C. botulinum* by refrigeration is necessary, in which case storage at 38˚F (3.3˚C) is usually appropriate;
• Additional verification is now recommended, as follows:
  - The accuracy of recorder thermometers and other instruments used to monitor temperature in transportation cargo areas should be checked on new suppliers' vehicles and at least quarterly for each supplier thereafter;
  - When visual checks of ice or cooling media are used to monitor the adequacy of coolant, the internal temperatures of the fish should be periodically checked to ensure that the ice or cooling media is sufficient to maintain product temperatures at 40˚F (4.4˚C) or less;
• There is now a specific acknowledgement that frozen product storage and receipt of frozen raw materials are not likely CCPs;
• Background information on the pathogens of concern now indicates that the infective doses of *Listeria monocytogenes* and *Vibrio parahaemolyticus* are unknown;

• The example HACCP plans in Tables 12-1 and 12-2 are modified to correct an error in the Second Edition, in which the cooked crab cooler step was inadvertently included as a CCP in the Gulf Coast blue crab processing method (Table 12-1), rather than the East Coast blue crab processing method (Table 12-2).
• It is now recognized that when refrigerated fishery products are transported only short distances (4 hours or less) from processor to processor, a suitable alternative to requiring continuous monitoring during transit may be for the secondary processor to check the internal temperature of the fish upon receipt;
• It is no longer recommended that maximum indicating thermometers be used to monitor ambient air temperature in storage coolers;
• It is now recommended that high temperature alarms used to monitor ambient air temperature in storage coolers be connected to a 24-hour monitoring service.

The recommendations in Chapter 13 for the control of *C. botulinum* toxin formation are changed as follows:

• The introductory material is extensively reorganized and revised to provide greater clarity;
• Information is now provided on a recommended minimum oxygen transmission rate for oxygen-permeable packages (10,000 cc/m^2/24 hrs);
• Fishery products packaged in deep containers from which the air is expressed are now identified as presenting a *C. botulinum* toxin formation hazard;
• Hot smoked product in aerobic packaging is no longer identified as presenting a *C. botulinum* toxin formation hazard sufficient to require preventive controls in a HACCP plan. However, note that the Association of Food and Drug Officials recommends a minimum water phase salt content of 2.5% in aerobically-packaged smoked fish;
• Controls are no longer recommended specifically for the control of *C. botulinum* toxin formation as a result of time/temperature abuse during the processing of unpackaged product. Instead it is now recommended that the controls recommended for pathogens other than C. *botulinum* be applied as appropriate. The chapter also acknowledges that *C. botulinum* toxin formation is possible in unpackaged or aerobically packaged product, but that, under those conditions, it requires the type of severe temperature abuse that is not reasonably likely to occur in most food processing environments;
• It is now recognized that when refrigerated fishery products are transported only short distances (4 hours or less) from processor to processor, a suitable alternative to requiring continuous monitoring during transit may be for the secondary processor to check the internal temperature of the fish upon receipt;
• It now states that 20% salt is the level needed to ensure the safety of a shelf stable product relative to all pathogens (based on the maximum salt level for growth of *S. aureus*), rather than providing the apparently misleading statement that 10% salt is the level needed in a shelf stable product for the control of *C. botulinum* type A and proteolytic types B and F;
• It now provides instruction to consult Chapter 12 for information on refrigerated storage temperature critical limits suitable for the control of pathogens other than *C. botulinum*, rather than providing the apparently misleading statement that 50˚F (10˚C) is an appropriate critical limit for the control of *C. botulinum* type A and proteolytic types B and F. Refrigeration at or below 40˚F (4.4˚C) is recommended for the control of all pathogens;
• Specific guidance is now provided for control of *C. botulinum* toxin formation in refrigerated, reduced oxygen packaged, pasteurized fishery products, including: 1) those that receive a nonproteolytic *C. botulinum* pasteurization process in the final container; and 2) those that receive a nonproteolytic *C. botulinum* cook and are then hot filled into the final container;
• Specific guidance is now provided for control of *C. botulinum* toxin formation in refrigerated, reduced oxygen packaged pasteurized surimi-based products, including a recommended control of 2.5% salt in combination with a pasteurization process in the finished product container of 185˚F (85˚C) (internal temperature) for at least 15 minutes;
• The use of recorder thermometers or digital time/temperature data loggers throughout distribution and retail storage and sales is no longer recommended as an alternative to a second barrier to toxin formation by *C. botulinum* type E and nonproteolytic types B and F;
• It is now acknowledged that, for refrigerated products that are packaged in oxygen-permeable packaging, an oxygen-impermeable overwrap may be used to extend shelf life while the product is under the control of the processor, as long as the overwrap is removed before the product leaves the processor's control;

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• It is now recommended that nitrite analysis accompany water phase salt analysis, as appropriate, when such analysis is used as the means of monitoring the brining, dry salting and/or drying steps;
• It is now recommended that the accuracy of time/temperature data loggers or recorder thermometers on vehicles delivering fish to secondary processors be checked on all new suppliers' vehicles and at least quarterly thereafter;
• It is no longer recommended that maximum indicating thermometers be used to monitor ambient air temperature in storage coolers;
• It is now recommended that high temperature alarms used to monitor ambient air temperature in storage coolers be connected to a 24-hour monitoring service.

The recommendations in Chapter 14 for the control of pathogen growth and toxin formation as a result of inadequate drying are changed as follows:

• Controls are now provided for partial drying of refrigerated, reduced oxygen packaged foods, where drying is targeted for the control of *C. botulinum* type E and nonproteolytic types B and F. The controls are designed to ensure that the water activity of the finished product is below 0.97;
• The importance of packaging in preventing rehydration of dried products is now noted.

The recommendations in Chapter 16 for the control of pathogen survival through cooking are changed as follows:

• The concept of exceptionally lethal cooking processes is eliminated;
• Information is now provided about the target organism and degree of destruction for cooking processes, including recommendations that:
  - The target organism should ordinarily be *L. monocytogenes;*
  - The cook should ordinarily provide a 6D process;
• Information is now provided about cooking processes that are designed to eliminate the spores of *Clostridium botulinum* type E and nonproteolytic types B and F, such as cooking of soups and sauces that will be reduced oxygen packaged (e.g. vacuum packaged) and distributed refrigerated. The information includes the recommendation that such products be hot filled in a continuous filling system to minimize the risk of recontamination between cooking and finished product packaging.

The recommendations in Chapter 17 for the control of pathogen survival through pasteurization are changed as follows:

• Information is now provided about the target organism and degree of destruction for pasteurization processes, including recommendations that:
  - The target organism should ordinarily be *Clostridium botulinum* type E and nonproteolytic types B and F if the product is reduced oxygen packaged (e.g. vacuum packaged), does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen, and is stored or distributed refrigerated (not frozen);
  - The target organism should ordinarily be *L. monocytogenes* for other products (e.g. frozen products)*;*
  - The pasteurization process should ordinarily provide a 6D reduction in the numbers of the target pathogen.

The recommendations in Chapter 18 for the control of pathogen introduction after pasteurization are changed as follows:

• Information is now provided on hot filling products such as soups and sauces that are cooked to eliminate the spores of *Clostridium botulinum* type E and nonproteolytic types B and F, and then reduced oxygen packaged (e.g. vacuum packaged) and then distributed refrigerated (not frozen). The minimum recommended hot fill temperature, 185˚F (85˚C), is designed to minimize the risk of recontamination between cooking and finished product packaging;
• It is now recommended that cooling water flow rate be controlled when UV treatment is used to treat container cooling water.

The recommendations in Chapter 19 for the control of allergens, food intolerance substances and prohibited food and color additives are changed as follows:

• Controls similar to those previously recommended for use by primary processors are now recommended for use by secondary processors, except that reliance on raw material labeling or documents accompanying the raw material shipment (in the case of unlabeled product) are included as recommended control strategies when the raw material is received from another processor;

• Undeclared sulfiting agents are now identified as a potential hazard in cooked octopus;
• General information is now provided on the control of allergenic proteins in foods. Controls similar to those previously recommended to ensure proper labeling for certain food and color additives are now recommended if foods that contain allergenic proteins are part of or are directly added to a fishery product. Additionally, reference is made to controlling inadvertent introduction of allergenic proteins, because of cross-contact, through a rigorous sanitation regime, either as part of a prerequisite program or as part of HACCP itself.

The recommendations in Chapter 20 for the control of metal inclusion are changed as follows:

• The reference to the point at which FDA's Health Hazard Evaluation Board has supported regulatory action is corrected to indicate a metal fragment of between 0.3" [7 mm] and 1.0" [25 mm];
• The recommended corrective actions to regain control over the operation after metal is detected in the product now include:
  - Locating and correcting the source of the metal fragments; and
  - Making adjustments to the materials, equipment, and/or process, as needed, to prevent future introduction of metal fragments;
• Injection needles and metal ties are now identified as additional sources of metal fragments in the processing environment;
• It is now recognized that visually inspecting equipment for damage or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire-mesh belts.

Chapter 21 has been added to provide guidance on the control of glass inclusion as a result of the use of glass containers.

The recommendations in the Appendices are changed as follows:

• The maximum water phase salt level for growth of *Bacillus cereus* is now given as 10 percent;
• The maximum water phase salt level for growth of *Staphylococcus aureus* is now given as 20 percent;
• The minimum temperature for growth of pathogenic strains of *Escherichia coli* is now given as 43.7˚F (6.5˚C);
• The maximum temperature for growth of *Vibrio parahaemolyticus* is now given as 113.5˚F (45.3˚C);
• Maximum cumulative exposure times are now provided for *Bacillus cereus,* as follows: 5 days at temperatures between 39.2 and 43˚F (4-6˚C); 17 hours at temperatures between 44 and 50˚F (7-10˚C); 6 hours at temperatures between 51 and 70˚F (11-21˚C); and 3 hours at temperatures above 70˚F (above 21˚C);
• Maximum cumulative exposure times are now provided for *Clostridium perfringens*, as follows: 21 days at temperatures between 50 and 54˚F (10-12˚C); 1 day at temperatures between 55 and 57˚F (13-14˚C); 6 hours at temperatures between 58 and 70˚F (15-21˚C); and 2 hours at temperatures above 70˚F (above 21˚C);
• The maximum cumulative exposure times for proteolytic *Clostridium botulinum* are now given as: 11 hours for temperatures between 50 and 70˚F (10-21˚C); and 2 hours for temperatures above 70˚F (above 21˚C);
• The maximum cumulative exposure times for nonproteolytic *Clostridium botulinum* are now given as: 7 days for temperatures between 37.9 and 41˚F (3.3 - 5˚C); 2 days for temperatures between 42 and 50˚F (6-10˚C); 11 hours for temperatures between 51 and 70˚F (11-21˚C); and 6 hours for temperatures above 70˚F (above 21˚C);
• The maximum cumulative exposure times for *Listeria monocytogenes* are now given as: 7 days for temperatures between 31.3 and 41˚F (-0.4 - 5˚C); and 2 days for temperatures between 42 and 50˚F (6-10˚C);
• The maximum cumulative exposure time for *Shigella* spp. is now given as 12 hours for temperatures between 51 and 70˚F (11-21˚C);

• Tables of lethal rates and process times for 6D cooks for a range of internal product temperatures are now provided for *Listeria monocytogenes* and nonproteolytic *Clostridium botulinum* type B (Tables A-3 and A-4, respectively).
• The FDA guideline for hard or sharp objects, found in Compliance Policy Guide #555.425, is included in the listing of FDA and EPA guidance levels – generally 0.3" [7 mm] to 1.0" [25 mm] in length;
• A listing of the most common food allergens is included (Appendix 6).

Numerous additional references are now included in the Bibliography, and a number of the original references are corrected.

In addition to using the above listing to direct you to relevant changes in this guidance, you should carefully review the chapters that are applicable to your product and process.

Additional Copies

Single copies of this guidance may be obtained as long as supplies last from FDA district offices and from:

U.S. Food and Drug Administration
Office of Seafood
200 C St., S.W.
Washington, D.C. 20204
202-418-3133 (phone)
202-418-3196 (fax)

Multiple copies of this guidance may be obtained from:

Florida Sea Grant
IFAS - Extension Bookstore
University of Florida
P.O. Box 110011
Gainesville, FL 32611-0011
1-800-226-1764

This guidance is also available electronically at:

http://www.fda.gov

Select "foods;" then select "seafood;" then select "HACCP."

The HACCP Plan Form

This guidance is designed to walk you through a series of eighteen steps that will yield a completed HACCP plan. A blank HACCP Plan Form is contained in Appendix 1. Note that this is a two page form, with the second page to be used if your process has more critical control points than can be listed on one page. The Seafood HACCP Regulation requires that you prepare a HACCP plan for fish and fishery products that you process (where significant safety hazards exist). The regulation does not require that you use the form included in Appendix 1. However, using this standardized form will likely help you develop an acceptable plan and will expedite regulatory review.

The Hazard Analysis Worksheet

In order to Complete the HACCP Plan Form you will need to perform a process called "hazard analysis." FDA has found that the use of a standardized Hazard Analysis Worksheet assists in this process. A blank Hazard Analysis Worksheet is contained in Appendix 1. Note that this is also a two page form, with the second page to be used if your process has more processing steps than can be listed on one page. While the Seafood HACCP Regulation requires that processors perform a hazard analysis, it does not require that it be kept in writing. However, FDA expects that a written hazard analysis will be very useful when you perform mandatory HACCP plan reassessments, and when you are asked by regulators to justify why certain hazards were or were not included in your HACCP plan.

The Steps

Following is a listing of the steps that this guidance uses in HACCP plan development:

- Preliminary Steps
  - General information
  - Describe the food
  - Describe the method of distribution and storage
  - Identify the intended use and consumer
  - Develop a flow diagram
- Hazard Analysis Worksheet
  - Set up the Hazard Analysis Worksheet
  - Identify the potential species-related hazards
  - Identify the potential process-related hazards
  - Complete the Hazard Analysis Worksheet
  - Understand the potential hazard
  - Determine if the potential hazard is significant
  - Identify the critical control points (CCP)
- HACCP Plan Form
  - Complete the HACCP Plan Form
  - Set the critical limits (CL)
  - Establish monitoring procedures
    - What
    - How
    - Frequency
    - Who
  - Establish corrective action procedures
  - Establish a recordkeeping system
  - Establish verification procedures

Continued

Preliminary Steps

STEP #1: *GENERAL INFORMATION.*

Record the name and address of your processing facility in the spaces provided on the first page of the Hazard Analysis Worksheet and the HACCP Plan Form (Appendix 1).

STEP #2: *DESCRIBE THE FOOD.*

Identify the market name or Latin name (species) of the fishery component(s) of the product.

Examples:
- *tuna*
- *shrimp*
- *jack mackerel*

Fully describe the finished product food.

Examples:
- *individually quick frozen, cooked, peeled shrimp*
- *fresh tuna steaks*
- *frozen, surimi-based, imitation king crab legs*
- *fresh, raw drum, in-the-round*
- *raw shrimp, in-shell*
- *raw, shucked soft clams*
- *fresh seafood salad, with shrimp and blue crab meat*
- *frozen, breaded pollock sticks*
- *frozen lobster cakes*

Describe the packaging type.

Examples:
- *vacuum-packaged plastic bag*
- *aluminum can*
- *bulk, in wax-coated paperboard box*
- *plastic container with snap lid*

Record this information in the space provided on the first page of the Hazard Analysis Worksheet and the HACCP Plan Form.

STEP #3: *DESCRIBE THE METHOD OF DISTRIBUTION AND STORAGE.*

Identify how the product is distributed and stored after distribution (e.g. frozen, refrigerated, on ice, or dry). Identify whether any special shipping methods, such as mail order, are used.

Examples:
- *stored and distributed frozen*
- *distributed on ice and then stored under refrigeration or on ice*
- *distributed through mail order with chemical refrigerant and then stored under refrigeration*

Record this information in the space provided on the first page of the Hazard Analysis Worksheet and the HACCP Plan Form.

STEP #4: *IDENTIFY THE INTENDED USE AND CONSUMER.*

IDENTIFY HOW THE product will be used by the end user or consumer.

Examples:
- *to be heated (but not fully cooked) and served*
- *to be eaten with or without further cooking*
- *to be eaten raw or lightly cooked*
- *to be fully cooked before consumption*
- *to be further processed into a heat and serve product*

Identify the intended consumer or user of the product. The intended consumer may be the general public or a particular segment of the population, such as infants or the elderly. The intended user may be another processor, who will further process the product.

Examples:
- *by the general public*
- *by the general public, including some distribution to hospitals and nursing homes*
- *by another processing facility*

Record this information in the space provided on the first page of the Hazard Analysis Worksheet and the HACCP Plan Form.

STEP #5: *DEVELOP A FLOW DIAGRAM.*

The purpose of the diagram is to provide a clear, simple description of the steps involved in the processing of your fishery product and its associated ingredients as they "flow" from receipt to distribution. The flow diagram should cover all of the steps in the process which your firm performs. Receiving and storage steps for each of the ingredients, including non-fishery ingredients, should be included. The flow diagram should be verified on-site for accuracy.

Figure # A-1 (Appendix 2) is an example of a flow diagram.

Hazard Analysis Worksheet

STEP #6: *SET UP THE HAZARD ANALYSIS WORKSHEET.*

Record each of the processing steps (from the flow diagram) in Column 1 of the Hazard Analysis Worksheet.

STEP #7: *IDENTIFY THE POTENTIAL SPECIES-RELATED HAZARDS.*

Find in Table #3-1 (Chapter 3) or Table #3-2 (Chapter 3) the market name (Column 1) or Latin name (Column 2) of the product that you identified in Step #2. Use Table #3-1 for vertebrates (animals with backbones), such as finfish. Use Table #3-2 for invertebrates (animals without backbones), such as shrimp, oysters, crab, and lobster. Determine if it has a potential species related hazard by looking for a "✓" mark (or three letter code for a natural toxin) in the right-hand columns of the table. If so, record the potential hazard(s) in Column 2 of the Hazard Analysis Worksheet, at each processing step.

Tables #3-1 and 3-2 include the best information currently available to FDA concerning hazards that are specific to each species of fish. You should use your own expertise, or that of outside experts, as necessary, to identify any hazards that may not be included in the table (e.g. those that may be new or unique to your region).

You may already have effective controls in place for a number of these hazards as part of your routine or traditional handling practices. The presence of such controls does not mean that the hazard is not significant. The likelihood of a hazard should be judged in the absence of controls. For example, the fact that histamine development in a particular species of fish has not been noted, may be the result of: 1) the inability of the fish to produce histamine; or 2) the existence of controls that are already in place to prevent its development (e.g. harvest vessel temperature controls). In the first case the hazard is not reasonably likely to occur. In the second case the controls should be included in the HACCP plan.

FDA plans to update Tables #3-1 and 3-2 as the agency becomes aware of new information.

STEP #8: *IDENTIFY THE POTENTIAL PROCESS-RELATED HAZARDS.*

Find in Table #3-3 (Chapter 3) the finished product, package type, and method of distribution and storage that most closely matches the information that you developed in Steps #2 and 3. Record the potential hazard(s) listed in the table for that product into Column 2 of the Hazard Analysis Worksheet at each processing step.

You may need to include potential hazards for more than one finished product food category in Table #3-3. This will happen when your product fits more than one description. For example if you process shrimp salad using raw shrimp as a raw material, you are processing both a cooked product (i.e. the intermediate cooked shrimp) and a salad (i.e. the finished product shrimp salad). Potential hazards from both finished product food categories apply to your product and should be listed in Column 2 of the Hazard Analysis Worksheet.

Table #3-3 includes the best information currently available to FDA concerning hazards that are related to specific processing techniques. You should use your own expertise, or that of outside experts as necessary, to identify any hazards that may not be included in the table (e.g. those that are new or unique to your physical plant, equipment, or process). This is more likely with more complex or innovative products.

FDA plans to update Table #3-3 as the agency becomes aware of new information.

STEP #9: *COMPLETE THE HAZARD ANALYSIS WORKSHEET.*

Consult the hazards and controls chapters of this guidance (Chapters 4 through 21) for each of the potential hazards that you entered in Column 2 of the Hazard Analysis Worksheet. These chapters offer guidance for completing your hazard analysis and developing your HACCP plan.

Complete Steps #10 through 12 in the chapters relating to each of the potential hazards. These steps involve: understanding the potential hazard; determining if the potential hazard is significant; and identifying the critical control points. When you have finished these steps for all of the potential hazards that relate to your product, you will have completed the Hazard Analysis Worksheet. You may then proceed to Step #13.

STEP #13: *COMPLETE THE HACCP PLAN FORM.*

Find the processing steps which you have identified as CCPs in Column 6 of the Hazard Analysis Worksheet. Record the names of these processing steps in Column 1 of the HACCP Plan Form. Enter the hazard(s) for which these processing steps were identified as CCPs in Column 2 of the HACCP Plan Form. This information can be found in Column 2 of the Hazard Analysis Worksheet.

Complete the HACCP Plan Form by consulting the hazards and controls chapters of this guidance (Chapters 4 through 21) for each of the significant hazards that you entered in Column 2 of the HACCP Plan Form. Complete Steps #14-18 in the chapters relating to each of the significant hazards. These steps involve: setting the critical limits; establishing monitoring procedures; establishing corrective action procedures; establishing a recordkeeping system; and establishing verification procedures. When you have finished these steps for all of the significant hazards that relate to your product, you will have completed the HACCP Plan Form.

You should then sign and date the first page of the HACCP Plan Form. The signature must be that of the most responsible individual on-site at your processing facility or a higher level official. It signifies that the HACCP plan has been accepted for implementation by your firm.

Purpose

This chapter contains three tables, which provide the following information:

- Table #3-1
  Potential Vertebrate Species Related Hazards
  contains a listing of potential hazards that are associated with specific species of vertebrate fish (fish with backbones). These hazards are referred to as species-related hazards;

- Table #3-2
  Potential Invertebrate Species Related Hazards
  contains a listing of potential hazards that are associated with specific species of invertebrate fish (fish without backbones). These hazards are also referred to as species-related hazards;

- Table #3-3
  Potential Process Related Hazards
  contains a listing of potential hazards that are associated with specific finished fishery products. These hazards are referred to as process-related hazards.

It is important to note that the tables provide listings of potential hazards. You should use the tables together with the information provided in chapters 4 through 21 in order to determine whether the hazard is significant for your particular product, and, if so, how it should be controlled.

Continued

Table #3-1

Potential Vertebrate Species Related Hazards

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

Note: This table does not provide information about methyl mercury, which may be a potential species related hazard in some species of vertebrate fish. FDA policy concerning this matter is under re-evaluation. See Chapter 10 (Methyl Mercury) for further information.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
AHOLEHOLE	*Kuhlia spp.*		**CFP**			
ALEWIFE or RIVER HERRING	*Alosa pseudoharengus*			✓		
ALFONSINO	*Beryx spp.* *Trachichthodes spp.*					
ALLIGATOR	*Alligator mississippiensis* *Alligator sienensis*				✓ ✓	
ALLIGATOR AQUACULTURED	*Alligator mississippiensis* *Alligator sienensis*				✓ ✓	✓ ✓
AMBERJACK or YELLOWTAIL	*Seriola spp.*		**CFP**	✓		
ANCHOVY	*Anchoa spp.* *Anchoviella spp.* *Cetengraulis mysticetus* *Engraulis spp.* *Stolephorus spp.*		**ASP[6]** **ASP[6]** **ASP[6]** **ASP[6]** **ASP[6]**	✓ ✓ ✓ ✓ ✓		
ANGELFISH	*Holacanthus spp.* *Pomacanthus spp.*					
ARGENTINE QUEENFISH	*Argentina elongata*					
BARRACUDA	*Sphyraena spp.*		**CFP**		✓	

6 – This hazard only applies if the product is marketed uneviscerated.

Market Names	Latin Names	Hazards				
		Biological	*Chemical*			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
BARRAMUNDI	*Lates calcarifer*				✓	
BASS	*Ambloplites spp.*				✓	
	Micropterus spp.				✓	
	Morone spp.				✓	
	Stereolepis gigas				✓	
	Synagrops bellus				✓	
BASS AQUACULTURED	*Morone spp.*				✓	✓
	Centropristis spp.				✓	✓
BASS, SEA	*Acanthistius brasilianus*	✓ [4]				
	Centropristis spp.	✓ [4]				
	Dicentrarchus labrax	✓ [4]				
	Lateolabrax japonicus	✓ [4]				
	Paralabrax spp.	✓ [4]				
	Paranthias furcifer	✓ [4]				
	Polyprion americanus	✓ [4]				
	Polyprion oxygeneios	✓ [4]				
	Polyprion yanezi	✓ [4]				
BIGEYE	*Priacanthus arenatus*					
	Pristigenys alta					
BLUEFISH	*Pomatomus saltatrix*			✓	✓	
BLUEGILL	*Lepomis macrochirus*				✓	
BLUENOSE	*Hyperoglyphe antarctica*					
BOMBAY DUCK	*Harpadon nehereus*				✓	
BONITO	*Cybiosarda elegans*			✓		
	Gymnosarda unicolor			✓		
	Orcynopsis unicolor			✓		
	Sarda spp.			✓		
BOWFIN and roe	*Amia calva*				✓	
BREAM	*Abramis brama*					
	Argyrops spp.					
	Sparus auratus					
BREAM or BOGUE	*Boops boops*					

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
BREAM, THREADFIN	*Nemipterus japonicus*					
BUFFALOFISH	*Ictiobus spp.*				✓	
BULLHEAD	*Ameiurus spp.*				✓	
BURBOT	*Lota lota*				✓	
BUTTERFISH	*Odax pullus*				✓	
	Peprilus spp.				✓	
	Stromateus cinereus				✓	
CAPELIN and roe	*Mallotus villosus*	✓ [4]				
CARP	*Cyprinus carpio*				✓	
	Hypophthalmichthys molitrix				✓	
CARP AQUACULTURED	*Cyprinus carpio*				✓	✓
	Hypophthalmichthys molitrix				✓	✓
CATFISH	*Ameiurus catus*				✓	
	Brachyplatystoma spp.				✓	
	Ictalurus spp.				✓	
	Pinirampus pirinampu				✓	
	Platynematichthy notatus				✓	
	Pseudoplatystoma tigrinum				✓	
	Pylodictis oliveris				✓	
CATFISH AQUACULTURED	*Ictalurus spp.*				✓	✓
CATFISH, SEA	*Ariopsis felis*					
	Arius spp.					
	Bagre marinus					
CHAR	*Salvelinus alpinus*				✓	
CHAR AQUACULTURED	*Salvelinus alpinus*				✓	✓
CHIMAERA	*Harriota raleighana*					
	Hydrolagus spp.					

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
CHUB	*Coregonus kiyi*				✓	
	Kyphosus spp.				✓	
	Semotilus atromaculatus				✓	
CISCO or CHUB	*Coregonus alpenae*				✓	
	Coregonus reighardi				✓	
	Coregonus zenithicus				✓	
CISCO or TULLIBEE	*Coregonus artedii*				✓	
COBIA	*Rachycentron canadum*	✓ [4]				
COD	*Arctogadus spp.*	✓ [4]				
	Boreogadus saida	✓ [4]				
	Eleginus gracilis	✓ [4]				
	Gadus spp.	✓ [4]				
COD or ALASKA COD	*Gadus macrocephalus*	✓ [4]				
COD, MORID	*Lotella rhacina*	✓ [4]				
	Mora pacifica	✓ [4]				
	Physiculus barbatus	✓ [4]				
	Pseudophycis spp.	✓ [4]				
CORVINA	*Cilus montii*	✓ [4]				
	Micropogonias opercularis	✓ [4]				
CRAPPIE	*Pomoxis spp.*				✓	
CROAKER	*Argyrosomus spp.*				✓	
	Bairdiella spp.				✓	
	Cheilotrema saturnum				✓	
	Genyonemus lineatus				✓	
	Micropogonias spp.				✓	
	Nebris microps				✓	
	Nibea spp.				✓	
	Pachypops spp.				✓	
	Pachyurus spp.				✓	
	Paralonchurus spp.				✓	
	Plagioscion spp.				✓	
	Pseudotolithus spp.				✓	
	Pterotolithus spp.				✓	
	Roncador stearnsi				✓	
	Umbrina roncador				✓	
	Odontoscion dentex				✓	

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
CROAKER or CORVINA	*Cynoscion spp.*				✓	
CROAKER or SHADEFISH	*Argyrosomus regius*				✓	
CROAKER or YELLOWFISH	*Pseudosciaena manchurica*				✓	
CUSK	*Brosme brosme*					
CUSK-EEL	*Lepophidium spp.*					
CUTLASSFISH	*Aphanopus carbo* *Lepidopus caudatus* *Trichiurus spp.*					
DACE	*Rhinichthys ssp.*				✓	
DORY	*Cyttus novaezealandiae* *Zenopsis spp.* *Zeus spp.*					
DRIFTFISH	*Hyperoglyphe spp.*					
DRUM	*Equetus punctatus* *Larimus spp.* *Pogonias cromis* *Stellifer spp.* *Totoaba macdonaldi* *Umbrina coroides*				✓ ✓ ✓ ✓ ✓ ✓	
DRUM or CUBBYU	*Equetus umbrosus*				✓	
DRUM, FRESHWATER	*Aplodinotus grunniens*				✓	
DRUM or LION FISH	*Collichthys spp.*				✓	
DRUM or MEAGRE	*Sciaena aquila*				✓	
DRUM or QUEENFISH	*Seriphus politus*				✓	

Market Names	Latin Names	Hazards				
		Biological	*Chemical*			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
DRUM or REDFISH	*Sciaenops ocellatus*				✓	
DRUM or REDFISH AQUACULTURED	*Sciaenops ocellatus*				✓	✓
EEL	*Anguilla spp.*					
EEL AQUACULTURED	*Anguilla anguilla*				✓	✓
	Anguilla australis				✓	✓
	Anguilla dieffenbachii				✓	✓
	Anguilla japonicus				✓	✓
EEL, CONGER	*Ariosoma balearicum*				✓	
	Conger spp.				✓	
	Gnathophis catalinensis				✓	
	Hildebrandia spp.				✓	
	Paraconger caudilimbatus				✓	
EEL, FRESHWATER	*Anguilla rostrata*				✓	
EEL, FRESHWATER AQUACULTURED	*Anguilla rostrata*				✓	✓
EEL, MORAY	*Gymnothorax funebris*		**CFP**			
	Lycodontis javanicus		**CFP**			
	Muraena retifera		**CFP**			
EEL, SPINY	*Notacanthus chemnitzi*					
EELPOUT	*Macrozoarces americanus*	✓ [4]				
	Zoarces viviparus	✓ [4]				
ELEPHANT FISH	*Callorhynchus millii*					
EMPEROR	*Lethrinus spp.*					
ESCOLAR or OILFISH	*Lepidocybium flavobrunneum*		**G**	✓		
	Ruvettus pretiosus		**G**	✓		

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
FLOUNDER	*Ancylopsetta dilecta*	✓ [4]			✓ [1]	
	Arnoglossus scapha	✓ [4]			✓ [1]	
	Atheresthes evermanni	✓ [4]			✓ [1]	
	Bothus spp.	✓ [4]			✓ [1]	
	Chascanopsetta crumenalis	✓ [4]			✓ [1]	
	Cleisthenes pinetorum	✓ [4]			✓ [1]	
	Colistium spp.	✓ [4]			✓ [1]	
	Cyclopsetta chittendeni	✓ [4]			✓ [1]	
	Hippoglossoides robustus	✓ [4]			✓ [1]	
	Limanda ferruginea	✓ [4]			✓ [1]	
	Liopsetta glacialis	✓ [4]			✓ [1]	
	Microstomus achne	✓ [4]			✓ [1]	
	Paralichthys albigutta	✓ [4]			✓ [1]	
	Paralichthys oblongus	✓ [4]			✓ [1]	
	Paralichthys olivaceus	✓ [4]			✓ [1]	
	Paralichthys patagonicus	✓ [4]			✓ [1]	
	Paralichthys squamilentus	✓ [4]			✓ [1]	
	Pelotretis flavilatus	✓ [4]			✓ [1]	
	Peltorhampus novaezeelandiae	✓ [4]			✓ [1]	
	Platichthys spp.	✓ [4]			✓ [1]	
	Pseudorhombus spp.	✓ [4]			✓ [1]	
	Rhombosolea spp.	✓ [4]			✓ [1]	
	Samariscus triocellatus	✓ [4]			✓ [1]	
	Scophthalmus spp.	✓ [4]			✓ [1]	

1 – This hazard does not apply to offshore catch (e.g. areas not subject to shoreside contaminant discharges).
4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
FLOUNDER AQUACULTURED	*Ancylopsetta dilecta*	✓ 4, 5			✓	✓
	Arnoglossus scapha	✓ 4, 5			✓	✓
	Atheresthes evermanni	✓ 4, 5			✓	✓
	Bothus spp.	✓ 4, 5			✓	✓
	Chascanopsetta crumenalis	✓ 4, 5			✓	✓
	Cleisthenes pinetorum	✓ 4, 5			✓	✓
	Colistium spp.	✓ 4, 5			✓	✓
	Cyclopsetta chittendeni	✓ 4, 5			✓	✓
	Hippoglossoides robustus	✓ 4, 5			✓	✓
	Limanda ferruginea	✓ 4, 5			✓	✓
	Liopsetta glacialis	✓ 4, 5			✓	✓
	Microstomus achne	✓ 4, 5			✓	✓
	Paralichthys spp.	✓ 4, 5			✓	✓
	Pelotretis flavilatus	✓ 4, 5			✓	✓
	Peltorhampus novaezeelandiae	✓ 4, 5			✓	✓
	Pseudorhombus spp.	✓ 4, 5			✓	✓
	Rhombosolea spp.	✓ 4, 5			✓	✓
	Samariscus triocellatus	✓ 4, 5			✓	✓
	Scophthalmus spp.	✓ 4, 5			✓	✓
FLOUNDER or DAB	*Pleuronectes limanda*	✓ 4			✓ 1	
	Pleuronectes proboscidea	✓ 4			✓ 1	
	Pleuronectes punctatissimus	✓ 4			✓ 1	
FLOUNDER or FLUKE	*Paralichthys dentatus*	✓ 4			✓ 1	
	Paralichthys lethostigma	✓ 4			✓ 1	
	Paralichthys microps	✓ 4			✓ 1	
	Platylichthys flesus	✓ 4			✓ 1	
FLOUNDER, ARROWTOOTH	*Atheresthes stomias*	✓ 4				

1 – This hazard does not apply to offshore catch (e.g. areas not subject to shoreside contaminant discharges).
4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.
5 – This hazard only applies if fresh fish or plankton is used as feed.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
FLYINGFISH and roe	*Cypselurus spp.* *Exocoetus spp.* *Fodiator acutus* *Hirundichthys spp.* *Oxyporhamphus micropterus* *Parexocoetus brachypterus* *Prognichthys gibbifrons*					
FROG	*Rana spp.*				✓	
GAR	*Lepisosteus spp.*				✓	
GEMFISH	*Epinnula magistralis* *Nesiarchus nasutus* *Lepidocybium flavobrunneum*		**G**	✓		
GEMFISH or BARRACOUTA	*Rexea solandri* *Thyrsites atun*					
GEMFISH or CABALLA	*Thyrsites lepidopoides*					
GOATFISH	*Mulloidichthys spp.* *Mullus auratus* *Parupeneus spp.* *Pseudupeneus spp.* *Upeneichthys lineatus* *Upeneus spp.*		**CFP** **CFP** **CFP**			
GRAYLING	*Thymallus arcticus*				✓	
GREENBONE	*Coridodax pullus*					
GREENLING	*Hexagrammos spp.*					
GRENADIER	*Coryphaenoides spp.* *Lepidorhynchus denticulatus* *Macrourus spp.* *Nezumia bairdi* *Trachyrhynchus murray*					

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

Market Names	Latin Names	Hazards				
		Biological	*Chemical*			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
GROUPER	*Caprodon schlegelii*	✓ [4]	**CFP**			
	Cephalopholis spp.	✓ [4]	**CFP**			
	Diplectrum formosum	✓ [4]	**CFP**			
	Epinephelus spp.	✓ [4]	**CFP**			
	Mycteroperca spp.	✓ [4]	**CFP**			
GROUPER or GAG	*Mycteroperca microlepsis*	✓ [4]	**CFP**			
GROUPER or HIND	*Epinephelus guttatus*	✓ [4]	**CFP**			
GROUPER or JEWFISH	*Epinephelus itajara*	✓ [4]	**CFP**			
GRUNION	*Leuresthes tenuis*					
GRUNT	*Anisotremus interruptus*					
	Conodon nobilis					
	Haemulon spp.					
	Orthopristis chrysoptera					
	Pomadasys crocro					
GRUNT or CATALINA	*Anisotremus taeniatus*					
GRUNT or MARGATE	*Haemulon album*					
	Haemulon surinamensis					
GRUNT or SWEETLIPS	*Plectorhynchus spp.*					
HADDOCK	*Melanogrammus aeglefinus*					
HAKE	*Urophycis spp.*					
HALIBUT	*Hippoglossus spp.*	✓ [4]				
HALIBUT AQUACULTURED	*Hippoglossus spp.*	✓ [4, 5]			✓	✓
HALIBUT or CALIFORNIA HALIBUT	*Paralichthys californicus*	✓ [4]				

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.
5 – This hazard only applies if fresh fish or plankton is used as feed.

Market Names	Latin Names	Hazards				
		Biological	*Chemical*			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
HAMLET, MUTTON	*Epinephelus afer*					
HERRING	*Etrumeus teres*	✓ [4]		✓	✓	
	Harengula thrissina	✓ [4]		✓	✓	
	Ilisha spp.	✓ [4]		✓	✓	
	Opisthopterus tardoore	✓ [4]		✓	✓	
	Pellona ditchela	✓ [4]		✓	✓	
	Alosa spp.			✓	✓	
HERRING or SEA HERRING or SILD and roe	*Clupea spp.*	✓ [4]		✓		
HERRING, THREAD	*Opisthonema spp.*			✓	✓	
HIND	*Epinephelus guttatus*	✓ [4]	**CFP**			
	Epinephelus adscensionis	✓ [4]	**CFP**			
	Epinephelus drummondhayi	✓ [4]	**CFP**			
HOGFISH	*Lachnolaimus maximus*	✓ [4]	**CFP**			
JACK	*Caranx spp.*	✓ [4]	**CFP**	✓		
	Oligoplites saurus	✓ [4]	**CFP**	✓		
	Selene spp.	✓ [4]	**CFP**	✓		
	Seriola rivoliana	✓ [4]	**CFP**	✓		
	Urapsis secunda	✓ [4]	**CFP**	✓		
JACK or BLUE RUNNER	*Caranx crysos*	✓ [4]	**CFP**	✓		
JACK or CREVALLE	*Alectis indica*	✓ [4]	**CFP**	✓		
JACK or RAINBOW RUNNER	*Elagatis bipinnulata*	✓ [4]	**CFP**	✓		
JACK or ROOSTERFISH	*Nematistius pectoralis*	✓ [4]	**CFP**	✓		
JOBFISH	*Aphareus spp.*	✓ [4]	**CFP**	✓		
	Aprion virescens	✓ [4]	**CFP**	✓		
	Pristipomoides spp.	✓ [4]	**CFP**	✓		

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	*Chemical*			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
KAHAWAI	*Arripis spp.*	✓ [4]	**CFP**	✓		
KINGFISH	*Menticirrhus spp.*					
KINGKLIP	*Genypterus spp.*					
LADYFISH	*Elops spp.*					
LING	*Molva spp.*					
LING, MEDITERRANEAN	*Molva macrophthalmus*					
LINGCOD	*Ophiodon elongatus*					
LIZARDFISH	*Synodus spp.*					
LUMPFISH roe	*Cyclopterus lumpus*					
MACKEREL	*Gasterochisma melampus* *Grammatorcynus spp.* *Rastrelliger kanagurta* *Scomber scombrus*	✓ [4] ✓ [4] ✓ [4] ✓ [4]		✓ ✓ ✓ ✓		
MACKEREL, ATKA	*Pleurogrammus monopterygius*	✓ [4]				
MACKEREL, CHUB	*Scomber spp.*	✓ [4]		✓		
MACKEREL, JACK	*Trachurus spp.*	✓ [4]		✓		
MACKEREL, SPANISH	*Scomberomorus spp.* *Scomberomorus cavalla*	✓ [4] ✓ [4]	 **CFP**	✓ ✓		
MAHI-MAHI	*Coryphaena spp.*			✓		
MAHI-MAHI AQUACULTURED	*Coryphaena spp.*			✓	✓	✓
MARLIN	*Makaira spp.* *Tetrapturus spp.*			✓ ✓		
MENHADEN	*Brevoortia spp.* *Ethmidium maculatum*					
MILKFISH	*Chanos chanos*				✓	

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
MILKFISH AQUACULTURED	*Chanos chanos*				✓	✓
MONKFISH	*Lophius spp.*	✓ [4]				
MORWONG	*Aplodactylus meandratus* *Cheilodactylus spp.* *Nemadactylus spp.*					
MULLET	*Agonostomus monticola*	✓ [4]			✓	
	Aldrichetta forsteri	✓ [4]			✓	
	Crenimugil crenilabis	✓ [4]			✓	
	Mugil spp.	✓ [4]			✓	
	Mullus spp.	✓ [4]			✓	
	Neomyxus chaptalii	✓ [4]			✓	
	Xenomugil thoburni	✓ [4]			✓	
MUSKELLUNGE	*Esox masquinongy*				✓	
OPAH	*Lampris guttatus*					
OPALEYE	*Girella nigricans*					
OREO DORY	*Allocyttus niger* *Pseudocyttus maculatus*					
OSCAR	*Astronotus ocellatus*				✓	
OSCAR AQUACULTURED	*Astronotus ocellatus*				✓	✓
PACU	*Myleus pacu*					
PADDLEFISH and roe	*Polyodon spp.*				✓	
PADDLEFISH and roe AQUACULTURED	*Polyodon spp.*				✓	✓
PARROTFISH	*Scarus spp.*		**CFP**[2]			
PATAGONIAN TOOTHFISH or CHILEAN SEA BASS	*Dissotichus eleginoides*	✓ [4]				

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

2 – Indicates that the cigutera hazard is only associated with this species in the tropical Pacific Ocean.
4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
PERCH	*Hermosilla azurea* *Perca fluviatilis*				✓ ✓	
PERCH, LAKE or YELLOW	*Perca flavescens*				✓	
PERCH, NILE	*Lates niloticus*				✓	
PERCH, NILE AQUACULTURED	*Lates niloticus*				✓	✓
PERCH, OCEAN	*Sebastes spp.*	✓ [4]				
PERCH, PILE	*Rhacochilus vacca*				✓	
PERCH, SILVER	*Bairdiella chrysoura*				✓	
PERCH, WHITE	*Morone americana*				✓	
PICAREL	*Spicara maena*				✓	
PICKEREL	*Esox spp.*				✓	
PIKE	*Esox lucius*				✓	
PILCHARD or SARDINE	*Sardina pilchardus* *Sardinops spp.*			✓ ✓		
PLAICE	*Hippoglossoides platessoides* *Pleuronectes platessa* *Pleuronectes quadrituberculatus*	✓ [4] ✓ [4] ✓ [4]				
POLLOCK	*Pollachius pollachius* *Pollachius virens*	✓ [4] ✓ [4]				
POLLOCK or ALASKA POLLOCK	*Theragra chalcogramma*	✓ [4]				
POMFRET	*Brama spp.* *Taracetes rubescens*					
POMPANO	*Alectis ciliaris* *Parastromateus niger* *Trachinotus spp.*		**CFP**			

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	*Chemical*			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
POMPANO or PERMIT	*Trachinotus kennedyi* *Trachinotus falcatus*					
POMPANO or POMPANITO	*Trachinotus rhodopus*					
PORGY	*Calamus spp.* *Chrysophrys auratus* *Dentex spp.* *Diplodus spp.* *Lagodon rhomboides* *Pagrus spp.* *Pterogymnus laniarus* *Stenotomus caprinus*					
PORGY or SCUP	*Stenotomus chrysops*					
PUFFER	*Arothron spp.* *Fugu spp.* *Lagocephalus spp.* *Sphoeroides maculatus*		**T** **T**			
RACEHORSE	*Congiopodus leucopaecilus*					
ROCKFISH	*Helicolenus papillosus* *Scorpaena cardinalis* *Sebastes spp.*	✓ [4] ✓ [4] ✓ [4]				
ROCKLING	*Ciliata spp.* *Enchelyopus cimbrius*					
ROSEFISH	*Helicolenus dactylopterus*					
ROUGHY	*Paratrachichthys trailli*					
ROUGHY, ORANGE	*Hoplostethus atlanticus*					
ROUGHY, SILVER	*Hoplostethus mediterraneus*					
SABLEFISH	*Anoplopoma fimbria*	✓ [4]				
SALMON and roe, AQUACULTURED	*Oncorhynchus spp.* *Salmo salar*	✓ [4, 5] ✓ [4, 5]			✓ ✓	✓ ✓

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.
5 – This hazard only applies if fresh fish or plankton is used as feed.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
SALMON and roe (WILD) (FRESHWATER)	*Oncorhynchus spp.*				✓	
	Salmo salar				✓	
SALMON and roe, (WILD) (OCEAN)	*Oncorhynchus spp.*	✓ [4]				
	Salmo salar	✓ [4]				
SANDDAB	*Citharichthys sordidus*				✓	
SANDPERCH	*Mugiloides chilensis*					
	Parapercis spp.					
SARDINE	*Harengula spp.*			✓		
	Sardinella spp.			✓		
SAUGER	*Stizostedion canadense*					
SAURY	*Cololabis saira*			✓		
	Scomberesox saurus			✓		
SCAD	*Caranx mate*	✓ [4]				
	Decapterus spp.	✓ [4]				
	Selar crumenophthalmus	✓ [4]				
	Trachurus spp.	✓ [4]				
SCULPIN	*Hemitripterus americanus*					
	Myoxocephalus polyacanthocephalus					
	Scorpaenichthys marmoratus					
SEA BREAM	*Archosargus rhomboidalis*					
	Chrysophrys unicolor					
	Pagellus spp.					
SEAROBIN	*Chelidonichthys spp.*					
	Peristedion miniatum					
	Prionotus carolinus					
	Pterygotrigla picta					
SEATROUT	*Cynoscion spp.*	✓ [4]				
SHAD and roe	*Alosa spp.*			✓	✓	

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	*Chemical*			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
SHAD, GIZZARD	*Dorosoma spp.*			✓	✓	
	Nematalosa vlaminghi			✓	✓	
SHARK	*Carcharhinus spp.* *Cetorhinus maximus* *Galeocerdo cuviere* *Galeorhinus spp.* *Hexanchus griseus* *Lamna ditropis* *Negaprion brevirostris* *Notorynchus cepedianus* *Prionace glauca* *Sphyrna spp.* *Triaenodon obesus* *Triakis semifasciata*					
SHARK or PORBEAGLE	*Lamna nasus*					
SHARK or SMOOTHHOUND	*Mustelus spp.*					
SHARK, ANGEL	*Squatina spp.*					
SHARK, DOGFISH or CAPE SHARK	*Centrophorus spp.* *Mustelus spp.* *Scyliorhinus spp.* *Squalus spp.*					
SHARK, MAKO	*Isurus spp.*					
SHARK, THRESHER	*Alopias spp.*					
SHEEPHEAD	*Semicossyphus pulcher*				✓	
	Archosargus probatocephalus				✓	
SHINER	*Notropis spp.*				✓	
SILVERSIDE	*Atherinops spp.*				✓	
	Basilichthys australis				✓	
	Menidia menidia				✓	
SKATE	*Bathyraja spp.*				✓	
	Raja spp.				✓	

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
SKILLFISH	*Erilepis zonifer*					
SMELT	*Allosmerus elongatus*				✓	
	Argentina spp.				✓	
	Hypomesus spp.				✓	
	Osmerus spp.				✓	
	Plecoglossus altivelis				✓	
	Retropinna retropinna				✓	
	Spirinchus spp.				✓	
	Thaleichthys pacificus				✓	
SNAKEHEAD	*Channa striata*					
	Ophicephalus obscurus					
SNAPPER	*Apsilus dentatus*					
	Etelis spp.		**CFP**			
	Lutjanus spp.		**CFP**			
	Macolor spp.					
	Ocyurus chrysurus					
	Pristipomoides spp.	✓ [4]	**CFP**	✓		
	Rhomboplites aurorubens					
	Symphorichthys spilurus					
SNOOK	*Centropomus spp.*				✓	
SOLE or FLOUNDER	*Aseraggodes spp.*	✓ [4]				
	Austroglossus spp.	✓ [4]				
	Buglossidium luteum	✓ [4]				
	Clidoderma asperrimum	✓ [4]				
	Embassichthys bathybius	✓ [4]				
	Eopsetta exilis	✓ [4]				
	Eopsetta jordani	✓ [4]				
	Errex zachirus	✓ [4]				
	Glyptocephalus spp.	✓ [4]				
	Gymnachirus melas	✓ [4]				
	Hippoglossina spp.	✓ [4]				
	Lepidopsetta bilineata	✓ [4]				
	Microchirus spp.	✓ [4]				
	Microstomus kitt	✓ [4]				
	Microstomus pacificus	✓ [4]				
	Pleuronectes americanus	✓ [4]				
	Pleuronectes vetulus	✓ [4]				
	Psettichthys melanostictus	✓ [4]				
	Solea vulgaris	✓ [4]				
	Synaptura orientalis	✓ [4]				
	Trinectes spp.	✓ [4]				
	Xystreurys liolepis	✓ [4]				

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	*Chemical*			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
SOLE or FLOUNDER AQUACULTURED	*Aseraggodes spp.*	✓ [4, 5]			✓	✓
	Austroglossus spp.	✓ [4, 5]			✓	✓
	Buglossidium luteum	✓ [4, 5]			✓	✓
	Clidoderma asperrimum	✓ [4, 5]			✓	✓
	Embassichthys bathybius	✓ [4, 5]			✓	✓
	Eopsetta exilis	✓ [4, 5]			✓	✓
	Eopsetta jordani	✓ [4, 5]			✓	✓
	Errex zachirus	✓ [4, 5]			✓	✓
	Glyptocephalus spp.	✓ [4, 5]			✓	✓
	Gymnachirus melas	✓ [4, 5]			✓	✓
	Hippoglossina spp.	✓ [4, 5]			✓	✓
	Lepidopsetta bilineata	✓ [4, 5]			✓	✓
	Microchirus spp.	✓ [4, 5]			✓	✓
	Pleuronectes americanus	✓ [4, 5]			✓	✓
	Pleuronectes vetulus	✓ [4, 5]			✓	✓
	Psettichthys melanostictus	✓ [4, 5]			✓	✓
	Solea vulgaris	✓ [4, 5]			✓	✓
	Synaptura orientalis	✓ [4, 5]			✓	✓
	Trinectes spp.	✓ [4, 5]			✓	✓
	Xystreurys liolepis	✓ [4, 5]			✓	✓
SPADEFISH	*Chaetodipterus spp.*					
SPEARFISH	*Tetrapturus spp.*					
SPOT	*Leiostomus xanthurus*				✓	
SPRAT or BRISTLING	*Sprattus spp.*	✓ [4]		✓		
SQUIRRELFISH	*Holocentrus spp.* *Myripristis spp.* *Sargocentron spp.*		**CFP**			
STURGEON and roe	*Acipenser spp.*				✓	
	Huso huso				✓	
	Pseudoscaphirhynchus spp.				✓	
	Scaphirhynchus spp.				✓	
STURGEON and roe AQUACULTURED	*Acipenser spp.*				✓	✓
	Huso huso				✓	✓
	Pseudoscaphirhynchus spp.				✓	✓
	Scaphirhynchus spp.				✓	✓

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.
5 – This hazard only applies if fresh fish or plankton is used as feed.

Market Names	Latin Names	Hazards				
		Biological	*Chemical*			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
SUCKER	*Carpiodes spp.*				✓	
	Catostomus commersoni				✓	
	Cycleptus elongatus				✓	
SUCKER or REDHORSE	*Moxostoma macrolepidotum*				✓	
SUNFISH (not *Mola mola*)	*Archoplites interruptus*				✓	
	Lepomis spp.				✓	
SURFPERCH	*Amphistichus spp.*				✓	
	Cymatogaster aggregata				✓	
	Embiotoca spp.				✓	
	Hyperprosopon argenteum				✓	
	Rhacochilus toxotes				✓	
SWORDFISH	*Xiphias gladius*					
TANG	*Acanthurus spp.*		**CFP**[3]			
	Ctenochaetus spp.		**CFP**[3]			
	Tenthis spp.		**CFP**[3]			
	Zebrasoma spp.		**CFP**[3]			
TARPON	*Megalops atlanticus*				✓	
TAUTOG	*Tautoga onitis*				✓	
THORNYHEAD	*Sebastolobus spp.*	✓ [4]			✓	
THREADFIN	*Eleutheronema tetradactylum*					
	Galeoides decadactylus					
	Polydactylus spp.					
TILAPIA	*Tilapia spp.*				✓	
TILAPIA AQUACULTURED	*Tilapia spp.*				✓	✓
TILEFISH	*Caulolatilus spp.*					
	Lopholatilus chamaeleonticeps					
	Malacanthus plumieri					
	Prolatilus jugularis					
TOMCOD	*Microgadus spp.*	✓ [4]				

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

3 – Indicates that the ciguatera hazard is only associated with this species in the tropical Pacific Ocean.
4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	*Chemical*			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
TONGUESOLE	*Cynoglossus spp.*	✓ [4]				
TREVALLY	*Caranx sexfasciatus*	✓ [4]	**CFP**	✓		
TRIGGERFISH	*Balistes spp.*		**CFP**			
	Canthidermis sufflamen		**CFP**			
	Melichthys niger		**CFP**			
	Navodon spp.					
TRIPLETAIL	*Datnioides quadrifasciatus*					
	Lobotes spp.					
TROUT (AQUACULTURE)	*Oncorhynchus aguabonita*				✓	✓
	Oncorhynchus clarki				✓	✓
	Oncorhynchus gilae				✓	✓
	Oncorhynchus mykiss				✓	✓
	Salmo trutta				✓	✓
	Salvelinus fontalis				✓	✓
	Salvelinus malma				✓	✓
	Salvelinus namaycush				✓	✓
	Stenodus leucichthys				✓	✓
TROUT, RAINBOW or STEELHEAD	*Oncorhynchus mykiss*	✓ [4]				
TRUMPETER	*Latridopis spp.*				✓	
	Latris lineata				✓	
TUNA (small)	*Allothunnus fallai*	✓ [4]		✓		
	Auxis spp.	✓ [4]		✓		
	Euthynnus spp.	✓ [4]		✓		
	Katsuwonus pelamis	✓ [4]		✓		
	Thunnus tonggol	✓ [4]		✓		
TUNA (large)	*Thunnus alalunga*			✓		
	Thunnus albacares			✓		
	Thunnus atlanticus			✓		
	Thunnus maccoyii			✓		
	Thunnus obesus			✓		
	Thunnus thynnus			✓		

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Market Names	Latin Names	Hazards				
		Biological	***Chemical***			
		Parasites CHP 5	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
TURBOT	*Hypsopsetta guttulata*	✓ [4]				
	Pleuronichthys spp.	✓ [4]				
	Psettodes spp.	✓ [4]				
	Reinhardtius hippoglossoides	✓ [4]				
	Scophthalmus maximum	✓ [4]				
WAHOO	*Acanthocybium solandri*			✓		
WALLEYE	*Stizostedion spp.*				✓	
WAREHOU	*Seriolella spp.*					
WEAKFISH	*Cynoscion spp.*					
	Macrodon ancylodon					
WHITEFISH	*Coregonus spp.*				✓	
	Prosopium cylindraceum				✓	
WHITING	*Merluccius gayi*					
	Merluccius hubbsi					
	Merluccius merluccius					
WHITING, BLUE	*Micromesistius spp.*					
WHITING or PACIFIC WHITING	*Merluccius productus*					
WHITING, NEW ZEALAND	*Macruronus novaezelandiae*					
WOLFFISH	*Anarhichas spp.*	✓ [4]				
YELLOWTAIL or AMBERJACK	*Seriola lalandei*		**CFP**	✓		
ZANDER	*Stizostedion lucioperca*				✓	

Note: ASP = amnesic shellfish poison; CFP = ciguatera fish poison; G = gempylotoxin; PSP = paralytic fish poison; T = tetrodotoxin.

4 – This hazard does not apply if the product is intended to be cooked by the consumer or end-user.

Table #3-2

Potential Invertebrate Species Related Hazards

Market Names	Latin Names	Hazards				
		Biological		*Chemical*		
		Pathogens CHP 4	Parasites CHP 5	Natural Toxins CHP 6	Chemical CHP 9	Drugs CHP 11
ABALONE	*Haliotis spp.*				✓	
	Marinauris roei				✓	
	Notohaliotis ruber				✓	
	Schismotis laevigata				✓	
AQUACULTURED INVERTEBRATES	ALL SPECIES	✓		✓	✓	✓
ARKSHELL	*Anadara subcrenata*	✓		✓	✓	
	Arca spp.	✓		✓	✓	
CLAM, BENTNOSE	*Macoma nasuta*	✓		✓	✓	
CLAM BUTTER	*Saxidomus spp.*	✓		✓	✓	
CLAM, CALICO	*Macrocallista maculata*	✓		✓	✓	
CLAM, GEODUCK	*Panopea abrupta*	✓		✓	✓	
	Panopea bitruncata	✓		✓	✓	
CLAM, HARD	*Arctica islandica*	✓		✓	✓	
	Meretricinae spp.	✓		✓	✓	
	Meretrix spp.	✓		✓	✓	
	Venus mortoni	✓		✓	✓	
CLAM, HARDSHELL or QUAHOG	*Protothaca thaca*	✓		✓	✓	
	Mercenaria spp.	✓		✓	✓	
CLAM, LITTLENECK	*Protothaca staminea*	✓		✓	✓	
	Protothaca tenerrima	✓		✓	✓	
	Tapes aureus	✓		✓	✓	
	Tapes decussatus	✓		✓	✓	
	Tapes semidecussata	✓		✓	✓	
	Tapes variegata	✓		✓	✓	
	Tapes virginea	✓		✓	✓	
	Venerupis philippinarum	✓		✓	✓	
CLAM, MARSH	*Corbicula japonica*	✓		✓	✓	
CLAM, PISMO	*Tivela stultorum*	✓		✓	✓	

Market Names	Latin Names	Hazards				
		Biological		*Chemical*		
		Pathogens CHP 4	Parasites CHP 5	Natural Toxins CHP 6	Chemical CHP 9	Drugs CHP 11
CLAM, RAZOR	*Ensis spp.*	✓		✓	✓	
	Siliqua spp.	✓		✓	✓	
	Solen spp.	✓		✓	✓	
	Tagelus spp.	✓		✓	✓	
CLAM, SANGUIN	*Sanguinolaria spp.*	✓		✓	✓	
CLAM, SOFTSHELL	*Mya arenaria*	✓		✓	✓	
CLAM, SURF SURFCLAM	*Mactra spp.*	✓		✓	✓	
	Mactrellona alata	✓		✓	✓	
	Mactromeris spp.	✓		✓	✓	
	Mactrotomas spp.	✓		✓	✓	
	Simomactra spp.	✓		✓	✓	
	Spisula spp.	✓		✓	✓	
	Tresus spp.	✓		✓	✓	
CLAM, SURF AQUACULTURED	*Mactra schalinensis*	✓		✓	✓	
CLAM, VENUS	*Chione spp.*	✓		✓	✓	
	Macrocallista nimbosa	✓		✓	✓	
CLAM, WEDGE	*Paphies spp.*	✓		✓	✓	
COCKLE	*Cardium spp.*	✓		✓	✓	
	Clinocardium spp.	✓		✓	✓	
	Dinocardium robustum	✓		✓	✓	
	Serripes groenlandicus	✓		✓	✓	
CONCH	*Strombus spp.*					
COQUINA	*Donax spp.*	✓		✓	✓	
COQUINA, FALSE	*Iphigenia brasiliana*	✓		✓	✓	
CRAB, BLUE	*Callinectes sapidus*				✓	
CRAB, BROWN	*Geryon fenneri*					
CRAB, BROWN KING	*Lithodes aequispina*					
CRAB, CENTOLLA	*Lithodes antarcticus* *Lithodes murrayi*					
CRAB, DEEPSEA	*Paralomis granulosa*					

Market Names	Latin Names	Hazards				
		Biological		*Chemical*		
		Pathogens CHP 4	Parasites CHP 5	Natural Toxins CHP 6	Chemical CHP 9	Drugs CHP 11
CRAB, DUNGENESS	*Cancer magister*			✓ [2]	✓	
CRAB, JONAH	*Cancer borealis*			✓ [2]		
CRAB, KING	*Paralithodes camtschaticus* *Paralithodes platypus*					
CRAB, KING or HANASAKI	*Paralithodes brevipes*					
CRAB, KOREAN or KEGANI	*Erimacrus isenbeckii*					
CRAB, LITHODES	*Neolithodes brodiei*					
CRAB, RED	*Geryon quinquedens*					
CRAB, RED ROCK	*Cancer productus*			✓ [2]		
CRAB, ROCK	*Cancer irroratus* *Cancer pagurus*					
CRAB, SNOW	*Chionoecetes angulatus* *Chionoecetes bairdi* *Chionoecetes opilio* *Chionoecetes tanneri*					
CRAB, SPIDER	*Jacquinotia edwardsii* *Maja squinado*					
CRAB, STONE	*Menippi spp.*					
CRAB, SWIMMING	*Callinectes arcuatus* *Callinectes toxotes* *Portunus spp.*				✓ ✓ ✓	
CRAWFISH or CRAYFISH	*Cambarus spp.* *Cherax spp.* *Euastacus armatus* *Pacifastacus spp.* *Paranephrops spp.* *Procambarus spp.* *Astacus spp.*				✓ ✓ ✓ ✓ ✓ ✓ ✓	

2 – This hazard only applies if the product is marketed uneviscerated.

Market Names	Latin Names	Hazards				
		Biological		*Chemical*		
		Pathogens CHP 4	Parasites CHP 5	Natural Toxins CHP 6	Chemical CHP 9	Drugs CHP 11
CRAWFISH or CRAYFISH AQUACULTURED	*Cambarus spp.*				✓	✓
	Cherax spp.				✓	✓
	Euastacus armatus				✓	✓
	Pacifastacus spp.				✓	✓
	Paranephrops spp.				✓	✓
	Procambarus spp.				✓	✓
	Astacus spp.				✓	✓
CUTTLEFISH	*Sepia spp.*					
JELLYFISH	*Rhopilema spp.*					
KRILL	*Euphausia spp.*				✓	
	Meganyctiphanes norvegica					
	Thysandoessa inermis					
LANGOSTINO	*Cervimunida johni*					
	Munida gregaria					
	Pleuroncodes monodon					
LIMPET	*Acmaea testitudinalis*					
	Cellana denticulata					
	Diodora aspera					
	Fissurella maxima					
	Lottia gigantea					
	Patella caerulea					
LOBSTER	*Homarus spp.*					✓ [7]
LOBSTER, NORWAY	*Nephrops norvegicus*					
LOBSTER, ROCK	*Jasus spp.*					
LOBSTER, ROCK or SPINY	*Palinurus spp.*					
	Panulirus spp.					
LOBSTER, SLIPPER	*Ibacus ciliatus*					
	Scyllarides spp.					
	Thenus orientalis					
LOBSTERETTE	*Metanephrops spp.*					
	Nephropsis aculeata					

7 – This hazard only applies if the lobster are held in pounds.

Market Names	Latin Names	Hazards				
		Biological		*Chemical*		
		Pathogens CHP 4	Parasites CHP 5	Natural Toxins CHP 6	Chemical CHP 9	Drugs CHP 11
MUSSEL	*Modiolus spp.*	✓		✓	✓	
	Mytilus spp.	✓		✓	✓	
	Perna canaliculus	✓		✓	✓	
OCTOPUS	*Eledone spp.*		✓ [1]			
	Octopus spp.		✓ [1]			
OYSTER	*Crassostrea spp.*	✓		✓	✓	
	Ostrea spp.	✓		✓	✓	
	Tiostrea spp.	✓		✓	✓	
PEN SHELL	*Atrina pectinata*	✓		✓	✓	
PERIWINKLE	*Littorina littorea*					
	Lunatatia spp.					
SCALLOP	*Aequipecten spp.*	✓ [2]		✓ [2]	✓	
	Amusium spp.	✓ [2]		✓ [2]	✓	
	Argopecten nucleus	✓ [2]		✓ [2]	✓	
	Chlamys spp.	✓ [2]		✓ [2]	✓	
	Patinopecten yessoensis	✓ [2]		✓ [2]	✓	
	Pecten spp.	✓ [2]		✓ [2]	✓	
	Placopectin magellanicus	✓ [2]		✓ [2]	✓	
SCALLOP AQUACULTURED	*Aequipecten spp.*	✓ [2]		✓ [2]	✓	
	Amusium spp.	✓ [2]		✓ [2]	✓	
	Argopecten nucleus	✓ [2]		✓ [2]	✓	
	Chlamys spp.	✓ [2]		✓ [2]	✓	
	Patinopecten yessoensis	✓ [2]		✓ [2]	✓	
	Pecten spp.	✓ [2]		✓ [2]	✓	
	Placopectin magellanicus	✓ [2]		✓ [2]	✓	
SCALLOP or BAY SCALLOP	*Argopecten irradians*	✓ [2]		✓ [2]	✓	
SCALLOP, CALICO	*Argopecten gibbus*	✓ [2]		✓ [2]	✓	
SCALLOP or WEATHERVANE	*Patinopecten caurinus*	✓ [2]		✓ [2]	✓	
SEA CUCUMBER	*Cucumaria spp.*				✓	
	Holothuria spp.				✓	
	Parastichopus spp.				✓	
	Stichopus spp.				✓	

1 – This hazard only applies if the product is intended to be consumed raw or partially cooked.
2 – This hazard only applies if the product is marketed uneviscerated.

Market Names	Latin Names	Hazards				
		Biological		*Chemical*		
		Pathogens CHP 4	Parasites CHP 5	Natural Toxins CHP 6	Chemical CHP 9	Drugs CHP 11
SEA URCHIN roe	*Echinus esculentus*				✓	
	Evechinus chloroticus				✓	
	Heliocidaris spp.				✓	
	Loxechimus spp.				✓	
	Paracentrotus spp.				✓	
	Pseudocentrotus spp.				✓	
	Strongylocentrotus spp.				✓	
SEABOB	*Xiphopenaeus kroyeri*					
SHRIMP	*Crangon spp.*					
	Metapenaeus affinis					
	Palaemon serratus					
	Palaemonetes vulgaris					
	Pandalopsis dispar					
	Pandalus spp.					
	Penaeus spp.					
	Plesionika martia					
SHRIMP AQUACULTURED	*Crangon spp.*				✓	✓
	Exopalaemon styliferus				✓	✓
	Macrobrachium spp.				✓	✓
	Metapenaeus spp.				✓	✓
	Palaemon serratus				✓	✓
	Palaemonetes vulgaris				✓	✓
	Pandalopsis dispar				✓	✓
	Pandalus spp.				✓	✓
	Penaeus spp.				✓	✓
	Plesionika martia				✓	✓
SHRIMP, FRESHWATER	*Macrobrachium spp.*					
SHRIMP, FRESHWATER AQUACULTURED	*Macrobrachium spp.*				✓	✓
SHRIMP, ROCK	*Sicyonia brevirostris*					
SHRIMP, ROYAL	*Pleoticus robustus*					
SHRIMP or PINK SHRIMP	*Pandalus borealis*					
	Pandalus jordani					

Market Names	Latin Names	Hazards				
		Biological		*Chemical*		
		Pathogens CHP 4	Parasites CHP 5	Natural Toxins CHP 6	Chemical CHP 9	Drugs CHP 11
SHRIMP or PRAWN	*Hymenopenaeus sibogae*					
SNAIL or ESCARGOT	*Otala spp.*				✓	
	Helix pomatia				✓	
	Achatina fulica		✓ [1]			
SQUID	*Alloteuthis media*		✓ [1]			
	Berryteuthis magister		✓ [1]			
	Dosidicus gigas		✓ [1]			
	Illex spp.		✓ [1]			
	Loligo spp.		✓ [1]			
	Lolliguncula spp.		✓ [1]			
	Nototodarus spp.		✓ [1]			
	Ommastrephes spp.		✓ [1]			
	Rossia macrosoma		✓ [1]			
	Sepiola rondeleti		✓ [1]			
	Sepioteuthis spp.		✓ [1]			
	Todarodes sagittatus		✓ [1]			
TOP SHELL	*Turbo cornutus*					
	Nonodonta turbinata					
WHELK or SEA SNAIL	*Buccinum spp.*					
	Busycon spp.					
	Neptunea spp.			✓ [2]		

1 – This hazard only applies if the product is intended to be consumed raw or partially cooked.
2 – This hazard only applies if the product is marketed uneviscerated.

Table #3-3
Potential Process Related Hazards

Finished Product Food	Package Type	Method of Distribution and Storage	Hazards									
			Biological							*Chemical*	*Physical*	
			Pathogen growth-temperature abuse CHP 12	*C. botulinum* growth CHP 13	Toxin formation-inadequate drying CHP 14	*S. aureus* toxin batter CHP 15	Pathogen survival through cooking CHP 16	Pathogen survival through pasteurization CHP 17	Pathogen contamination after pasteurization CHP 18	Allergens/ Additives CHP 19	Metal inclusion CHP 20	Glass inclusion CHP 21
Cooked shrimp, crab, lobster, and other fish, including cooked meat, sections, and whole fish, and including surimi-based analog products	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Frozen	✓				✓			✓	✓	
Cooked shrimp, crab, lobster, and other fish, including cooked meat, sections, and whole fish, and including surimi-based analog products	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Other than frozen	✓	✓			✓			✓	✓	
Cooked shrimp, crab, lobster, and other fish, including cooked meat, sections, and whole fish, and including surimi-based analog products	Other than vacuum packaged, MAP, CAP, hermetically sealed or packed in oil	All	✓				✓			✓	✓	
Pasteurized crab, lobster, and other fish, including pasteurized surimi-based analog products	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Frozen	✓					✓	✓	✓	✓	

Note: MAP = modified atmosphere packaging; CAP = controlled atmosphere packaging

Finished Product Food	Package Type	Method of Distribution and Storage	Hazards									
			Biological							*Chemical*	*Physical*	
			Pathogen growth-temperature abuse CHP 12	*C. botulinum* growth CHP 13	Toxin formation-inadequate drying CHP 14	*S. aureus* toxin batter CHP 15	Pathogen survival through cooking CHP 16	Pathogen survival through pasteurization CHP 17	Pathogen contamination after pasteurization CHP 18	Allergens/ Additives CHP 19	Metal inclusion CHP 20	Glass inclusion CHP 21
Pasteurized crab, lobster, and other fish, including pasteurized surimi-based analog products	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Other than frozen	✓	✓				✓	✓	✓	✓	
Pasteurized crab, lobster, and other fish, including pasteurized surimi-based analog products	Other than vacuum packaged, MAP, CAP, hermetically sealed or packed in oil	All	✓					✓	✓	✓	✓	
Smoked fish	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Frozen	✓							✓	✓	
Smoked fish	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Other than frozen	✓	✓						✓	✓	
Smoked fish	Other than vacuum packaged, MAP, CAP, hermetically sealed or packed in oil	All	✓							✓	✓	

Note: MAP = modified atmosphere packaging; CAP = controlled atmosphere packaging

Finished Product Food	Package Type	Method of Distribution and Storage	Hazards									
			Biological							*Chemical*	*Physical*	
			Pathogen growth-temperature abuse CHP 12	*C. botulinum* growth CHP 13	Toxin formation-inadequate drying CHP 14	*S. aureus* toxin batter CHP 15	Pathogen survival through cooking CHP 16	Pathogen survival through pasteurization CHP 17	Pathogen contamination after pasteurization CHP 18	Allergens/ Additives CHP 19	Metal inclusion CHP 20	Glass inclusion CHP 21
Salads and cocktails prepared from ready-to-eat fishery products	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Frozen	✓							✓	✓	✓
Salads and cocktails prepared from ready-to-eat fishery products	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Other than frozen	✓	✓						✓	✓	✓
Salads and cocktails prepared from ready-to-eat fishery products	Other than vacuum packaged, MAP, CAP, hermetically sealed or packed in oil	All	✓							✓	✓	✓
Raw, breaded shrimp, finfish, oysters, clams, squid, and other fish	All	All				✓				✓	✓	
Stuffed crab, shrimp, finfish, and other fish	All	All	✓							✓	✓	
Dried fish	All	All	✓	✓	✓					✓	✓	

Note: MAP = modified atmosphere packaging; CAP = controlled atmosphere packaging

Finished Product Food	Package Type	Method of Distribution and Storage	Hazards									
			Biological							*Chemical*	*Physical*	
			Pathogen growth-temperature abuse CHP 12	*C. botulinum* growth CHP 13	Toxin formation-inadequate drying CHP 14	*S. aureus* toxin batter CHP 15	Pathogen survival through cooking CHP 16	Pathogen survival through pasteurization CHP 17	Pathogen contamination after pasteurization CHP 18	Allergens/ Additives CHP 19	Metal inclusion CHP 20	Glass inclusion CHP 21
Raw oysters, clams and mussels	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Frozen	✓							✓	✓	✓
Raw oysters, clams and mussels	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed n oil	Other than frozen	✓	✓						✓	✓	✓
Raw oysters, clams and mussels	Other than vacuum packaged, MAP, CAP, hermetically sealed or packed in oil	All	✓							✓	✓	✓
Raw fish other than oysters, clams and mussels (includes non-finfish species)	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Frozen								✓	✓	

Note: MAP = modified atmosphere packaging; CAP = controlled atmosphere packaging

Finished Product Food	Package Type	Method of Distribution and Storage	Hazards									
			Biological							*Chemical*	*Physical*	
			Pathogen growth-temperature abuse CHP 12	*C. botulinum* growth CHP 13	Toxin formation-inadequate drying CHP 14	*S. aureus* toxin batter CHP 15	Pathogen survival through cooking CHP 16	Pathogen survival through pasteurization CHP 17	Pathogen contamination after pasteurization CHP 18	Allergens/ Additives CHP 19	Metal inclusion CHP 20	Glass inclusion CHP 21
Raw fish other than oysters, clams and mussels (includes non-finfish species)	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Other than frozen	✓	✓						✓	✓	
Raw fish other than oysters, clams and mussels (includes non-finfish species)	Other than vacuum packaged, MAP, CAP, hermetically sealed or packed in oil	All								✓	✓	
Partially cooked or uncooked prepared foods	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Frozen	✓							✓	✓	✓
Partially cooked or uncooked prepared foods	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Other than frozen	✓	✓						✓	✓	✓
Partially cooked or uncooked prepared foods	Other than vacuum packaged, MAP, CAP, hermetically sealed or packed in oil	All	✓							✓	✓	✓

Note: MAP = modified atmosphere packaging; CAP = controlled atmosphere packaging

Finished Product Food	Package Type	Method of Distribution and Storage	Hazards									
			Biological							*Chemical*	*Physical*	
			Pathogen growth-temperature abuse CHP 12	*C. botulinum* growth CHP 13	Toxin formation-inadequate drying CHP 14	*S. aureus* toxin batter CHP 15	Pathogen survival through cooking CHP 16	Pathogen survival through pasteurization CHP 17	Pathogen contamination after pasteurization CHP 18	Allergens/ Additives CHP 19	Metal inclusion CHP 20	Glass inclusion CHP 21
Fully cooked prepared foods	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Frozen	✓				✓	✓	✓	✓	✓	✓
Fully cooked prepared foods	Vacuum packaged (e.g. mechanical vacuum, steam sweep, hot fill), MAP, CAP, hermetically sealed or packed in oil	Other than frozen	✓	✓			✓	✓	✓	✓	✓	✓
Fully cooked prepared foods	Other than vacuum packaged, MAP, CAP, hermetically sealed or packed in oil	All	✓				✓	✓	✓	✓	✓	✓
Fermented, acidified, pickled, salted, and low acid canned foods	All	All	✓	✓*						✓	✓	✓

Note: MAP = modified atmosphere packaging; CAP = controlled atmosphere packaging

* Note: Controls for this hazard need not be included in HACCP plans for shelf-stable, acidified and low acid canned foods. See 21 CFR 113 and 114 for mandatory controls.

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

- Pathogens in molluscan shellfish

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. 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 and viruses (e.g., hepatitis A virus, Norwalk virus, Norwalk-like viruses).

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 to 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.

- Control of pathogens of human/animal origin

Certain pathogens, such as *Vibrio cholerae* 01, *Salmonella* spp., *Shigella* spp., *Campylobacter jejuni,* hepatitis A virus, Norwalk virus, and Norwalk-like viruses, are of sewage or animal origin. To minimize the risk of molluscan shellfish containing these pathogens, State 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 then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been permitted.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; 2) a requirement that molluscan shellfish harvesters be licensed (note that licensing may not be required in all jurisdictions); 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the processor's name, address, and certification number.

Some bacterial pathogens of human sewage or animal waste origin, such as *Vibrio cholerae* 01, and *Salmonella* spp., that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependent upon the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

These controls serve to minimize the risk of molluscan shellfish containing pathogens of sewage 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.

Continued

Processors can also eliminate the hazard of "pathogens from the harvest area" by properly cooking or retorting the product. Guidance on cooking controls is provided in Chapter 16. Mandatory retorting controls are described in the low acid canned foods regulation (21 CFR 113). It should be noted that neither cooking nor retorting will eliminate the hazards of "natural toxins" or "chemical contamination" that may be associated with molluscan shellfish that are harvested from closed waters (see Chapters 6 and 9). These hazards must be controlled at receiving. 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.

- Control of naturally occurring pathogens

Certain pathogens, such as *Vibrio vulnificus, Vibrio parahaemolyticus,* and *Vibrio cholerae* non 01, are naturally occurring. Their presence is not associated with human sewage or animal waste. *V. vulnificus* illness is associated with the consumption of raw oysters harvested from the Gulf of Mexico during the warm weather months. *V. parahaemolyticus* and *V. cholerae* non 01 illness is associated with the consumption of raw oysters harvested during the warm weather months from the Atlantic, Pacific, and Gulf of Mexico regions of the U.S., and similar climates world-wide. To minimize the risk of illness from the consumption of molluscan shellfish containing these pathogens, Shellfish Control Authorities place certain controls on the harvest of molluscan shellfish.

Control for *V. parahaemolyticus* involves monitoring by Shellfish Control Authorities of waters that have been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past three years. Monitoring is performed for both total *V. parahaemolyticus* numbers and for the presence of virulent strains of *V. parahaemolyticus* (i.e. tdh+ strains). As a result of the monitoring, Shellfish Control Authorities may temporarily close some waters to the harvesting of oysters that are intended for raw consumption.

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/temperature abuse. To minimize the risk of *Vibrio parahaemolyticus* and *Vibrio cholerae* non 01 pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. As with pathogens of sewage or animal origin, the length of time is dependent upon the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

In most cases, control for *V. vulnificus* similarly involves limits on the time from harvest to refrigeration. The length of time is dependent upon the average monthly maximum water temperature (AMMWT) at the time of harvest, which is also determined by the Shellfish Control Authority.

As with pathogens of sewage origin, the above controls for naturally occurring pathogens minimize the risk of molluscan shellfish containing these pathogens, 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 a warning relative to raw and undercooked consumption (described above).

The controls for *V. vulnificus* and *V. parahaemolyticus* discussed in this chapter only apply to molluscan shellfish if they are intended for raw consumption. For example, they would not be applied to oyster shellstock from the Gulf of Mexico if tags on the containers of shellstock indicate that they must be shucked and cooked before consumption.

V. vulnificus, V. parahaemolyticus, and *V. cholerae* non 01 can be eliminated or reduced to nondetectable levels by cooking, pasteurizing, and retorting. Guidance for these control mechanisms can be found in Chapters 16 (cooking) and 17 (pasteurization) and the low acid canned foods regulation (21 CFR 113). Other mechanisms, such as freezing and hydrostatic pressure, are being studied.

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

- Pathogens in fish other than molluscan shellfish

It is possible that, in performing your hazard analysis, you may have identified pathogens from the harvest area as a potential hazard for fish types other than molluscan shellfish. In some cases, this would be an appropriate decision, as pathogens, may be found on raw fish as a result of near-shore harvest water contamination, contamination on the harvest vessel and poor aquacultural practices.

This hazard can be controlled by the processor by proper cooking, pasteurizing, or retorting. Guidance for these control mechanisms can be found in Chapters 16 (cooking) and 17 (pasteurizing), and the low acid canned foods 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 HACCP controls that may exist internationally for the control of pathogens in fish and fishery products that are intended to be fully cooked by the consumer or end user before consumption, other than a rigorous sanitation regime as part of either a prerequisite program or as part of HACCP itself. The Seafood HACCP Regulation requires such a regime. The proper application of sanitation controls is essential because of the likelihood that any pathogens that may be present in seafood products are introduced through poor handling practices (e.g. by the aquacultural producer, the fisherman, or the processor).

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

The guidance contained in the remainder of this chapter applies to molluscan shellfish, only.

STEP #11: *DETERMINE IF THE POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "pathogens from the harvest area" is a significant hazard. The criteria are:

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

Under ordinary circumstances, it would be reasonably likely that pathogens from the harvest area could enter the process at unsafe levels at the receiving step from the following types of fish:
- Raw oysters;
- Raw clams;
- Raw mussels;
- Raw scallops

(See information provided under "Intended use").

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

Under ordinary circumstances, it would be reasonably likely that *V. parahaemolyticus* could enter the process from oysters harvested in an area which has been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past three years.

Continued

2. Can unsafe levels of pathogens from the harvest area, which were introduced at the receiving step, be eliminated or reduced to an acceptable level at this processing step? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step 12.)

"Pathogens from the harvest area" should also be considered a significant hazard at any processing step where a preventive measure is or can be used to eliminate unsafe levels of pathogens that are reasonably likely to come in with the raw materials, or where a preventive measure is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. Preventive measures for pathogens from the harvest area could 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 the pathogens by cooking (covered in Chapter #16), pasteurizing (covered in Chapter #17), or retorting (covered by the low acid canned foods regulation, 21 CFR 113). It should be noted that neither cooking nor retorting will eliminate the hazards of "natural toxins" or "chemical contamination" that may be associated with molluscan shellfish that are harvested from closed waters;
- Minimizing the growth of *V. cholerae*, *V. parahaemolyticus*, *V. vulnificus*, and *L. monocytogenes* by limiting the time from harvest to refrigeration.
- Including a warning on tags on containers of molluscan shellfish intended for raw consumption 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.

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

- Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. 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 above criteria.

However, where the product consists of scallop adductor muscle only, it is 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. You should then enter "No" in Column 3 of the Hazard Analysis Worksheet for each of the processing steps. For each "No" entry briefly explain in Column 4 that the product is not ordinarily consumed raw. In this case, you need not complete Steps #12 through 18 for this hazard.

Additionally, the controls for *V. vulnificus* and *V. parahaemolyticus* that are discussed in this chapter only need be applied to molluscan shellfish if they are intended 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 and cooked before consumption.

Similarly, the raw consumption warning need not be applied to containers of shucked shellfish, because these products are generally cooked before consumption.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "pathogens from the harvest area" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "pathogens from the harvest area":

1. Will the product be cooked or retorted sufficiently to kill pathogens during processing in your facility?

    a. If it will be, you may identify the cook 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, it should be noted that neither cooking nor retorting will eliminate the hazards of "natural toxins" or "environmental chemical contaminants and pesticides" that may be associated with molluscan shellfish that are harvested from closed waters (see Chapters 6 and 9). These hazards must be controlled at receiving. 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.

    Example:

    A canned clam chowder processor sets the critical control point for pathogens from the harvest area at the retorting step, and does not identify the receiving step as a critical control point for this hazard.

    In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the cooking or retorting step, and enter "No" for the receiving step. In addition, note in Column 5 that the hazard is controlled by the cooking or retorting step. (Note: if you have not previously identified "pathogens from the harvest area" as a significant hazard at the cooking or retorting step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes.") If you chose to follow this approach you should refer to Chapter 16 (cooking) or to the low acid canned foods regulation (retorting) for further guidance.

    b. If the product will not be cooked or retorted sufficiently to kill 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 harvest to refrigeration to control pathogens from the harvest area. If the finished product is shellstock intended for raw consumption, you should also identify the labeling step as a CCP, where you can ensure that the raw consumption warning is on the tag.

    Example:

    A processor that shucks raw oysters and ships a raw product checks the tags of incoming shellstock (in-shell oysters), the license of the harvesters that supply the shellstock, and the length of time between harvesting and refrigeration. The processor identifies receiving as the CCP for this hazard.

    Example:

    A processor that ships oyster shellstock checks the tags of incoming shellstock, the license of the harvesters that supply the shellstock, and the length of time between harvesting and refrigeration. The processor identifies receiving as a CCP for this hazard. The processor also identifies the labeling step as a CCP for this hazard, and checks for the presence of the raw consumption warning.

Continued

In this case, You should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 1" in Steps #14 through 18. Note that this control strategy is identical to Control Strategy Example 6 for "environmental chemical contaminants and pesticides" (Chapter 9) and Control Strategy Example 1 for "natural toxins" (Chapter 6). If you choose an identical control strategy for two or more of these hazards, you may combine the hazards in the HACCP Plan Form.

You only need to answer Questions 2 and 3 if you answered "no" to Question 1.

2. If the finished product is raw oyster shellstock intended for raw consumption and is from the Gulf of Mexico (i.e., States which have ever been confirmed as the original source of oysters associated with two or more *V. Vulnificus* illnesses), will it be pasteurized sufficiently to kill *V. vulnificus* during processing in your facility (i.e. reduced to a nondetectable level; less than 3 MPN/gram, as defined by the NSSP)? Other mechanisms, such as freezing and hydrostatic pressure, are being studied and may also be suitable for control of these pathogens.

   a. If it will be, you may identify the pasteurization step as the CCP for control of *V. vulnificus*. In this case you will not need to identify the receiving step as a CCP for the control of *V. vulnificus*.

   Example:
   An oyster processor on the Gulf of Mexico sets the critical control point for V. vulnificus at the pasteurizing step, and does not identify the receiving step as a critical control point for that pathogen.

   In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the pasteurizing step. (Note: if you have not previously identified pathogens from the harvest area as a significant hazard at the pasteurizing step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) If you chose to follow this approach you should refer to Chapter 17 (pasteurizing) for further guidance.

   b. If the product will not be pasteurized sufficiently to kill *V. vulnificus* during processing in your facility, you should identify the receiving step as a CCP, where you can exercise control over the time from harvest to refrigeration to control *V. vulnificus*. You should also identify the labeling step as a CCP for this hazard, where you can ensure that the raw consumption warning is on the tag.

   Example:
   Another oyster processor on the Gulf of Mexico sets the critical controls point for V. vulnificus at the receiving step and the tagging step.

   In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 2" in Steps #14-18.

   Note that the controls listed under "2," above, should be considered in addition to those listed under "1," above and "3," below. In some cases, two or more types of controls will be necessary.

3. If the finished product is raw oyster shellstock intended for raw consumption and is from an area which has been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past three years, will it be pasteurized sufficiently to kill *V. parahaemolyticus* during processing in your facility? Other mechanisms, such as freezing and hydrostatic pressure, are being studied and may also be suitable for control of these pathogens.

a. If it will be, you may identify the pasteurization step as the CCP for control of *V. parahaemolyticus*. In this case you will not need to identify the receiving step as a CCP for the control of *V. parahaemolyticus*.

Example:

An oyster processor sets the critical control point for V. parahaemolyticus at the pasteurizing step, and does not identify the receiving step as a critical control point for that pathogen.

In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the pasteurizing step. (Note: if you have not previously identified pathogens from the harvest area as a significant hazard at the pasteurizing step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) If you chose to follow this approach you should refer to Chapter 17 (pasteurizing) for further guidance.

b. If the product will not be pasteurized sufficiently to kill *V. parahaemolyticus* during processing in your facility, you should identify the receiving step as a CCP, where you can exercise control over the time from harvest to refrigeration to control *V. parahaemolyticus*. You should also identify the labeling step as a CCP for this hazard, where you can ensure that the raw consumption warning is on the tag.

Example:

Another oyster processor sets the critical control point for V. parahaemolyticus at the receiving step and the tagging step.

In this case, You should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 3" in Steps 14-18.

Note that the controls listed under "3," above, should be considered in addition to those listed under "1," and "2" above. In many cases, two or more types of controls will be necessary.

The time to refrigeration controls for *V. vulnificus* that are discussed in this chapter need only be applied by the primary processor (the processor who takes possession of the molluscan shellfish from the harvester), since this is the processor that is in the best position to control the time from harvest to refrigeration.

It is important to note that you may select a control strategy that is different from those which are suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "pathogens from the harvest area" is identified as a significant hazard on the HACCP Plan Form identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy examples discussed in Step #12.

Continued

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Critical Limit: All shellstock (in-shell molluscan shellfish) containers must bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (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, accept shellstock only if it is accompanied by a bill of lading or other similar shipping document that contains the same information;

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 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 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

The following criteria is met for the maximum time from harvest to refrigeration:

- For AMMAT of less than 66˚F (less than 19˚C): 36 hours;
- For AMMAT of 66 to 80˚F (19 to 27˚C): 24 hours;
- For AMMAT of greater than 80˚F (greater than 27˚C): 20 hours.

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: Average Monthly Maximum Air Temperature (AMMAT) is determined by the Shellfish Control Authority)

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls relative to the identification of the harvester, the harvester's license, the approval status of the harvest waters, or the time-of-harvest to time-of-refrigeration.)

- CONTROL STRATEGY EXAMPLE 2 - *V. VULNIFICUS* CONTROL

Critical Limit: Maximum time from harvest to refrigeration (Note: these apply only to certain products, as described in Steps #11 and 12):

- For AMMWT of less than 65˚F (less than18˚C): 36 hours
- For AMMWT of 65 to 74˚F (18 to 23˚C): 14 hours;
- For AMMWT of greater than 74 to 84˚F (greater than 23 to 28˚C): 12 hours;
- For AMMWT of greater than 84˚F (greater than 28˚C): 10 hours

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: Average Monthly Maximum Water Temperature (AMMWT) is determined by the Shellfish Control Authority.)

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls for time-of-harvest to time-of-refrigeration.)

- CONTROL STRATEGY EXAMPLE 3 – *V. PARAHAEMOLYTICUS* CONTROL

Critical Limit: Maximum time from harvest to refrigeration (Note: these apply only to certain products, as described in Steps #11 and 12):

- For AMMAT of less than 66˚F (less than 19˚C): 36 hours
- For AMMAT of 66˚F to 80˚F (19˚C to 27˚C): 12 hours
- For AMMAT of greater than 80˚F (greater than 27˚C): 10 hours

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: Average Monthly Maximum Air Temperature (AMMAT) is determined by the Shellfish Control Authority.)

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls for time-of harvest to time of refrigeration.).

Much of Control Strategy Example 1 is specifically mandated by 21 CFR 123.28. However, for those provisions that are not specifically included in the regulation, you may select a different control strategy, provided that it assures an equivalent degree of safety of the product.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "pathogens from the harvest area" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy examples discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

Continued

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

What: The tags on containers of incoming shellstock. The Bill of Lading or other similar shipping document accompanying bulk shipments of shellstock;
AND
The harvest site listed on the tag or on the Bill of Lading or other similar shipping document;
AND
The labels on containers of incoming shucked molluscan shellfish;
AND
The license of fishermen, where applicable;
AND
The certification number of suppliers (other than fishermen) of shellstock or shucked molluscan shellfish;
AND
Time harvesting began;
AND
Time shellstock was placed under refrigeration;
AND
The raw consumption advisory on tags on containers of finished product shellstock intended for raw consumption.

- CONTROL STRATEGY EXAMPLES 2 & 3

What: Time harvesting began;
AND
Time shellstock was placed under refrigeration;
AND
The raw consumption advisory on tags on containers of finished product shellstock intended for raw consumption.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

How: Visual checks;
AND
For time of harvest:
- Obtain information from Shellfish Control Authority;

OR
- Check harvester's log;

OR
- Note time of departure from dock;

OR
- Ask harvester.

- CONTROL STRATEGY EXAMPLES 2 & 3

How: Visual checks;
AND
For time of harvest:
- Obtain information from Shellfish Control Authority;

OR
- Check harvester's log;

OR
- Note time of departure from dock;

OR
- Ask harvester.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Frequency: For checking incoming tags: every container;
AND
For checking harvest site: every lot;
AND
For checking incoming labels: at least three containers randomly selected from throughout every lot;
AND
For checking licenses: every delivery;

AND
For checking certification numbers: every delivery;
AND
For checking time-of-harvest and time-of-refrigeration: every delivery;
AND
For checking raw consumption advisory on finished product tags: each lot of finished product or each lot of tags (at receipt of tags).

- CONTROL STRATEGY EXAMPLES 2 & 3

Frequency: Every delivery;
AND
For checking raw consumption advisory on finished product tags: each lot of finished product or each lot of tags (at receipt of tags).

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Who: Monitoring may be performed by the receiving employee, a supervisor, a member of the quality control staff, or any other person who has an understanding of the nature of the controls.

- CONTROL STRATEGY EXAMPLES 2 & 3

Who: Monitoring may be performed by the receiving employee, a supervisor, a member of the quality control staff, or any other person who has an understanding of the nature of the controls.

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls relative to the identification of the harvester, the harvester's license, the approval status of the harvest waters, or the time-of-harvest to time-of-refrigeration.)

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "pathogens from the harvest area" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Corrective Action: Reject incoming shellstock that is not properly tagged or is not accompanied by a proper shipping document;
AND
Reject incoming shucked molluscan shellfish that is not properly labeled;
AND
Reject incoming molluscan shellfish that has been harvested from unapproved waters;
AND
Reject incoming molluscan shellfish that is not from a licensed harvester or certified processor;
AND
Reject incoming shellstock that does not meet the time-of-harvest to time-of-refrigeration critical limits;
AND
Relabel finished product shellstock intended for raw consumption that does not bear a tag that contains the raw consumption warning;
OR
Reject any incoming tags to be used on finished product shellstock intended for raw consumption that do not contain the raw consumption warning;
AND
Discontinue use of supplier until evidence is obtained that harvesting, tagging, and/or labeling practices have changed.

Continued

- CONTROL STRATEGY EXAMPLES 2 & 3

Corrective Action: Reject lots that do not meet the CL;
OR
Relabel the shellstock with tags that identify its use for shucking and cooking only;
OR
Subject the shellstock to a pasteurization process that reduces *V. vulnificus* or *Vibrio parahaemolyticus*, as appropriate, in the shellstock to a non-detectable level (i.e. less than 3 MPN/gram, as defined in the NSSP). See Chapter 17 for further guidance on pasteurization.
AND
Relabel finished product shellstock that does not bear a tag that contains the raw consumption warning;
OR
Reject any incoming tags to be used on finished product shellstock that do not contain the raw consumption warning;
AND
Discontinue use of supplier until evidence is obtained that harvesting, tagging, and/or labeling practices have changed.

Note: If an incoming lot that fails to meet a receiving critical limit is mistakenly accepted, and the error is later detected, the following actions should be taken: 1) the lot and any products processed from that lot should be destroyed, diverted to a nonfood use or to a use in which the critical limit is not applicable, or placed on hold until a food safety evaluation can be completed; and 2) any products processed from that lot that have already been distributed should be recalled and subjected to the actions described above.

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls relative to the identification of the harvester, the harvester's license, the approval status of the harvest waters, or the time-of-harvest to time-of-refrigeration.)

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "pathogens from the harvest area" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

For shellstock:

Records: 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;

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

AND
- Certification number of the shipper, where applicable;

AND
- Time harvesting began;

AND
- Time shellstock was placed under refrigeration;

AND
- AMMAT, where applicable;

AND
- For shellstock intended for raw consumption, labeling record that documents the presence of the raw consumption warning.

For shucked molluscan shellfish:

Records: Receiving record that documents:

- Date of receipt;

AND

- Quantity and type of shellfish;

AND

- Name and certification number of the packer or repacker.

- CONTROL STRATEGY EXAMPLES 2 & 3

Records: Receiving record that documents:

- Time harvesting began;

AND

- Time shellstock was placed under refrigeration;

AND

- AMMWT;

AND

- For shellstock intended for raw consumption, labeling record that documents the presence of the raw consumption warning.

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls relative to the identification of the harvester, the harvester's license, the approval status of the harvest waters, or the time-of-harvest to time-of-refrigeration.)

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "pathogens from the harvest area" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "pathogens from the harvest area"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Verification: Review monitoring and corrective action records within one week of preparation.

- CONTROL STRATEGY EXAMPLES 2 & 3

Verification: Review monitoring and corrective action records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #4-1

Control Strategy Example 1 - Source control

This table is an example of a portion of a HACCP plan relating to the control of pathogens from the harvest area for a primary processor (processor that takes possession of the oysters from the harvester) of shellstock oysters (shellstock shipper), using Control Strategy Example 1 - Source controls. It is provided for illustrative purposes only. Pathogens from the harvest area may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. natural toxins, chemical contaminants, pathogens during processing, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving - shellstock	Pathogens from harvest area	• All incoming shellstock must be tagged	• Incoming shellstock tags	• Visual	• Every sack	• Receiving employee	• Reject untagged sacks	• Receiving record	• Review monitoring and corrective action records within one week of preparation
		• All shellstock must be from open waters	• Harvest site on tags	• Visual	• Every lot	• Receiving employee	• Reject lots from unapproved waters	• Receiving record	
		• All shellstock must be from licensed fishermen.	• License of fisherman	• Visual	• Every delivery	• Receiving employee	• Reject lots from unlicensed fishermen	• Receiving record	
		• Maximum time from harvest to refrigeration: AMMAT <66°F: 36 hours; AMMAT 66-80°F: 24 hours; AMMAT >80°F: 20 hours.	• Time of harvest	• Harvester's log	• Every delivery	• Receiving employee	• Reject lot	• Receiving record	
			• Time placed in refrigeration	• Visual	• Every delivery	• Receiving employee	• Discontinue use of supplier until evidence is obtained that harvesting, tagging, and/or labeling practices have changed	• Receiving record	
Receiving - labels	Pathogens from harvest area	• All shellstock labels must contain the raw consumption warning	• Tags for finished product shellstock	• Visual	• Three tags from each lot of tags	• Receiving employee	• Reject tags	• Receiving record	• Review monitoring and corrective action records within one week of preparation

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Parasites (in the larval stage) consumed in uncooked, or undercooked, unfrozen seafood can present a human health hazard. Among parasites, the nematodes or roundworms (*Anisakis spp., Pseudoterranova spp., Eustrongylides spp.* and *Gnathostoma spp.*), cestodes or tapeworms (*Diphyllobothrium spp.*) and trematodes or flukes (*Chlonorchis sinensis, Opisthorchis spp., Heterophyes spp., Metagonimus spp., Nanophyetes salminicola and Paragonimus spp.*) are of most concern in seafood. Some products that have been implicated in human infection are: ceviche (fish and spices marinated in lime juice); lomi lomi (salmon marinated in lemon juice, onion and tomato); poisson cru (fish marinated in citrus juice, onion, tomato and coconut milk); herring roe; sashimi (slices of raw fish); sushi (pieces of raw fish with rice and other ingredients); green herring (lightly brined herring); drunken crabs (crabs marinated in wine and pepper); cold-smoked fish; and, undercooked grilled fish. A recent survey of U.S. gastroenterologists has confirmed that seafood-borne parasitic infections occur in the U.S. with sufficient frequency to make preventive controls necessary during the processing of parasite-containing species of fish that are intended for raw consumption.

- Controlling parasites

The process of heating raw fish sufficiently to kill bacterial pathogens is also sufficient to kill parasites. Guidance concerning cooking and pasteurizing to kill pathogens is provided in Chapters 16 and 17. Regulatory requirements for retorting (low acid canned foods) are contained in 21 CFR 113. This Guide does not provide further guidance on retorting.

The effectiveness of freezing to kill parasites depends on several factors, including the temperature of the freezing process, the length of time needed to freeze the fish tissue, the length of time the fish is held frozen, the fat content of the fish, and the type of parasite present. The temperature of the freezing process, the length of time the fish is held frozen, and the type of parasite appear to be the most important factors. For example, tapeworms are more susceptible to freezing than are roundworms. Flukes appear to be more resistant than roundworms.

Freezing and storing at -4˚F (-20˚C) or below for 7 days (total time), or freezing at -31˚F (-35˚C) or below until solid and storing at -31˚F (-35˚C) or below for 15 hours, or freezing at -31˚F (-35˚C) or below until solid and storing at -4˚F (-20˚C) or below for 24 hours is sufficient to kill parasites. FDA's Food Code recommends these freezing conditions to retailers who provide fish intended for raw consumption. Note: these conditions may not be suitable for freezing particularly large fish (e.g. thicker than six inches).

The effectiveness of hydrostatic pressure in the elimination of parasites from fish flesh is being studied.

Brining and pickling may reduce the parasite hazard in a fish, but they do not eliminate it, nor do they minimize it to an acceptable level. Nematode larvae have been shown to survive 28 days in an 80˚ salinometer brine (21% salt by weight).

Fish that contain parasites in their flesh may also contain parasites within their egg skeins, but generally not within the eggs themselves. For this reason, eggs that have been removed from the skein and rinsed are not likely to contain parasites.

Trimming away the belly flaps of fish or candling and physically removing parasites are effective methods for reducing the numbers of parasites. However, they do not completely eliminate the hazard, nor do they minimize it to an acceptable level.

Continued

STEP #11: ***DETERMINE IF THE HAZARD IS SIGNIFICANT.***

Determine if "parasites" is a significant hazard at each processing step.

1. Is it reasonably likely that parasites will be introduced at the receiving step (e.g. do they come in with the raw material)?

Tables #3-1 and 3-2 (Chapter 3) list those species for which FDA has information that a potential parasite hazard exists. Ordinarily, you should identify the receiving step for these species as having a significant parasite hazard if you will market the fish for consumption without cooking by the end user (e.g. raw).

Species that normally have parasites as a result of consuming infected prey, apparently do not have the same parasite hazard when raised on pelleted food in an aquaculture operation. You need not consider such aquacultured fish as having a parasite hazard.

On the other hand, aquacultured fish that are fed processing waste and by-catch fish may have a parasite hazard, even when wild caught fish of that species do not normally have a parasite hazard. Species of fish other than those identified in Tables #3-1 and 3-2 may have a parasite hazard in certain localized areas. You should consider this possibility in your hazard analysis.

If the finished product is fish eggs that have been removed from the skein and rinsed, it is not reasonably likely that it will contain parasites. You need not consider such product as having a parasite hazard. However, unrinsed fish eggs or fish eggs that remain in the skein ordinarily will have a parasite hazard if the species is identified in Tables #3-1 or 3-2 as having a parasite hazard.

It is not reasonably likely that parasites will enter the process at other processing steps.

2. Can the parasite hazard be eliminated or reduced to an acceptable level here? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12.)

Parasites should also be considered a significant hazard at any processing step where a preventive measure is or can be used to eliminate (or reduce the likelihood of occurrence to an acceptable level) parasites that are reasonably likely to come in with the raw material. Preventive measures for parasites can include:

- Retorting (covered in 21 CFR 113);
- Cooking (covered in Chapter 16);
- Pasteurizing (covered in Chapter 17);
- Freezing (covered in this chapter);
- Brining or pickling (not a complete control);
- Candling and physical removal (not a complete control);
- Trimming away the belly flap (not a complete control).

List such preventive measures in Column 5 of the Hazard Analysis Worksheet, at the appropriate processing step(s).

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

You should also consider the likelihood that, without proper controls, parasites would survive your cooking process. Some cooking processes (e.g. retorting) may be exceptionally lethal to parasites, because the process is designed to kill more heat-stable bacterial pathogens. In such cases, even significant underprocessing would not jeopardize the safety of the product relative to parasites, and it may not be necessary to identify "parasites" as a significant hazard.

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where the critical control point is located.

- Intended use

In determining whether a hazard is significant, you should also consider the intended use of the product, which you developed in Step #4. If the fish is intended to be cooked by the consumer before consumption, then you do not need to consider the hazard significant even if the species is listed as having a potential parasite hazard in Table #3-1 or 3-2. Similarly, if you have assurance that the fish will be processed by a subsequent processor, restauranteur or institutional user (e.g. prison, nursing home) in a way that will kill the parasites, you do not need to identify parasites as a significant hazard.

Example:
A primary processor receives whole salmon from the harvest vessel and re-ices the fish for shipment to a second processor. The primary processor has assurance that the second processor butchers the fish and freezes it for the sushi market. The primary processor would not need to identify parasites as a significant hazard.

It is important to note that, at certain levels in certain species of fish, parasites constitute filth, and, as a result, cause the fish to be adulterated. See Compliance Policy Guide section 540.590. However, since these defect action levels relate to a filth issue, preventive controls to assure that they are not exceeded need not be included in your HACCP plan.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "parasites" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "parasites":

1. Does the process contain a heating step, such as retorting, cooking, or pasteurizing, that is designed to kill pathogens?

   a. If it does, you may identify the heating step as the CCP.

      In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the heating step, and enter "No" for the receiving step. In addition, for the "No" entry, note in Column 5 that the hazard is controlled by the heating step. (Note: if you have not previously identified "parasites" as a significant hazard at the heating step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) See Chapters 16 (cooking) and 17 (pasteurizing) for further guidance on this control strategy.

      Example:
      A hot-smoked salmon processor could set the critical control point for parasites at the hot-smoking step, and would not need to identify the receiving step as a critical control point for this hazard.

   b. If the process does not contain a heating step, you should identify a freezing step as the CCP.

      In this case you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the freezing step, and enter "No" for the receiving step. In addition, for the "No" entry, note in Column 5 that the hazard is controlled by the freezing step. (Note: if you have not previously identified "parasites" as a significant hazard at the freezing step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) This control approach will be referred to as "Control Strategy Example 1" in Steps #14 through 18.

Continued

Example:

A salmon processor that sells the finished product for raw consumption should identify a freezing step as the CCP for parasites. The processor would not need to identify the receiving step as a critical control point for this hazard.

It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "parasites" is identified as a significant hazard on the HACCP Plan Form identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product will be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

Critical Limit: Freezing and storing at -4˚F (-20˚C) or below for 7 days (total time);

OR

Freezing at -31˚F (-35˚C) or below until solid and storing at -31˚F (-35˚C) or below for 15 hours;

OR

Freezing at -31˚F (-35˚C) or below until solid and storing at -4˚F (-20˚C) or below for 24 hours.

Note: these conditions may not be suitable for freezing particularly large fish (e.g. thicker than six inches).

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "parasites" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy example discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

What: Freezer temperature;
AND
Length of time fish is held at freezer temperature or held frozen, as appropriate.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

How: Use a recording thermometer, digital time/temperature data logger, or similar device;
AND
Visual check on time and solid frozen condition, as appropriate.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

For temperature:

Frequency: Continuous monitoring, with visual check at least once during the cycle, but no less than once per day.

For time:

Frequency: Start and end of each freezing cycle;
OR
Time when fish is solid frozen and end of freezing cycle for each freezing cycle.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

Who: Monitoring may be performed by the freezer operator, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the monitoring device and the critical limit.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "parasites" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

Corrective Action: Take one or more of the following actions as necessary to regain control over the operation after a critical limit deviation:
- Make repairs or adjustments to the freezer;

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

AND
Refreeze and store the product at -4˚F (-20˚C) or below for 7 days (total time), or refreeze at -31˚F (-35˚C) or below until solid and store at -31˚F (-35˚C) or below for 15 hours, or refreeze at -31˚F (-35˚C) or below until solid and store at -4˚F (-20˚C) or below for 24 hours.

Note: these conditions may not be suitable for freezing particularly large fish (e.g. thicker than six inches).

Continued

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "parasites" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a record keeping system for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

Records: Temperature recorder chart, digital time/temperature data logger printout, with notations for start and end of freezing cycle or time when fish is solid frozen and end of freezing cycle, as appropriate.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "parasites" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "parasites"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

Verification: When digital time/temperature data loggers, or recorder thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) at least once per day;

AND

Review monitoring, corrective action and verification records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #5-1

Control Strategy Example 1 - Freezing

This table is an example of a portion of a HACCP plan relating to the control of parasites for a processor of frozen salmon fillets with pin bones removed, where the finished product is distributed to other processors for the production of lox, using Control Strategy Example 1 - Freezing. It is provided for illustrative purposes only. Parasites may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, aquaculture drugs, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Freezing	Parasites	Freeze at -31°F or below until solid and hold at -4°F or below for 24 hours	• Temperature of blast freezer and storage freezer	• Recorder themometers	• Continuous, with visual check at end of each freezing cycle	• Freezer operator	• Adjust freezer • Refreeze product	• Recorder chart with notations for solid frozen and end of each cycle	• Review monitoring, corrective action and verification records within one week of preparation
			• Length of time held frozen	• Visual check of when first fish is solid frozen and at end of freezing cycle	• When fish is solid frozen and at end of each freezing cycle	• Freezer operator	• Same		• Check the accuracy of the temperature recording devices daily

Notes:

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Contamination of fish with natural toxins from the harvest area can cause consumer illness. Most of these toxins are produced by species of naturally occurring marine algae (phytoplankton). They accumulate in fish when they feed on the algae or on other fish that have fed on the algae. There are also a few natural toxins which are naturally occurring in certain species of fish.

There are five recognized fish poisoning syndromes in the United States: paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP), diarrhetic shellfish poisoning (DSP), amnesic shellfish poisoning (ASP), and ciguatera fish poisoning (CFP). Scombrotoxin formation, the subject of Chapter 7, is not considered a natural toxin.

- Species involved

This section will provide information about species and geographic areas which have been linked to one of the five fish poisoning syndromes by historical occurrence of the syndrome. However, it is important to note that historical occurrence may be an inadequate guide to future occurrence in the case of natural toxins, since the source algae vary in their distribution. Processors need to be alert to the potential for emerging problems.

Paralytic shellfish poisoning in the U.S. is generally associated with the consumption of molluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, Dungeness crabs, tanner crabs, and red rock crabs. While the viscera of mackerel are not normally eaten, the viscera of lobster and crabs are. However, the levels of PSP toxin that are found in lobster tomale are not likely to pose a health hazard unless large quantities are eaten from a heavily contaminated area.

Neurotoxic shellfish poisoning in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

Diarrhetic shellfish poisoning is generally associated with the consumption of molluscan shellfish. There has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produces the toxin has been found there. ASP toxin has recently been identified as a problem in the viscera of Dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States. The viscera of anchovies are also eaten.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. These species are not generally

Continued

associated with ciguatera in the northern Gulf of Mexico. Many other species of large fish-eating fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

• Natural toxin detection

FDA has established action levels for all of the natural toxins except CFP.

- PSP- 0.8 ppm (80ug/100g) saxitoxin equivalent;
- NSP- 0.8 ppm (20 mouse units/100g) brevetoxin-2 equivalent;
- DSP- 0.2 ppm okadaic acid plus 35-methyl okadaic acid (DXT 1);
- ASP- 20 ppm domoic acid, except in the viscera of Dungeness crab, where 30 ppm is permitted.

There are no validated, rapid methods that are suitable for shipboard, dockside, or commercial testing of lots of fish for any of these toxins.

• Natural toxin control

Natural toxins cannot be reliably eliminated by heat. However, severe heating processes, such as retorting, may be effective at reducing the levels of some natural toxins.

To minimize the risk of molluscan shellfish containing natural toxins from the harvest area, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on the presence of natural toxins. 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 then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been permitted. Molluscan shellfish include oysters, clams, mussels, and scallops, except where the scallop product contains the shucked adductor muscle only.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the processor's name, address, and certification number.

An established water classification system similar to the molluscan shellfish system is not in place for controlling CFP in fin fish. However, some states issue advisories regarding reefs that are known to be toxic. In areas where there is no such advisory system, fishermen and processors must depend on first-hand knowledge about the safety of the reefs from which they obtain fish.

Where PSP or ASP have become a problem in fin fish or crustaceans, states generally have closed or restricted the appropriate fisheries. In addition, removal and destruction of the viscera will eliminate the hazard.

• Escolar, puffer fish, and whelk

There are naturally occurring toxins in some species that do not involve marine algae. Escolar or oilfish (i.e. *Lepidocybium flavobrunneum, Ruvettus pretiosus*) contains a strong purgative oil, called gempylotoxin, that may cause diarrhea when consumed. FDA advises against importation and interstate marketing of these fish.

Puffer fish, or fugu, may contain tetrodotoxin. Poisonings from tetrodotoxin have usually been associated with the consumption of puffer fish from waters of the Indo-Pacific ocean regions. However, several reported cases of poisonings, including fatalities, involved puffer fish from the Atlantic Ocean, Gulf of Mexico, and Gulf of California. There have been no confirmed cases of poisonings from *Spheroides maculatus* but there is still reason for concern.

Tetramine is a toxin that is found in the salivary glands of *Neptunia* spp., a type of whelk. The hazard can be controlled by removing the glands.

FDA makes no recommendations in this Guide and has no specific expectations with regard to controls for tetrodotoxin or tetramine in processors' HACCP plans.

STEP #11: *DETERMINE IF THE POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "natural toxins" is a significant hazard. The criteria are:

1. Is it reasonably likely that unsafe levels of natural toxins will be introduced here (e.g. does it come in on the raw material at an unsafe level)?

Tables #3-1 and 3-2 (Chapter 3) identify the species of fish for which natural toxins is known to be a potential hazard. Under ordinary circumstances, it would be reasonably likely to expect that, without proper controls, natural toxins from the harvest area could enter the process at unsafe levels at the receiving step from those species. There may be circumstances in your geographic area that would allow you to conclude that it is not reasonably likely for a particular natural toxin to occur at unsafe levels in fish from your area. You should be guided by the historical occurrence of the toxin, at levels above the established guidance levels, in your geographic area. However, you should remain alert to the potential for emerging problems.

If you are receiving fish, other than molluscan shellfish, from another processor you should not need to identify "natural toxins" as a significant hazard. This hazard should have been fully controlled by the primary (first) processor.

2. Can natural toxins which were introduced at unsafe levels at an earlier step be eliminated or reduced to an acceptable level here? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12).

"Natural toxins" should also be considered a significant hazard at any processing step where a preventive measure is or can be used to eliminate (or is adequate to reduce the likelihood of occurrence to an acceptable level) unsafe levels of natural toxins that are reasonably likely to come in with the raw material. Preventive measures for "natural toxins" can include:

- Making sure that incoming fish have not been caught in an area that has been closed because of a natural toxin problem;
- Making sure that incoming fin fish have not been caught in an area for which there is a CFP advisory or for which you have knowledge there is a CFP problem;
- 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.

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at the receiving step and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

Continued

• Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, in most cases, it is not likely that the significance of this hazard will be affected by the intended use of the product. One exception is with products in which only the muscle tissue will be consumed. For example, where the finished product is only the shucked adductor muscle of the scallop, or the muscle tissue of a crab or finfish, it is reasonable to assume that the product as consumed will not contain natural toxins. Similarly, in species, such as mackerel, in which the viscera is not normally consumed, it is reasonable to assume that the product as consumed will not contain natural toxins. In either case you should then enter "No" in Column 3 of the Hazard Analysis Worksheet for each of the processing steps. For each "No" entry briefly explain in Column 4 that the product is consumed without the viscera. In this case, you need not complete Steps #12 through 18 for this hazard.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "natural toxins" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "natural toxins":

1. Where preventive measures, such as those described in Step #11 are available to you, the hazard of "natural toxins" can best be controlled at the receiving step.

In these cases, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 1" in Steps #14 through 18. Note that this control strategy is identical to Control Strategy Example 1 for "pathogens from the harvest area" (Chapter 4) and Control Strategy Example 6 for "environmental chemical contaminants and pesticides" (Chapter 9). If you choose an identical control strategy for two or more of these hazards, you may combine the hazards in the HACCP Plan Form.

It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "natural toxins" is identified as a significant hazard on the HACCP Plan Form identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product will be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Critical Limit: No fish may be harvested from:

- An area that is closed to fishing by foreign, federal, state, or local authorities;

OR

- An area that is the subject of a CFP advisory;

OR

- An area for which you have knowledge that there is a CFP problem;

AND

All shellstock (in-shell molluscan shellfish) must bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (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 (loose shellstock), the shellstock must be accompanied by a bill of lading or other similar shipping document that contains the same information.

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 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 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.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "natural toxins" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy example discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

Continued

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

For molluscan shellfish:

What:

- The tags on containers of shellstock. The Bill of Lading or other similar shipping document accompanying bulk shipments of shellstock;

AND

- The harvest site listed on the tag or on the Bill of Lading or other similar shipping document;

AND

- The labels on containers of shucked molluscan shellfish;

AND

- The license of fishermen, where applicable;

AND

- The certification number of suppliers (other than fishermen) of shellstock or shucked molluscan shellfish;

For other fish:

What: The harvest area location.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

For molluscan shellfish:

How: Make visual checks;

For other fish:

How: Ask the harvester for the harvest site at the time of receipt, or obtain the information from the harvester's catch record, where applicable.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

For Molluscan Shellfish:

Frequency:

- For checking tags: every container;

AND

- For checking harvest site: every lot;

AND

- For checking labels: at least three containers randomly selected from throughout every lot;

AND

- For checking licenses: every delivery;

AND

- For checking certification numbers: every delivery.

For other fish:

Frequency: Every lot of fish received.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Who: Monitoring may be performed by a receiving or production employee or supervisor, a member of the quality control staff, or any other person who has an understanding of the nature of the controls.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "natural toxins" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

For molluscan shellfish:

Corrective Action:

- Reject shellstock that is not properly tagged or is not accompanied by a proper shipping document;

AND

- Reject shucked molluscan shellfish that is not properly labeled;

AND

- Reject molluscan shellfish that has been harvested from unapproved waters;

AND

- Reject molluscan shellfish that is not from a licensed harvester or certified processor;

AND

- Discontinue use of supplier until evidence is obtained that harvesting, tagging, and/or labeling practices have changed.

Note: If an incoming lot that fails to meet a receiving critical limit is mistakenly accepted, and the error is later detected, the following actions should be taken: 1) the lot and any products processed from that lot should be destroyed, diverted to a nonfood use or to a use in which the critical limit is not applicable, or placed on hold until a food safety evaluation can be completed; and 2) any products processed from that lot that have already been distributed should be recalled and subjected to the actions described above.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

For other fish that fail to meet the CL:

Corrective Action: Reject the lot;
AND

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

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "natural toxins" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROLS

For molluscan shellfish shellstock:

Records: A 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;

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

AND
- Certification number of the shipper, where applicable.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

For shucked molluscan shellfish:

Records: Receiving record that documents:
- Date of receipt;

AND
- Quantity and type of shellfish;

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

For other fish:

Records: Receiving record that documents the harvest area.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "natural toxins" are identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "natural toxins"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Verification: Review monitoring and corrective action records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #6-1

Control Strategy Example 1 - Source control

This table is an example of a portion of a HACCP plan relating to the control of natural toxins for a fish processor in Hawaii that receives locally harvested barracuda, using Control Strategy Example 1 - Source control. It is provided for illustrative purposes only. Natural toxins may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants). Table #4-1 (Chapter 4) provides guidance for source controls for molluscan shellfish.

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving - fresh fish	Natural toxins - CFP	No fish may be harvested from an area that is covered by a State CFP advisory, or for which there is information from fishermen, news media, academia, or other sources that there is a current CFP problem.	Identify harvest area	Ask fishermen for the harvest location	Every lot	Receiving employee	Reject lot Discontinue use of supplier until evidence is obtained that harvesting practices have changed	Receiving record	Review monitoring and corrective action records within one week of preparation

Notes:

Hazard Analysis Worksheet

STEP #1O: *UNDERSTAND THE POTENTIAL HAZARD.*

Scombrotoxin formation as a result of time/temperature abuse of certain species of fish can cause consumer illness. The illness is most closely linked to the development of histamine in these fish. In most cases histamine levels in illness-causing fish have been above 200 ppm, often above 500 ppm. However, there is some evidence that other chemicals (e.g. biogenic amines, such as putrescine and cadaverine) may also play a role in the illness. The possible role of these chemicals in consumer illness is discussed in Chapter 8.

Scombroid poisonings have primarily been associated with the consumption of tuna, mahi mahi, and bluefish. However, Table #3-1 (Chapter 3) lists a number of species that are also capable of developing elevated levels of histamine when temperature abused.

- Scombrotoxin formation

Certain bacteria produce the enzyme histidine decarboxylase during growth. This enzyme reacts with free histidine, a naturally occurring chemical that is present in larger quantities in some fish than in others. The result is the formation of histamine.

Histamine-forming bacteria are capable of growing and producing histamine over a wide temperature range. Growth is more rapid, however, at high-abuse temperatures (e.g. 70˚F [21.1˚C]) than at moderate-abuse temperatures (e.g. 45˚F [7.2˚C]). Growth is particularly rapid at temperatures near 90˚F (32.2˚C). Histamine is more commonly the result of high temperature spoilage than of long term, relatively low temperature spoilage. Nonetheless, there are a number of opportunities for histamine to form under more moderate abuse temperature conditions.

Once the enzyme histidine decarboxylase has been formed, it can continue to produce histamine in the fish even if the bacteria are not active. The enzyme can be active at or near refrigeration temperatures. The enzyme is likely to remain stable while in the frozen state and may be reactivated very rapidly after thawing.

Freezing may inactivate the enzyme-forming bacteria. Both the enzyme and the bacteria can be inactivated by cooking. However, once histamine is formed, it cannot be eliminated by heat (including retorting) or freezing. After cooking, recontamination of the fish with the enzyme-forming bacteria is necessary for additional histamine to form. For these reasons, histamine development is more likely in raw, unfrozen fish.

The kinds of bacteria that are associated with histamine development are commonly present in the salt water environment. They naturally exist on the gills and in the gut of live, salt water fish, with no harm to the fish. Upon death, the defense mechanisms of the fish no longer inhibit bacterial growth, and histamine-forming bacteria start to grow and produce histamine. Evisceration and removal of the gills in a sanitary manner may reduce, but not eliminate, the number of histamine-forming bacteria. However, when done under insanitary conditions, these steps may accelerate the process of histamine development in the edible portions of the fish by spreading the bacteria to the flesh of the fish.

With some harvesting practices, such as long lining, death can occur before the fish is removed from the water. Under the worst conditions histamine formation can already be underway before the fish is landed on the vessel. This condition can be aggravated when the fish is allowed to remain on the line for a period of time after death, a situation that in certain tuna species may cause its internal temperature to increase to a more favorable growth range for the enzyme-forming bacteria.

Continued

The potential for histamine formation is increased when the flesh of the fish is directly exposed to the enzyme-forming bacteria. This occurs when the fish are processed (e.g. butchering or filleting).

At least some of the histamine-forming bacteria are halotolerant (salt-tolerant) or halophilic (salt-loving). This causes some salted and smoked fish products produced from scombrotoxin-forming species to continue to be suspect for histamine development. Further, a number of the histamine-forming bacteria are facultative anaerobes that can grow in reduced oxygen environments.

- Controlling scombrotoxin formation

Rapid chilling of fish immediately after death is the most important element in any strategy for preventing the formation of scombrotoxin, especially for fish that are exposed to warmer waters or air, and for large tuna that generate heat in the tissues of the fish following death. It is recommended that:

- Generally, fish should be placed in ice or in refrigerated seawater or brine at 40˚F (4.4˚C) or less within 12 hours of death, or placed in refrigerated seawater or brine at 50˚F (10˚C) or less within 9 hours of death;
- Fish exposed to air or water temperatures above 83˚F (28.3˚C), or large tuna (i.e., above 20 lbs.) that are eviscerated before on-board chilling, should be placed in ice (including packing the belly cavity of large tuna with ice) or in refrigerated seawater or brine at 40˚F (4.4˚C) or less within 6 hours of death;
- Large tuna (i.e., above 20 lbs.) that are not eviscerated before on-board chilling should be chilled to an internal temperature of 50˚F (10˚C) or less within 6 hours of death.

This will prevent the rapid formation of the enzyme histidine decarboxylase. Once this enzyme is formed, control of the hazard is unlikely.

Further chilling towards the freezing point is also desirable to safe-guard against longer-term, low-temperature development of histamine. Additionally, the shelf-life of the fish is significantly compromised when product temperature is not rapidly dropped to near freezing.

The time required to lower the internal temperature of fish after capture will be dependent upon a number of factors, including:

- The harvest method;
  - Delays in removing fish from a long line may significantly limit the amount of time left for chilling and may allow some fish to heat up after death;
  - The quantity of fish landed in a purse seine or on a long line may exceed a vessel's ability to rapidly chill the product;
- The size of the fish;
- The chilling method;
  - Ice alone takes longer to chill fish than does an ice slurry or recirculated refrigerated sea water or brine, a consequence of reduced contact area and heat transfer;
  - The quantity of ice or ice slurry and the capacity of refrigerated sea water or brine systems must be suitable for the quantity of catch.

Once chilled, the fish should be maintained as close as possible to the freezing point (or held frozen) until it is consumed. Exposure to ambient temperature should be minimized. The allowable exposure time is dependent primarily upon the speed with which the fish were chilled on-board the harvest vessel and whether the fish has been previously frozen (e.g. on-board the harvest vessel).

Unfrozen scombrotoxin-forming fish has a safe shelf-life (days before elevated levels of histamine are formed) that is dependent upon the harvest methods, the on-board handling, and the time/temperature exposures throughout processing, transit, and storage. This safe shelf-life can be as little as 5 to 7 days for product stored at 40˚F (4.4˚C).

Any exposure time above 40˚F (4.4˚C) significantly reduces the expected safe shelf-life. For this reason, fish that have not been previously frozen should not be exposed to temperatures above 40˚F (4.4C) for more than 4 hours, cumulatively, if any portion of that time is at temperatures above 70˚F (21˚C); or the fish should not be exposed to ambient temperatures above 40˚F (4.4˚C) for more than 8 hours, cumulatively, as long as no portion of that time is at tempera

tures above 70˚F (21˚C) after chilling on board the harvest vessel. The safety of these limits is dependent upon proper handling at sea.

Fish that have been previously frozen can safely withstand considerably more exposure to elevated temperatures during post-harvest handling. Such fish should not be exposed to temperatures above 40˚F (4.4C) for more than 12 hours, cumulatively, if any portion of that time is at temperatures above 70˚F (21˚C); or the fish should not be exposed to ambient temperatures above 40˚F (4.4˚C) for more than 24 hours, cumulatively, as long as no portion of that time is at temperatures above 70˚F (21˚C), after chilling on board the harvest vessel. The safety of these limits is again dependent upon proper handling at sea.

Extended frozen storage (e.g. 24 weeks) or cooking minimizes the risk of additional histamine development by inactivating the enzyme-forming bacteria and, in the case of cooking, the enzyme itself. As previously mentioned, recontamination with enzyme-forming bacteria and significant temperature abuse is necessary for histamine formation under these conditions. Such recontamination may not be likely if the fish is processed under a conscientious sanitation program.

- Detection

Sensory evaluation is generally used to screen fish for spoilage odors that develop when the fish is exposed to time/temperature abuse. It is an effective means of detecting fish that have been subjected to a variety of abusive conditions.

However, odors of decomposition that are typical of relatively low temperature spoilage may not be present if the fish has undergone high temperature spoilage. This condition makes sensory examination alone an ineffective control for scombrotoxin.

Chemical testing is an effective means of detecting the presence of histamine in fish flesh. However, the validity of such testing is dependent upon the design of the sampling plan. The amount of sampling required to accommodate such variability is necessarily quite large. For this reason, chemical testing alone will not normally provide adequate assurance that the hazard has been controlled. Because histamine is generally not uniformly distributed in a decomposed fish, a guidance level of 50 ppm has been set. If 50 ppm is found in one section, there is the possibility that other sections may exceed 500 ppm.

Observations for the presence of honeycombing in precooked tuna loins intended for canning is also a valuable means of screening for fish that have been exposed to the kinds of temperature abuse that can lead to histamine development. Any fish that demonstrate the trait should be destroyed.

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "scombrotoxin formation" is a significant hazard. The criteria are:

1. Is it reasonably likely that unsafe levels of histamine will be introduced at this processing step (do unsafe levels come in with the raw material)?

Table #3-1 (Chapter 3) lists those species of fish that are generally known to be capable of producing elevated levels of histamine if temperature abused. This is because they contain naturally high levels of free histidine. It is also because they are marine fish that are likely to harbor the kinds of bacteria that produce histidine decarboxylase. It is, therefore, reasonable to assume that, without proper on-board controls, these species of fish will contain unsafe levels of histamine upon receipt by the primary (first) processor.

However, if the worst case environmental conditions (i.e. air and water temperatures) during the harvest season in a particular region would not permit the formation of histamine during the time necessary to harvest and transport the fish to the primary processor, on-board controls may not be necessary. For example, such conditions might exist if the fish are harvested when air and water temperatures do not exceed 40˚F (4.4˚C), or when the combination of air and water temperature and harvest/transport time are such that histamine formation is not reasonably likely to occur, as documented by a scientific study.

Continued

It is also reasonable to assume that, without proper controls during refrigerated (not frozen) transportation between processors, scombrotoxin-forming species of fish will contain unsafe levels of histamine upon receipt by the secondary processor (including warehouses). However, this may not be the case if the product being received is a cooked or frozen fish or fishery product.

Nevertheless, you may need to exercise control when receiving a refrigerated (not frozen) product from another processor to prevent pathogen growth or toxin formation (see Chapter 12).

2. Is it reasonably likely that unsafe levels of histamine will form at this processing step?

To answer this question you should consider the potential for time/temperature abuse in the absence of controls. You may already have controls in your process that minimize the potential for time/temperature abuse that could result in unsafe levels of histamine. This and the following steps will help you determine whether those or other controls should be included in your HACCP plan.

Time/temperature abuse that occurs at successive processing and storage steps may be sufficient to result in unsafe levels of histamine, even when abuse at one step alone would not result in such levels. For this reason, you should consider the cumulative effect of time/temperature abuse during the entire process. Information is provided in Step #10 to help you assess the significance of time/temperature abuse that may occur in your process.

3. Can the formation of unsafe levels of histamine that are reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12.)

"Scombrotoxin formation" should also be considered a significant hazard at any processing or storage step where a preventive measure is or can be used to eliminate the hazard, if it is reasonably likely to occur. Preventive measures for "scombrotoxin formation" can include:

- Making sure through harvest vessel records that incoming fish were properly handled on-board the harvest vessel, including:
  - Rapidly chilling the fish immediately after death;
  - Controlling on-board refrigeration (other than frozen storage) temperatures;
  - Proper on-board icing;
- Testing incoming fish for histamine levels;
- Making sure that incoming fish were handled properly during refrigerated transportation from the previous processor, including:
  - Controlling refrigeration temperatures during transit;
  - Proper icing during transit;
- Checking incoming fish to ensure that they are not at an elevated temperature at time of receipt;
- Checking incoming fish to ensure that they are properly iced or refrigerated at time of receipt;
- Performing sensory examination on incoming fish to ensure that they do not show signs of decom position;
- Controlling refrigeration temperatures in your plant;
- Proper icing in your plant;
- Controlling the amount of time that the product is exposed to temperatures that would permit histamine formation during processing and storage.

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1, 2 or 3 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If none of the criteria is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

- Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, because of the stable nature of histamine, the intended use of the product is not likely to affect the significance of this hazard.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "scombrotoxin formation" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for scombrotoxin formation:

1. If you identified scombrotoxin formation as a significant hazard at the receiving step in Step #11, you should also identify receiving as a CCP for this hazard. Preventive measures, such as the first six described in Step #11, should be available to you at that step.

In this case you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. A control approach which includes screening incoming fish through harvest vessel records for on-board handling practices will be referred to as "Control Strategy Example 1" in Steps #14-18. A control approach which includes screening incoming fish through histamine testing will be referred to as "Control Strategy Example 2" in Steps #14-18. A control approach which includes screening incoming fish to ensure proper handling during transit from the previous processor will be referred to as "Control Strategy Example 3" in Steps #14-18.

2. If you identified scombrotoxin formation as a significant hazard at a processing or storage step in Step #11, it may be necessary for you to also identify that processing step as a CCP for this hazard. Preventive measures, such as the last three described in Step #11, should be available to you at those steps.

Example:
A fresh mahi mahi processor identifies a series of processing and storage steps (e.g. butchering, packaging, and refrigerated storage) as presenting a reasonable likelihood of scombrotoxin formation. The processor controls temperature during storage and time of exposure to unrefrigerated conditions during the processing steps. The processor identifies each of these processing and storage steps as CCPs for this hazard.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for each of those processing steps. This control approach will be referred to as "Control Strategy Example 1, 2 and 3" in Steps #14-18. It may apply to any of the three previously described control strategies.

It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

- Likely CCPs

Following is further guidance on processing steps that are likely to be identified as critical control points for this hazard:
- Receiving;
- Processing, such as:
  - Thawing;
  - Brining;
  - Heading and gutting;
  - Manual filleting and steaking;
  - Stuffing;
  - Mixing;
  - Portioning;
- Packaging;
- Final chilling after processing and packaging;
- Raw material, in-process product, and finished product refrigerated storage.

(Note: Rather than identify each processing step as an individual CCP when the controls are the same at those steps, it may be more convenient to combine into one CCP those processing steps that together contribute to a cumulative time/temperature exposure.)

Continued

- Unlikely CCPs

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

- Continuous, mechanical processing steps that are brief, such as:
  - Mechanical filleting;
- Processing steps that are brief and unlikely to contribute significantly to the cumulative time/temperature exposure, such as:
  - Date code stamping;
  - Case packing;
- Processing steps where the product is held in a frozen state, such as:
  - Assembly of orders for distribution;
  - Frozen product storage;
- Retorting and post-retorting steps (if the product is covered by the LACF regulations, 21 CFR 113);
- Canned tuna "precooking" and steps after precooking, if sanitation practices are sufficient to prevent recontamination with enzyme-forming bacteria.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "scombrotoxin formation" is identified as a significant hazard on the HACCP Plan Form, identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

Critical Limit: All lots received are accompanied by harvest vessel records that show:

- Generally, the fish were:
  - Placed in ice, or in refrigerated seawater or brine at 40˚F (4.4˚C) or less, within 12 hours of death;
    OR
  - Placed in refrigerated seawater or brine at 50˚F (10˚C) or less within 9 hours of death and chilling continued to bring the internal temperature of the fish to 40˚F (4.4˚C) or less;

OR

- Fish exposed to air or water temperatures above 83˚F (28.3˚C),), or large tuna (i.e., above 20 lbs.) that are eviscerated before on-board chilling, should be placed in ice (including packing the belly cavity of large tuna with ice) or in refrigerated seawater or brine at 40˚F (4.4˚C) or less within 6 hours of death;

OR

- Large tuna (i.e., above 20 lbs.) that are not eviscerated before on-board chilling: The internal temperature of the fish was brought to 50˚F (10˚C) or less within 6 hours of death and chilling continued to bring the internal temperature of the fish to 40˚F (4.4˚C) or less;

OR

- Other critical limits for on-board handling (e.g. maximum refrigerated brine or seawater temperature, maximum fish size, maximum fish to brine/seawater/ice ratio, maximum ambient temperature exposure time before chilling) necessary to achieve a cooling rate that will prevent development of histamine in the specific species, as established through a scientific study;

AND

- For fish held refrigerated (not frozen) on-board the vessel: The fish were stored at or below 40˚F (4.4˚C) thereafter;

AND

- Sensory examination of a representative sample of fish shows no more than 2.5% decomposition (persistent and readily perceptible) in the sample. For example, no more than 3 fish in a sample of 118 fish may show signs of decomposition;

AND

- For fish held iced or refrigerated (not frozen) on-board the vessel and delivered 24 or more hours after death: The internal temperature should be 40˚F (4.4˚C) or below;

OR

- For fish held iced or refrigerated (not frozen) on-board the vessel and delivered from 12 to less than 24 hours after death: The internal temperature should be 50˚F (10˚C) or below;

OR

- For fish held iced or refrigerated (not frozen) on-board the vessel and delivered in less than 12 hours after death: The internal temperature should demonstrate that appropriate chilling methods were used onboard the harvest vessel. Chilling of the fish must begin on the harvest vessel regardless of the time from death to delivery, unless the environmental conditions (e.g. air and water temperatures) are consistently below 40˚F (4.4˚C) from the time of death to delivery.

- CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

Critical Limit: Analysis of a representative sample of fish shows less than 50 ppm histamine in all fish in the sample;

AND

- Sensory examination of a representative sample of fish shows no more than 2.5% decomposition (persistent and readily perceptible) in the sample. For example, no more than 3 fish in a sample of 118 fish may show signs of decomposition;

AND

- For fish held iced or refrigerated (not frozen) on-board the vessel and delivered 24 or more hours after death: The internal temperature should be 40˚F (4.4˚C) or below;

OR

- For fish held iced or refrigerated (not frozen) on-board the vessel and delivered from 12 to less than 24 hours after death: The internal temperature should be 50˚F (10˚C) or below;

OR

- For fish held iced or refrigerated (not frozen) on-board the vessel and delivered in less than 12 hours after death: The internal temperature should demonstrate that appropriate chilling methods were used onboard the harvest vessel. Chilling of the fish must begin on the harvest vessel regardless of the time from death to delivery, unless the environmental conditions (e.g. air and water temperatures) are consistently below 40˚F (4.4˚C) from the time of death to delivery.

Continued

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

Critical Limit: For fish delivered refrigerated (not frozen): All lots received are accompanied by transportation records that show that the fish were held at or below 40˚F (4.4˚C) throughout transit;
OR
For fish held under ice or chemical cooling media: There is an adequate quantity of ice or other cooling media at the time of delivery to completely surround the product.

- CONTROL STRATEGY EXAMPLE 1, 2 & 3

For processing steps:

Critical Limit: During processing and refrigerated (not frozen) storage that occurs before cooking (e.g. canned tuna "precook"): For fish that have not been previously frozen:

- The fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 4 hours, cumulatively, if any portion of that time is at temperatures above 70˚F (21˚C);

OR

- The fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 8 hours, cumulatively, as long as no portion of that time is at temperatures above 70˚F (21˚C);

  (Note: Only one of the above two limits may be selected. They may not be added for a total exposure of 12 hours.)

OR

- For fish that have been previously frozen: The fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 12 hours, cumulatively, if any portion of that time is at temperatures above 70˚F (21˚C);

OR

- The fish are not exposed to ambient temperatures above 40˚F (4.4˚C) for more than 24 hours, cumulatively, as long as no portion of that time is at temperatures above 70˚F (21˚C).

  (Note: Only one of the above two limits may be selected. They may not be added for a total exposure of 12 hours.)

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "scombrotoxin formation" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy examples discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

What: Harvest vessel records containing the following information:

- Method of capture*;

AND

- Date and time of landing;

AND

- Where applicable to the critical limit, the air and water temperatures at time of landing on board the vessel*;

AND

- Estimated earliest date and time of death for fish landed at the same time (if other than time of landing)*;

AND

- Where applicable to the critical limit, method of cooling* and temperature of cooling media;

AND

- Where applicable to the critical limit, date and time cooling began;

AND

- Where applicable to the critical limit, cooling rate, as evidenced by:
  - Internal fish temperatures after 6 hours of cooling (or time when 50˚F [10˚C] is reached) for a representative number of the largest fish in the lot;

  OR

  - Those factors of the cooling process that have been established through a scientific study as critical to achieving the cooling rate critical limits (e.g. refrigerated brine or seawater temperature, fish size, fish to brine/seawater/ice ratio);

AND

- For fish held iced or refrigerated (not frozen) on-board the vessel: The storage temperature, as evidenced by:
  - The temperature of refrigerated seawater or brine in which the fish are stored;

  OR

  - The presence of an adequate quantity of ice to surround the fish;

AND

Date and time of off-loading;

AND

Decomposition in the lot;

AND

For fish held iced or refrigerated (not frozen) on-board the vessel: The internal temperature of a representative number of the largest fish in the lot at the time of delivery, concentrating on those that show signs of having been mishandled (e.g. inadequately iced).

* The asterisked information above may be documented by the primary (first) processor on the receiving records, rather than by the harvest vessel operator on the harvest vessel records, if the primary processor is knowledgeable about such factors. The other on-board handling information should be documented by the vessel operator. All of the relevant information should be maintained by the primary processor.

As an alternative to the primary processor receiving harvest vessel records that are maintained by the vessel operator, certain harvest operations may lend themselves to monitoring and record keeping entirely by the primary processor. This arrangement is suitable only if the primary processor has direct knowledge about those aspects of the harvesting practices that must be controlled to ensure that the appropriate critical limits are met.

Example:
A primary processor receives bluefish from several day-boats that catch the fish when the air and water temperatures are below 83˚F (28.3˚C). The day-boats take on ice at the processor's facility immediately before setting out for the day, and return within 12 hours to the processor's facility with the iced catch. The processor monitors and records: the date and time of departure of the vessels after they take on ice; the date and time of the vessels' return; the ambient water and air temperatures of the fishing grounds; and the adequacy of icing of the catch. The processor also conducts sensory evaluations and checks the internal temperature of the catch upon arrival. The harvest vessel operators perform no monitoring or record keeping.

Continued

- CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

What: Histamine content in the fish flesh;
AND
Decomposition in the lot;
AND
Date and time of off-loading;
AND
For fish held iced or refrigerated (not frozen) on-board the vessel: The internal temperature of a representative number of the largest fish in the lot at the time of delivery, concentrating on those that show signs of having been mishandled (e.g. inadequately iced).

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

What: For fish delivered refrigerated (not frozen): The internal temperature of the fish throughout transportation;
OR
For fish delivered refrigerated (not frozen): The temperature of the truck or other carrier throughout transportation;
OR
For fish delivered refrigerated (not frozen), with a transit time of four hours or less: The internal temperature of a representative number of fish in the lot at the time of delivery;
OR
For fish held under ice or chemical cooling media: The adequacy of ice or chemical cooling media at the time of delivery.

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

What: For raw material, in-process, or finished product refrigerated storage, or for refrigerated processing: The temperature of the cooler or the refrigerated processing area;
OR
For raw material, in-process, or finished product storage under ice or chemical cooling media: The adequacy of ice or chemical cooling media;
AND
For processing and packaging: The length of time the fish are exposed to unrefrigerated conditions (i.e., above 40˚F [4.4˚C]), and the ambient temperatures during the exposure periods.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

How: Review of harvest vessel records.
Temperature monitoring on the vessel should be performed using dial thermometers, digital time/temperature data loggers, or recorder thermometers;
AND
Sensory examination of at least 118 fish in each lot (or the entire lot, for lots smaller than 118 fish). Lots should consist of only one specie of fish. Note: If the fish are received frozen, this monitoring procedure may be performed by a sensory examination on the warmed flesh produced by drilling the frozen fish (drill method). It may also be performed after thawing, rather than at receipt;
AND
For fish held iced or refrigerated (not frozen) on-board the vessel: Use a dial or digital thermometer to measure the internal temperature of a representative number of the largest fish in each lot, concentrating on those that show signs

of having been mishandled (e.g. inadequately iced). For example, when receiving 10 tons or more of fish, measure a minimum of one fish per ton, and when receiving less than 10 tons of fish, measure a minimum of one fish per 1000 pounds. Measure a minimum of 12 fish, unless there are fewer than 12 fish in the lot, in which case measure all of the fish. Randomly select fish from throughout the lot. Lots that show a high level of temperature variability may require a larger sample size.

- CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

How: Histamine analysis of a minimum of 18 fish per lot where the fish are the same species and of common origin, unless there are fewer than 18 fish in the lot, in which case test all of the fish. The fish collected for analysis may be composited for analysis if the critical limit is reduced accordingly. For example, a sample of 18 fish may be composited into 6 units of 3 fish each, provided the critical limit is reduced from 50 ppm to 17 ppm for each unit;

AND

Sensory examination of at least 118 fish in each lot (or the entire lot for lots smaller than 118 fish). Lots should consist of only one specie of fish. Note: If the fish are received frozen, this monitoring procedure may be performed using the drill method. It may also be performed after thawing, rather than at receipt;

AND

For fish held iced or refrigerated (not frozen) on-board the vessel: Use a dial or digital thermometer to measure the internal temperature of a representative number of the largest fish in each lot, concentrating on those that show signs of having been mishandled (e.g. inadequately iced). For example, when receiving 10 tons or more of fish, measure a minimum of one fish per ton, and when receiving less than 10 tons of fish, measure a minimum of one fish per 1000 pounds. Measure a minimum of 12 fish, unless there are fewer than 12 fish in the lot, in which case measure all of the fish. Randomly select fish from throughout the lot. Lots that show a high level of temperature variability may require a larger sample size.

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

How: For fish delivered refrigerated (not frozen):

- Use a time/temperature integrator for internal product temperature monitoring during transit;

OR

- Use a digital time/temperature data logger for internal product temperature or ambient air temperature monitoring during transit;

OR

- Use a recorder thermometer for ambient air temperature monitoring during transit;

OR

- Use a dial or digital thermometer for internal product temperature monitoring at receipt;

OR

For fish held under ice or chemical cooling media: Make visual observations of the adequacy of ice or other cooling median a sufficient number of containers (e.g. cartons, totes, etc.) to represent all of the product.

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

How: For raw material, in-process, or finished product refrigerated storage or for refrigerated processing:

- Use a digital time/temperature data logger;

OR

- Use a recorder thermometer;

OR

- Use a high temperature alarm within 24-hour monitoring;

OR

For raw material, in-process, or finished product storage under ice or chemical cooling media: Make visual observations of the adequacy of ice or chemical cooling media in a sufficient number of containers (e.g. cartons, totes, etc.) to represent all of the product.;

Continued

AND

For processing and packaging:

- Make visual observations of the length of exposure to unrefrigerated conditions (i.e., above 40˚F [4.4˚C]);

AND

- Use a dial or digital thermometer to determine ambient air temperature.

Example:
A canned tuna processor using raw material that was not previously frozen has identified a series of processing steps as critical control points for scombrotoxin formation. The processor establishes a critical limit of no more than four cumulative hours of exposure to unrefrigerated temperatures in excess of 40˚F (4.4˚C) during these processing steps. The processor uses marked product to monitor the progress of the product through the processing steps. The time that the marked product is removed from and returned to refrigeration is monitored visually and recorded and the ambient air temperature is determined using a digital thermometer and recorded.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLES 1 & 2

For receipt by primary (first) processor:

Frequency: Every lot received.

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

Frequency: Every lot received.

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

Frequency: For raw material, in-process, or finished product refrigerated storage, or for refigerated processing: Continuous monitoring by the instrument itself, with visual check of the instrument at least once per day;

OR

For raw material, in-process, or finished product storage under ice or chemical cooling media:

- At least twice per day;

OR

- For finished product storage, at least immediately prior to shipment;

AND

For processing and packaging: At least every two hours.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

Who: With recorder thermometers, time/temperature integrators, high temperature alarms, maximum indicating thermometers, and digital data loggers, monitoring is performed by the equipment itself. However, anytime that such instruments are used, a visual check should be made at least once per day in order to ensure that the critical limits have consistently been met. Monitoring on-board the harvest vessel is performed by a member of the vessel's crew. However, the on-board records should be reviewed as part of monitoring at receipt to ensure that the critical limits were consistently met. These checks, as well as dial thermometer checks, time of exposure checks, and adequacy of ice or other cooling media checks may be performed by the receiving employee, the equipment operator, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the process and the monitoring procedure. Sensory examinations and histamine analyses should be performed by individuals who are qualified by training and experience.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "scombrotoxin formation" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

Corrective Action: In the absence of harvester records, or when one of the harvester critical limits has been violated, or when the internal temperature critical limit at receiving has been violated:

- Reject the lot;

OR

- Perform histamine analysis on the lot (i.e. fish of common origin) by analyzing 60 fish (or the entire lot for lots smaller than 60 fish) and rejecting the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found. The fish collected for analysis may be composited for analysis if the critical limit is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

AND

When the sensory examination critical limit has been violated:

- Reject the lot;

OR

- Perform histamine analysis on all fish that show decomposition (persistent and readily perceptible) and reject the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the rate recommended above (i. e. 60 fish per lot), rejecting those portions where a unit greater than or equal to 50 ppm is found;

OR

- Perform histamine analysis on the lot (i.e. fish of common origin) by analyzing 60 fish (or the entire lot for lots smaller than 60 fish) and rejecting the lot if any are found with hista mine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found. The fish collected for analysis may be composited for analysis if the critical limit is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

AND

- Perform a sensory examination of all fish in the lot;

AND

Any individual fish found to be decomposed (persistent and readily perceptible) should be destroyed or diverted to a non-food use;

AND

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

Continued

- CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

Corrective Action: When the histamine level or internal temperature critical limit at the receiving step has been violated:
- Reject the lot;

OR
- Subdivide the lot and analyze each portion at the rate recommended above (i.e. 60 fish per lot), rejecting those portions where a unit with 50 ppm or more histamine is found. The fish collected for analysis may be composited for analysis if the critical limit is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit.;

AND

When the sensory examination critical limit has been violated:
- Reject the lot;

OR
- Perform histamine analysis on all fish that show decomposition (persistent and readily perceptible) and reject the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the rate recommended above (i.e. 60 fish per lot), rejecting those portions where a unit greater than or equal to 50 ppm is found;

OR
- Perform histamine analysis on the lot (i.e. fish of common origin) by analyzing 60 fish (or the entire lot for lots smaller than 60 fish) and rejecting the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found. The fish collected for analysis may be composited for analysis if the critical limit is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit;

AND
- Perform a sensory examination of all fish in the lot;

AND

Any individual fish found to be decomposed (persistent and readily perceptible) should be destroyed or diverted to non-food use;

AND

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

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

Corrective Action: In the absence of transportation records or when a critical limit at this processing step has been violated:
- Reject the lot;

OR
- Perform histamine analysis on the lot (i.e fish of common origin) by analyzing 60 fish (or the entire lot for lots smaller than 60 fish) and rejecting the lot if any are found with histamine greater than or equal to 50 ppm. If found, the lot may be subdivided and reanalyzed at the same rate, rejecting those portions where a unit greater than or equal to 50 ppm is found. The fish collected for analysis may be composited for analysis if the critical limit is reduced accordingly. For example, a sample of 60 fish may be composited into 20 units of 3 fish each, provided the action point is reduced from 50 ppm to 17 ppm for each unit.;

OR
- Hold the product until it can be evaluated based on its total transit time/temperature exposure and reject any product that has exceeded the critical limits described for the "Processing Steps" at Step 14;

AND

Discontinue use of supplier or carrier until evidence is obtained that transportation practices have changed.

• CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

Corrective Action: Take one or several of the following actions as necessary to regain control over the operation after a CL deviation:
- Add ice to the affected product;

OR
- Make repairs or adjustments to the malfunctioning cooler;

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

OR
- Return the affected in-process product to the cooler;

OR
- Freeze the affected product;

OR
- Modify the process as needed to reduce the exposure time/temperature;

AND

Take one of the following actions to product involved in the critical limit deviation:
- Destroy the product;

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

OR
- Perform histamine analysis on the lot of affected product by analyzing 60 fish (or the entire lot for lots smaller than 60 fish). If any fish are found with histamine at 50 ppm or greater the lot should be destroyed or diverted to a non-food use.

Note: If an incoming lot that fails to meet a receiving critical limit is mistakenly accepted, and the error is later detected, the following actions should be taken: 1) the lot and any products processed from that lot should be destroyed, diverted to a nonfood use or to a use in which the critical limit is not applicable, or placed on hold until a food safety evaluation can be completed; and 2) any products processed from that lot that have already been distributed should be recalled and subjected to the actions described above.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "scombrotoxin formation" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15.

The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy examples discussed in Step #12.

• CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

Records: Harvest vessel records, containing the information described in Step #15.

AND

Receiving records showing
- Date and time of off-loading;

AND
- Results of sensory examination;

AND
- For fish held iced or refrigerated (not frozen) on-board the vessel: Internal temperatures of the fish.

• CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

Records: Receiving records showing:
- Date and time of off-loading;

AND
- Results of histamine analysis;

AND
- Results of sensory examination;

AND
- For fish held iced or refrigerated (not frozen) on-board the vessel: Internal temperatures of the fish.

Continued

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

Records: Receiving records showing:
- The results of the time/temperature integrator checks;

OR
- Printouts from digital time/temperature data logger;

OR
- Recorder thermometer charts;

OR
- The results of internal product temperature monitoring at receipt;

AND
- The date and time of departure and arrival of the vehicle;

OR
- The results of the ice or other cooling media checks.

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

Records: For raw material, in-process, or finished product refrigerated storage, or for refrigerated processing:
- Printouts from digital time/temperature data logger;

OR
- Recorder thermometer charts;

OR
- Storage records showing the results of the high temperature alarm checks;

OR

For raw material, in-process, or finished product storage under ice or chemical cooling media: Storage records showing the results of the ice or other cooling media checks;

AND

For processing and packaging: Processing records showing the results of time/temperature exposure checks.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "scombrotoxin formation" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "scombrotoxin formation"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

For receipt by primary (first) processor:

Verification: Review monitoring, corrective action, and verification records within one week of preparation;

AND

Collect a representative sample of the raw material, in-process product, or finished product and analyze for histamine at least quarterly;

AND

When dial or digital thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter. (Note: optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.)

- CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

For receipt by primary (first) processor:

Verification: Review monitoring, corrective action, and verification records within one week of preparation;

AND

When dial or digital thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter

(Note: Optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.)

- CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

For receipt by secondary processor (including warehouse):

Verification: Review monitoring, corrective action, and verification records within one week of preparation;
AND
When digital time/temperature data loggers or recorder thermometers are used for monitoring of transport conditions at receipt, check for accuracy against a known accurate thermometer (NIST-traceable). Verification should be conducted on new suppliers' vehicles and at least quarterly for each supplier thereafter. Additional verifications may be warranted based on observations at receipt (e.g., refrigeration units appear to be in poor repair, or readings appear to be erroneous);
OR
When dial or digital thermometers are used for monitoring conditions at receipt, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter. (Note: Optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.);
OR
When visual checks of ice or cooling media are used to monitor the adequacy of coolant, periodically measure internal temperatures of fish to ensure that the ice or cooling media is sufficient to maintain product temperatures at 40˚F (4.4˚C) or less.

- CONTROL STRATEGY EXAMPLES 1, 2 & 3

For processing steps:

Verification: Review monitoring, corrective action, and verification records within one week of preparation;
AND
When digital time/temperature data loggers, recorder thermometers, or high temperature alarms are used for in-plant monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) at least once per day;
AND
When dial or digital thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter. (Note: Optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.);
OR
When visual checks of ice or cooling media are used to monitor the adequacy of coolant, periodically measure internal temperatures of fish to ensure that the ice or cooling media is sufficient to maintain product temperatures at 40˚F (4.4˚C) or less.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #7-1

Control Strategy Example 1 - Harvest vessel control

This table is an example of a portion of a HACCP plan relating to the control of scombrotoxin formation for a fresh mahi mahi processor that receives the fish on ice from harvest vessels, using Control Strategy Example 1 - Harvest vessel control. It is provided for illustrative purposes only. Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. food and color additives, metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving - fresh mahi mahi on ice from harvest vessels	Scombrotoxin formation	• All lots received are accompanied by harvest vessel records that show: 1) icing on board the harvest vessel was performed in accordance with the vessel's cooling rate study that validates cooling to 50°F or below within 6 hrs. of death regardless of maximum exposure temperature, or placement on ice within 12 hrs. of death if the maximum exposure temperature does not exceed 83°F; 2) method of capture; 3) date and time of landing; 4) estimated time of death; 5) method of cooling; 6) date and time cooling began; 7) sea and air temperature if exposure temperature exceeds 83°F; 8) adequacy of ice during on-board holding.	• Harvest vessel records	• Visual review of the records	• Every lot received	• Receiving supervisor	• Reject lot Discontinue use of supplier until evidence is obtained that harvesting practices have changed	• Harvester vessel records	• Histamine analysis on one incoming lot every three months (10 fish per sample) • Review monitoring, corrective action and verification records within one week of preparation
		• No more than 2.5% decomposition (persistent and readily perceptible) in the incoming lot	• Amount of decomposition in incoming lot	• Sensory examination (118 fish per lot; or all fish in the lot if <118 fish)	• Every lot received	• Quality control staff	• Reject lot Discontinue use of supplier until evidence is obtained that harvesting practices have changed	• Receiving record	• Same
		• If the fish are delivered in less than 12 hours after death, an internal temperature below ambient air and water temperatures; if the fish are delivered 12 or more hours after death, an internal temperature of 50°F or below; if the fish are delivered 24 or more hours after death, an internal temperature of 40°F or below	• Internal temperature of fish at time of delivery	• Digital thermometer (1 fish/1000 lbs for lots up to 10 tons; 1 fish/ton for lots 10 tons or greater; minimum of 12 fish/lot)	• Every lot received	• Receiving supervisor	• Reject lot Discontinue use of supplier until evidence is obtained that harvesting practices have changed	• Receiving record	• Same
			• Date and time of off-loading	• Clock	• Every lot received	• Receiving supervisor		• Receiving record	• Check accuracy of digital thermometer once per year

TABLE #7-1, continued

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Raw material storage	Scombrotoxin formation	• Product completely covered in ice throughout storage	• Adequacy of ice surrounding product	• Visual examination	• Every lot at time of removal from raw material storage cooler and at least twice a day for lots not removed	• Production supervisor	• Add ice • Hold lot and evaluate based on total time/temperature exposure during raw material and finished product storage and butchering/packaging. Destroy lot if time above 40˚F exceeds 4 hours cumulatively if any of that time is above 70˚F, or if time above 40˚F exceeds 8 hours cumulatively as long as no portion of that time is above 70˚F.	• Processing record	• Review monitoring and corrective action records within one week of preparation
Butchering/packaging	Scombrotoxin formation	• Product is not exposed to temperatures above 40˚F for more than 4 hours cumulatively if any of that time is above 70˚F, or above 40˚F for more than 8 hours as long as no portion of that time is above 70˚F hours cumulatively	• Time of product exposure to unrefrigerated conditions during butchering/packaging	• Visual tracking of time for marked product to move through butchering/packaging.	• Every batch of fish marked when removed from raw material storage.	• Quality control supervisor	• Destroy lot	• Processing record	• Review monitoring and corrective action records within one week of preparation
Finished product storage	Scombrotoxin formation	• Product completely covered in ice throughout storage	• Adequacy of ice surrounding product	• Visual examination	• Every lot at time of removal from finished product storage cooler for shipment	• Shipping supervisor	• Add ice • Hold lot and evaluate based on total time/temperature exposure during raw material and finished product storage and butchering/packaging. Destroy lot if time above 40˚F exceeds 4 hours cumulatively if any of that time is above 70˚F, or if time above 40˚F exceeds 8 hours cumulatively as long as no portion of that time is above 70˚F.	• Shipping record	• Review monitoring and corrective action records within one week of preparation

TABLE #7-2

Control Strategy Example 2 - Histamine testing

This table is an example of a portion of a HACCP plan relating to the control of scombrotoxin formation for a canned tuna processor, using Control Strategy Example 2 - Histamine testing. It is provided for illustrative purposes only. Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. *C. botulinum*).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving - frozen tuna from harvest vessels	Scombrotoxin formation	• Less than 50 ppm histamine in all fish in the sample	• Fish flesh for histamine content	• Histamine analysis of 18 fish per lot	• Every lot received	• Quality assurance staff	• Subdivide lot and examine 60 fish per sub-lot for histamine. Reject sub-lots with one or more fish at 50 ppm or greater	• Reports of analysis	• Review monitoring, corrective action and verification records within one week of preparation
		• No more than 3 decomposed fish (persistent and readily perceptible) in a 118 fish sample	• Amount of decomposition in incoming lot	• Sensory examination (118 fish per lot, or all fish if lot is <118 fish)	• Every lot received	• Quality assurance staff	• Reject the lot • Discontinue use of supplier until evidence is obtained that harvesting practices have changed	• Quality assurance record	
Thawing, butchering and precook staging	Scombrotoxin formation	• No more than 24 hours at ambient air temperatures above 40°F or, if temperatures ever exceed 70°F, no more than 12 hours above 40°F, cumulative time for thawing, butchering, and precook staging.	• Time of product exposure to unrefrigerated conditions during thawing, butchering and precook staging	• Visual observation of time for marked product to move through process	• Start marked product at start of every thaw process	• Quality assurance staff	• Make adjustments to the thawing, butchering and precook staging process AND • Analyze representative sample of lot for histamine. Divert to non-food use if any unit is 50 ppm or greater	• Processing record	• Review monitoring and corrective action records within one week of preparation

Chapter 7 covers scombrotoxic poisonings in certain species of fish. These poisonings occur as a result of the formation of high levels of histamine during decomposition of the fish at improper holding temperatures.

There are indications that decomposition can result in the production of other toxins (e.g. biogenic amines, such as putrescine and cadaverine) that have the potential to cause illness, even in the absence of histamine formation. Such illnesses have been reported in a number of fish species. FDA has also received a number of consumer complaints concerning illnesses that are associated with the consumption of decomposed shrimp.

The agency intends to further evaluate the relationship between decomposition and illness. Guidance will be issued when the causes of these health effects are better understood and appropriate control measures can be recommended.

In the meantime, FDA requests that interested parties with information on this potential hazard supply any available data to the agency.

Notes:

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Environmental chemical contaminants and pesticides in fish pose a potential human health hazard. Fish are harvested from waters that are exposed to varying amounts of industrial chemicals, pesticides, and toxic elements. These contaminants may accumulate in fish at levels that can cause illness. The hazard is most commonly associated with long-term exposure to these contaminants; illnesses associated with a single exposure (one meal) are very rare. Concern for these contaminants primarily focuses on fish harvested from fresh water, estuaries, and near-shore coastal waters (e.g. areas subject to shoreside contaminant discharges), rather than from the open ocean. Pesticides used near aquaculture operations may also contaminate fish.

The hazard of methyl mercury is covered in Chapter 10.

• Control of chemical contaminants

Federal tolerances, action levels, and guidance levels are established for some of the most toxic and persistent contaminants that are found in fish. These levels are listed in Table #9-1. States often use the Federal tolerances, action levels, and guidance levels for deciding whether to issue consumption advisories or to close waters for commercial harvesting of all or certain species of fish.

In the case of molluscan shellfish, State and foreign government agencies, called Shellfish Control Authorities, consider the degree of chemical contamination as part of their classification of harvesting waters. 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 then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been permitted.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the processor's name, address, and certification number.

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "environmental chemical contaminants and pesticides" is a significant hazard. The criteria are:

1. Is it reasonably likely that unsafe levels of environmental chemical contaminants or pesticides will be introduced at the receiving step (e.g. does the raw material come in with an unsafe level of an environmental chemical contaminant or pesticide)?

Tables #3-1 and 3-2 (Chapter 3) identify the species of fish for which "environmental chemical contaminants and pesticides" is a potential hazard. Under ordinary circumstances, it would be reasonably likely to expect that, without proper controls, unsafe levels of environmental chemical contaminants and pesticides could enter the process at the receiving step from those species. There may be circumstances in your geographic area that would allow you to conclude that it is not reasonably likely for unsafe levels of environmental chemical contaminants and pesticides to occur in fish from your area. You should be guided by the historical occurrence of environmental chemical contaminants and pesticides, at levels above the established tolerances, action levels, or guidance levels, in fish from your geographic area.

Continued

Except in the case of molluscan shellfish, the hazard of "environmental chemical contaminants and pesticides" should be fully controlled by the primary processor. For this reason, secondary processors of fish other than molluscan shellfish need not identify this hazard as a significant hazard.

2. Can unsafe levels of environmental chemical contaminants and pesticides, which were introduced at an earlier step, be eliminated or reduced to an acceptable level here? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step 12)

"Environmental chemical contaminants and pesticides" should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to prevent or eliminate (or is adequate to reduce the likelihood of occurrence to an acceptable level) unsafe levels of environmental chemical contaminants and pesticides that are reasonably likely to occur. Preventive measures for environmental chemical contaminants and pesticides can include:

- Making sure that incoming fish have not been harvested from waters that are closed to the commercial harvest of that specie due to environmental chemical contaminants or pesticides;
- Making sure that incoming fish have not been harvested from waters that are under a consumption advisory by a federal, state or local regulatory authority based on a determination by the authority that fish harvested from the waters are reasonably likely to contain contaminants above the federal tolerances, action levels, or guidance levels. Note: many consumption advisories are not based on such a determination.
- Checking incoming molluscan shellfish to ensure that they are properly tagged or labeled;
- Screening incoming molluscan shellfish to ensure that they are supplied by a licensed harvester (where licensing is required by law) or by a certified dealer;
- Receipt of the aquacultural grower's lot-by-lot certification of harvesting from uncontaminated waters, coupled with appropriate verification (see Step #18 - Verification);
- Review, at time of receipt of aquacultured fish, of environmental chemical contaminant and pesticide test results of soil and water or fish flesh samples for those contaminants that are reasonably likely to be present, and monitoring of present land use practices in the area immediately surrounding the production area (tests and monitoring may be performed by the aquacultural grower, a State agency, or a third party organization);
- On-farm visits to the aquacultural grower to collect and analyze soil and water samples or fish samples for environmental chemical contaminants and pesticides that are reasonably likely to be present, and to review present land use practices in the area immediately surrounding the production area;
- Environmental chemical contaminant and pesticide testing of fish flesh at time of receipt for those contaminants that are reasonably likely to be present;
- Receipt of evidence (e.g. third party certificate) that the producer operates under a third party-audited Quality Assurance Program for environmental chemical contaminants and pesticides (e.g. the National Aquaculture Association's Fish Producers Quality Assurance Program).

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s). In the case of an integrated operation, where fish processing and grow-out are performed by the same firm, it may be possible and desirable to exercise preventive measures early in the process (ideally when the grow-out site is selected), rather than at receipt of the fish at the processing plant. Such preventive measures will not be covered in this chapter.

If the answer to either question 1 or 2 is "Yes," the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, in most cases, it is unlikely that the significance of this hazard will be affected by the intended use of the product.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "environmental chemical contaminants and pesticides" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "environmental chemical contaminants and pesticides":

Is the raw material an aquacultured product?

1. If it is, is your relationship with the grower one that enables you to visit the farm before receipt of the fish?

   a. If you have such a relationship with the grower, then you may identify a pre-harvest step as the CCP for "environmental chemical contaminants and pesticides." The preventive measure for this type of control is on-farm visits to the aquacultural grower to collect and analyze soil and water samples or fish samples for environmental chemical contaminants and pesticides that are reasonably likely to be present, and to review present land use practices in the area immediately surrounding the production area.

   Example:
   A processor of aquacultured catfish that regularly purchases from the same growers could visit the growers before the fish are harvested. The processor could collect and analyze soil and water samples or fish samples for environmental chemical contaminants and pesticides that are reasonably likely to be present and review present land use at the pond site and in the adjacent areas. The processor could then set the critical control point for environmental chemical contaminants and pesticides at the pre-harvest step.

   In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the pre-harvest step. This control approach will be referred to as "Control Strategy Example 1" in Steps #14 through 18. (Note: if you have not previously identified "environmental chemical contaminants and pesticides" as a significant hazard at the pre-harvest step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes.")

   b. If no such relationship exists, then you may identify the receiving step as the CCP for "environmental chemical contaminants and pesticides." At the receiving step you may exercise one of the following preventive measures:

   - Receipt of the aquacultural grower's lot-by-lot certification of harvesting from uncontaminated waters, coupled with appropriate verification (see Step #18 - Verification).

   Example:
   A processor of aquacultured shrimp that purchases raw material shrimp through various brokers could receive lot-by-lot certificates from the growers. The certificates would state that the shrimp were not harvested from waters that were so contaminated by chemicals as to make it reasonably likely that the levels in the fish flesh would be in excess of established tolerances or action levels.

Continued

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 2" in Steps #14 through 18.

- Review of environmental chemical contaminant and pesticide test results of soil and water samples or of fish flesh samples for those contaminants that are reasonably likely to be present, and monitoring of present land use practices in the area immediately surrounding the production area (tests and monitoring to be performed by the aquacultural grower, a State agency, or a third party organization).

Example:
A processor of farm-raised catfish purchases catfish from a grower with which the processor has no long term relationship. The processor requires all new suppliers to provide the results of soil and water chemical contaminant tests for those contaminants that are reasonably likely to be present, and reports on present agricultural and industrial land use at and near the pond site. The land use reports are updated annually. The testing and reports are done by the grower, a trade association, or the State Agriculture Department.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 3" in Steps #14 through 18.

- Environmental chemical contaminant and pesticide testing of fish flesh for those contaminants that are reasonably likely to be present. This screening can be performed by rapid analytical methods which may indicate the presence of industrial chemicals, pesticides and/or toxic elements. If the rapid screening test indicates that contaminants are present, further testing and/or follow-up with the supplier would be necessary.

Example:
A processor of aquacultured shrimp that purchases raw material shrimp through various brokers could screen all incoming lots of shrimp for pesticides that are likely to be used around the grow-out area.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 4" in Steps #14 through 18.

- Receipt of evidence (e.g. continuing or lot-by-lot third party certificate) that the producer operates under a third party-audited Quality Assurance program that covers environmental chemical contaminants and pesticides.

Example:
A processor of aquacultured trout that regularly purchases raw material trout from the same grower could obtain a third party certificate, valid for one year, that attests that the grower operates under a Quality Assurance Program that covers environmental chemical contaminants and pesticides.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 5" in Steps #14 through 18.

2. If the product is not an aquacultured product, you may identify the receiving step as the CCP for "environmental chemical contaminants and pesticides." At the receiving step you may exercise the following preventive measures:

Source control, including:
- Making sure that incoming fish have not been harvested from waters that are closed to commercial harvest due to environmental chemical contaminants or pesticides;

- Making sure that incoming fish have not been harvested from waters that are under a consumption advisory by a federal, state or local regulatory authority based on a determination by the authority that fish harvested from the waters are reasonably likely to contain contaminants above the federal tolerances, action levels, or guidance levels. Note: many consumption advisories are not based on such a determination.
- Checking incoming molluscan shellfish to ensure that they are properly tagged or labeled.
- Checking incoming molluscan shellfish to ensure that they are supplied by a licensed harvester (where licensing is required by law) or by a certified dealer.

Examples:

A processor purchases oysters directly from the harvester. The processor checks the harvest location on the tags attached to the sacks of oysters. The processor then compares the harvest area location to information on closed waters. The processor also checks the harvester's State license.

A processor purchases flounder directly from the harvester. The processor asks the harvester where the fish were caught. The processor then compares the harvest area location to his knowledge of the areas that are closed to commercial fishing by state or local regulatory authorities or that are under consumption advisories based on federal tolerance/action level/guidance levels.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 6" in Steps #14 through 18. Note that for molluscan shellfish this control strategy is identical to Control Strategy Example 1 for "pathogens from the harvest area" (Chapter 4) and Control Strategy Example 1 for "natural toxins" (Chapter 6). If you choose an identical control strategy for two or more of these hazards, you may combine the hazards in the HACCP Plan Form.

It is important to note that you may select a control strategy that is different from those which are suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "environmental chemical contaminants and pesticides" is identified as a significant hazard in the HACCP Plan Form identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the critical limit at the point that if not met the safety of the product is questionable. If you set a more restrictive critical limit you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a critical limit that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the critical limit. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the critical limit would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the critical limit.

Following is guidance on setting critical limits for the control strategy examples discussed in Step #12.

Continued

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT

Critical Limit: Levels of environmental chemical contaminants and pesticides that are reasonably likely to be present in soil and water samples must not be so high that they are likely to result in levels in the fish flesh that are above the established tolerances, action levels, or guidance levels (Note: federal guidance levels for environmental chemical contaminants and pesticides in soil and water have not been established);
OR
No lot of fish may exceed the established tolerances, action levels, or guidance levels for environmental chemical contaminants and pesticides for those contaminants that are reasonably likely to be present;
AND
Agricultural and industrial practices in the area immediately surrounding the production area must not be reasonably likely to cause contamination of the fish flesh above the established tolerances, action levels, or guidance levels.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Critical Limit: Certificate accompanying all lots received (lot-by-lot) that indicates that the fish were not harvested from waters that were so contaminated by chemicals as to make it reasonably likely that the levels in the fish flesh would be in excess of established tolerances, action levels, or guidance levels.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING

Critical Limit: Analyses of the soil and water from all new suppliers that show that levels of environmental chemical contaminants and pesticides that are reasonably likely to be present in the soil and water are not so high that they are likely to result in levels in the fish flesh that are above the established tolerances, action levels, or guidance levels (tests may be performed by the aquacultural grower, a State agency, or a third party organization). (Note: EPA has developed water quality documents that may be suitable for evaluating water quality in local situations);
OR
Analyses of fish flesh for each delivery that show that levels of environmental chemical contaminants and pesticides that are reasonably likely to be present are below the established tolerances, action levels, or guidance levels (tests may be performed by the aquacultural grower, a State agency, or a third party organization);
AND
Annually, reports from all suppliers that show that agricultural and industrial practices in the area immediately surrounding the aquaculture production area are not reasonably likely to cause contamination of the fish flesh above the established tolerances, action levels, or guidance levels (monitoring may be performed by the aquacultural grower, a State agency, or a third party organization).

- CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING

Critical Limit: No lot of fish may exceed the established tolerances, action levels, or guidance levels for environmental chemical contaminants and pesticides for those contaminants that are reasonably likely to be present.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Critical Limit: Third party certificate indicating that the producer operates under a third party-audited Quality Assurance program that covers environmental chemical contaminants and pesticides, either for each lot of incoming aquacultured fish or for each producer of incoming aquacultured fish.

- CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL

Critical Limit: No fish may be harvested from an area that is closed to commercial fishing by foreign, federal, state, or local authorities;

Continued

TABLE #9-1

Environmental Chemical Contaminant and Pesticide Tolerances, Action Levels, and Guidance Levels

Deleterious Substance	*Level*	*Food Commodity*	*Reference*
Aldrin/Dieldrin[a]	0.3 ppm	All fish	Compliance Policy Guide sec. 575.100
Benzene hexachloride	0.3 ppm	Frog legs	Compliance Policy Guide sec. 575.100
Chlordane	0.3 ppm	All fish	Compliance Policy Guide sec. 575.100
Chlordecone[b]	0.3 ppm	All fish	Compliance Policy Guide sec. 575.100
	0.4 ppm	Crabmeat	
DDT, TDE, DDE[c]	5.0 ppm	All fish	Compliance Policy Guide sec. 575.100
Diquat[d]	0.1 ppm	All fish	40 CFR 180.226
Fluridone[d]	0.5 ppm	Fin fish and crayfish	40 CFR 180.420
Glyphosate[d]	0.25 ppm	Fin fish	40 CFR 180.364
	3.0 ppm	Shellfish	
Toxic elements:			
Arsenic	76 ppm	Crustacea	FDA Guidance Document
	86 ppm	Molluscan bivalves	FDA Guidance Document
Cadmium	3 ppm	Crustacea	FDA Guidance Document
	4 ppm	Molluscan bivalves	FDA Guidance Document
Chromium	12 ppm	Crustacea	FDA Guidance Document
	13 ppm	Molluscan bivalves	FDA Guidance Document
Lead	1.5 ppm	Crustacea	FDA Guidance Document
	1.7 ppm	Molluscan bivalves	FDA Guidance Document
Nickel	70 ppm	Crustacea	FDA Guidance Document
	80 ppm	Molluscan bivalves	FDA Guidance Document
Methyl Mercury[f]	1 ppm	All fish	Compliance Policy Guide sec. 540.600
Heptachlor /Heptachlor Epoxide[e]	0.3 ppm	All fish	Compliance Policy Guide sec. 575.100
Mirex	0.1 ppm	All fish	Compliance Policy Guide sec. 575.100
Polychlorinated Biphenyls (PCB's)[d]	2.0 ppm	All fish	21 CFR 109.30
Simazine[d]	12 ppm	Fin fish	40 CFR 180.213a
2,4-D[d]	1.0 ppm	All fish	40 CFR 180.142

[a] The action level for aldrin and dieldrin are for residues of the pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin, do not count aldrin or dieldrin found at below 0.1 ppm.
[b] Previously listed as Kepone, the trade name of chlordecone.
[c] The action level for DDT, TDE, and DDE are for residues of the pesticides individually or in combination. However, in adding amounts of DDT, TDE, and DDE, do not count any of the three found below 0.2 ppm.
[d] The levels published in 21 CFR & 40 CFR represent tolerances, rather than guidance levels or action levels.
[e] The action level for heptachlor and heptachlor epoxide are for the pesticides individually or in combination. However, in adding amounts of heptachlor and heptachlor epoxide, do not count heptachlor or heptachlor epoxide found below 0.1 ppm.
[f] See Chapter 10 for additional information.

Note: the term "fish" refers to fresh or saltwater fin fish, crustaceans, other forms of aquatic animal life other than birds or mammals, and all mollusks, as defined in 21 CFR 123.3(d).

AND

No fish may be harvested from an area that is under a consumption advisory by a federal, state, or local regulatory authority based on a determination by the authority that fish harvested from the waters are reasonably likely to contain contaminants above the federal tolerances, action levels, or guidance levels. Note: many consumption advisories are not based on such a determination.

AND

For molluscan shellfish:

- All containers of shellstock (in-shell molluscan shellfish) must bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (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, all shellstock must be accompanied by a bill of lading or other similar shipping document that contains the same information.

AND

- All molluscan shellfish must be 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 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 containers of molluscan shellfish must be from a fisherman 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.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

- Tolerances, action levels, and guidance levels

Environmental chemical contaminant and pesticide tolerances, action levels, and guidance levels for poisonous or deleterious substances in the edible portion wet weight of fish are listed in Table #9-1.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "environmental chemical contaminants and pesticides" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the critical limit is being met. That is, the monitoring process should directly measure the feature for which you have established a critical limit.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the critical limit. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a critical limit has been violated.

Following is guidance on establishing monitoring procedures for the control strategy examples discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT

What: Environmental chemical contaminant and pesticide levels in soil and water or in fish flesh for those contaminants that are reasonably likely to be present;
AND
Agricultural and industrial practices near the production area.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

What: Presence of a certificate indicating harvesting from uncontaminated waters.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING

What: Soil and water, or fish flesh, chemical contaminant test results for those contaminants that are reasonably likely to be present;
AND
Agricultural and industrial practices monitoring results.

- CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING

What: Fish flesh for environmental chemical contaminants and pesticides that are reasonably likely to be present.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

What: Third party certificate indicating operation under third-party audited QA program.

- CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL

What: Location and status (e.g. open, closed) of the harvest area;
AND
For molluscan shellfish:
- The tags on containers of shellstock. The Bill of Lading or other similar shipping document accompanying bulk shipments of shellstock;

AND
- The harvest site listed on the tag or on the Bill of Lading or other similar shipping document;

AND
- The labels on containers of shucked molluscan shellfish;

AND
- The license of fishermen, where applicable;

AND
- The certification number of suppliers (other than fishermen) of shellstock or shucked molluscan shellfish.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT

How: Collect and analyze soil and water samples or fish flesh samples from each production area;
AND
Ask questions about and observe agricultural and industrial practices in the production area, such as:
- What crops are grown in the area immediately surrounding the production area?

AND
- What pesticides are used on these crops, how are they applied, and at what time of year?

AND
- What industrial discharges enter the watershed surrounding the production site?

Continued

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

How: Visual for presence of certificate.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING

How: Visual of test results and monitoring reports.

- CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING

How: Obtain samples and analyze for environmental chemical contaminants and pesticides using rapid screening methods.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

How: Visual for presence of certificate.

- CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL

How: Ask harvester;
AND
For molluscan shellfish: visual checks.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT

Frequency: For testing soil or water: before first delivery from each production area;
OR
For testing fish flesh: before each delivery;
AND
For monitoring: at least once per year for each aquaculture production site.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Frequency: Each lot received.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING

Frequency: For soil and water test results:
all new suppliers;
OR
For fish flesh test results: each delivery;
AND
For monitoring reports: at least once every year.

- CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING

Frequency: Each lot received.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Frequency: Each lot received checked for presence of certificate. Certificates may be issued on a lot-by-lot or continuing basis, but at least annually.

- CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL

Frequency: Each lot received;
AND
For Molluscan Shellfish:
- For checking tags: every container;

AND
- For checking harvest site: every lot;

AND
- For checking labels: at least three containers randomly selected from throughout every lot;

AND
- For checking licenses: every delivery;

AND
- For checking certification numbers: every delivery.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT

Who: Field agent (employee or contractor) or any other person who has an understanding of chemical contaminants and their limits.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Who: Receiving dock employee, production employee, production supervisor, a member of the quality control staff, or any other personnel who has an understanding of the control measure.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING

Who: Receiving dock personnel, production employee, production supervisor, a member of the quality control staff, or any other personnel who has an understanding of chemical contaminants and their limits.

- CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING

Who: Member of the quality control staff or contract laboratory.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Who: Receiving employee or supervisor, production supervisor, a member of the quality control staff, or any other person who has an understanding of the control procedure.

- CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL

Who: Receiving dock personnel, production employee, production supervisor, a member of the quality control staff, or any other personnel who has an understanding of the control measure.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "environmental chemical contaminants and pesticides" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the critical limit has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the critical limit deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT

Corrective Action: Do not have product shipped to plant, if the CL is not met;
AND
Discontinue use of supplier until evidence is obtained that the cause of the chemical contamination has been eliminated.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Corrective Action: Reject lot, if the CL is not met;
OR
Hold the lot until a certificate can be provided;
OR
Hold and analyze the lot for environmental chemical contaminants and pesticides. This screening can be performed by rapid analytical methods which may indicate the presence of industrial chemicals, pesticides and/or toxic elements. If the rapid screening test indicates that contaminants are present, further testing and/or follow-up with the supplier would be necessary.

Continued

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING

Corrective Action: Reject lot, if the CL is not met;
AND
Discontinue use of supplier until evidence is obtained that the cause of the chemical contamination has been eliminated.

- CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING

Corrective Action: Reject lot, if the CL is not met;
AND
Discontinue use of supplier until evidence is obtained that the cause of the chemical contamination has been eliminated.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Corrective Action: Reject lot, if the CL is not met.

- CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL

Corrective Action: Reject lot, if the CL is not met;
OR
For fish under a consumption advisory based on a federal tolerance/action level/guidance level: Sample the lot and analyze for the appropriate environmental contaminant. Reject the lot if the results exceed the federal tolerance/action level/ guidance level;
AND
For molluscan shellfish:
- Reject shellstock that is not properly tagged or is not accompanied by a proper shipping document;

AND
- Reject shucked molluscan shellfish that is not properly labeled;

AND
- Reject molluscan shellfish that has been harvested from unapproved waters;

AND
- Reject molluscan shellfish that is not from a licensed harvester or certified processor;

AND
- Discontinue use of the supplier until evidence is obtained that the supplier will comply with the established source control practices.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

Note: If an incoming lot that fails to meet a receiving critical limit is mistakenly accepted, and the error is later detected, the following actions should be taken: 1) the lot and any products processed from that lot should be destroyed, diverted to a nonfood use or to a use in which the critical limit is not applicable, or placed on hold until a food safety evaluation can be completed; and 2) any products processed from that lot that have already been distributed should be recalled and subjected to the actions described above.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "environmental chemical contaminants and pesticides" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT

Records: Test results;
AND
On-site audit report.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Records: Copy of certificate;
AND
Receiving record showing lots received and presence/absence of certificate.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING

Records: Test results;
AND
Monitoring reports.

- CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING

Records: Test results.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Records: Third party certificate;
AND
Receiving record showing lots received and presence/absence of certificate.

- CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL

Records: Receiving records that document the harvest location and status (e.g. open, closed) of the harvest area;
AND
For molluscan shellfish shellstock: a 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;

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

AND
- Certification number of the shipper, where applicable;

AND
For shucked molluscan shellfish: a receiving record that documents:
- Date of receipt;

AND
- Quantity and type of shellfish;

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

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "environmental chemical contaminants and pesticides" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT

Verification: Review monitoring and corrective action records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Verification: Visit all new aquacultured fish suppliers within the year and all existing fish suppliers at a predetermined frequency (e.g. 25% per year) to collect and analyze soil and/or water samples, as appropriate, for environmental chemical contaminants and pesticides, and review agricultural and industrial practices in the production area;

OR

Collect a representative sample of the raw material, in-process product, or finished product at least quarterly and analyze for drug residues;

AND

Review monitoring, corrective action, and verification records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING

Verification: Review monitoring and corrective action records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING

Verification: Review monitoring and corrective action records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Verification: Review monitoring and corrective action records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL

Verification: Review monitoring and corrective action records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #9-2

Control Strategy Example 1 - On-farm visits

This table is a an example of a portion of a HACCP plan relating to the control of environmental chemical contaminants and pesticides in pond-raised catfish, using Control Strategy Example 1 - On-farm visit. It is provided for illustrative purposes only. Chemical contaminants may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. aquaculture drugs and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Pre-harvest	Chemical contaminants	• Levels of environmental chemical contaminants and pesticides in fish flesh may not exceed established tolerances, action levels, and guidance levels for those contaminants that are reasonably likely to be present	• Environmental chemical contaminant and pesticide levels in fish flesh samples before harvest for those contaminants that are reasonably likely to be present	• Collect samples and analyze for environmental chemical contaminants and pesticides using rapid screening methods	• Before harvest	• Field agent will submit samples to contract laboratory	• Do not have product shipped to plant AND • Discontinue use of supplier until evidence is obtained that the cause of the chemical contamination has been eliminated	• Test results	• Review monitoring and corrective action records within one week of preparation
		• Agricultural and industrial practices in the area immediately surrounding the pond must not be reasonably likely to cause contamination of the fish flesh above the established tolerances, action levels, or guidance levels.	• Agricultural and industrial practices near the pond	• Ask questions and observe agricultural and industrial practices	• Once per year	• Field agent	• Same	• Field agent report	• Review monitoring and correction action records within one week of preparation

TABLE #9-3

Control Strategy Example 2 - Supplier's Certification

This table is an example of a portion of a HACCP plan relating to the control of environmental chemical contaminants and pesticides in aquacultured salmon, using Control Strategy Example 2 - Supplier's certification. It is provided for illustrative purposes only. Chemical contaminants may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. aquaculture drugs, chemical contaminants, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving	Environmental chemical contaminants and pesticides	Certificate accompanying all lots received indicates that the fish were not harvested from waters that were so contaminated by chemicals as to make it reasonably likely that the levels in the fish flesh would be in excess of established tolerances, action levels, or guidance levels.	Presence of a certificate	Visual	Each lot received	Receiving dock employee	Reject lot	• Copy of certificate • Receiving record	• Review monitoring, corrective action, and verification records within one week of preparation • Visit all new suppliers and 25% of existing suppliers each year and collect soil and/or water samples and review agricultural and industrial practices in the area

TABLE #9-4

Control Strategy Example 3 - Records of testing and monitoring

This table is an example of a portion of a HACCP plan relating to the control of environmental chemical contaminants and pesticides in farmed-raised trout, using Control Strategy Example 3 - Records of testing and monitoring. It is provided for illustrative purposes only. Chemical contaminants may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. aquaculture drugs and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving	Environmental chemical contaminants and pesticides	• Analyses of fish flesh for each delivery that show that levels of environmental chemical contaminants and pesticides that are reasonably likely to be present are below the established tolerances, action levels, or guidance levels (tests may be performed by the aquacultural grower, a State agency, or a trade association)	• Levels of environmental chemical contaminants and pesticides in soil and water samples for those contaminants that are reasonably likely to be present	• Visual	• Each delivery	• Quality control staff	• Reject lot, AND • Discontinue use of supplier until evidence is obtained that the source of the chemical contamination has been eliminated	• Test results	• Review monitoring and corrective action records within one week of preparation
		• Annually, reports from all suppliers that show that agricultural and industrial practices in the area immediately surrounding the production area are not reasonably likely to cause contamination of the fish flesh above the established tolerances, action levels, or guidance levels (monitoring may be performed by the aquacultural grower, a State agency, or a trade association)	• Agricultural and industrial practices near the production area	• Visual	• Once per year	• Quality control staff	• Same	• Monitoring reports	• Review monitoring and correction action records within on week of preparation

TABLE #9-5

Control Strategy Example 4 - Chemical contaminant testing

This table is an example of a portion of a HACCP plan relating to the control of environmental chemical contaminants and pesticides in pond-raised shrimp, using Control Strategy Example 4 - Chemical contaminant testing. It is provided for illustrative purposes only. Chemical contaminants may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. aquaculture drugs, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving	Environmental chemical contaminants and pesticides	No lot of fish may exceed the established tolerances, action levels, or guidance levels for environmental chemical contaminants and pesticides that are reasonably likely to be present	Fish flesh for chemical residues that are reasonably likely to be present	Obtain samples and analyze for environmental chemical contaminants and pesticides using rapid screening methods	Each lot received	Receiving employee will submit sample to quality control staff	• Reject lot AND • Discontinue use of supplier until evidence is obtained that the cause of the chemical contamination has been eliminated	Test results	Review monitoring and corrective action records within one week of preparation

TABLE #9-6

Control Strategy Example 5 - QA program

This table is an example of a portion of a HACCP plan relating to the control of environmental chemical contaminants and pesticides for an aquacultured trout processor, using Control Strategy Example 5 - QA program. It is provided for illustrative purposes only. Chemical contaminants may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. aquaculture drugs and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Receiving	Environmental chemical contaminants and pesticides	Third party certificate indicating that the producer operates under a Quality Assurance Program that covers environmental chemical contaminants and pesticides	Presence of third party certificate	Visual, for presence of certificate	Each lot checked to see if covered by certificate, which is renewed annually	Receiving dock employee	Reject lot AND Discontinue use of the supplier until evidence is obtained that the supplier will comply with the established source control practices	• Certificate • Receiving record	Review monitoring and corrective action records within one week of preparation

TABLE #9-7

Control Strategy Example 6 - Source control

This table is an example of a portion of a HACCP plan relating to the control of environmental chemical contaminants and pesticides in wild-caught flounder, using Control Strategy Example 6 - Source control. It is provided for illustrative purposes only. Guidance for processors of molluscan shellfish using source control is provided in Table #4-1 (Chapter 4).
Chemical contaminants may be only one of several significant hazards for this product.
Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. parasites and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5) Monitoring	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving	Environmental chemical contaminants and pesticides	No fish may be harvested from an area that is closed to commercial fishing by foreign federal, state, or local authorities No fish may be harvested from an area that is under a consumption advisory by a federal, state, or local regulatory authority based on a determination by the authority that fish harvested from the waters are reasonably likely to contain contaminants above the federal tolerances, action levels, or guidance levels. Note: many consumption advisories are not based on such a determination.	Location of harvest area	Ask harvester	Each lot received	Receiving dock employee	Reject lot AND Discontinue use of the supplier until evidence is obtained that the supplier will comply with the established source control practices	Receiving record	Review monitoring and corrective action record within one week of preparation

The draft Fish and Fishery Products Hazards and Controls Guide (February 16, 1994) listed methyl mercury as a potential safety hazard for bonito, halibut, Spanish mackerel, king mackerel, marlin, shark, swordfish, and bluefin tuna. The selection of these species was based on historical data on levels of methyl mercury found in fish consumed in the U.S. The selection was also based on an FDA action level of 1.0 ppm in the edible portion of fish.

While FDA has not changed the 1.0 ppm action level, the agency is re-evaluating it in light of significant new data on the health effects of methyl mercury from consumption of fish. These data have become available since the action level was developed.

When the action level re-evaluation is completed, FDA will, among other things, update this Guide by including advice on how to assess the significance of a potential methyl mercury hazard in fish, and what controls, if any, are necessary to ensure the safety of fish in this regard.

Notes:

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Unregulated/unapproved drugs administered to aquacultured fish pose a potential human health hazard. These substances may be carcinogenic, allergenic, and/or may cause antibiotic resistance in man. To control this hazard in food animals, all drugs, whether for direct medication or for addition to feed, must be approved by FDA. Under certain conditions authorized by FDA, unapproved new animal drugs may be used in conformance with the terms of an Investigational New Animal Drug (INAD) application.

Incentives for the use of animal drugs in aquatic animal species include the need to: 1) treat and prevent disease; 2) control parasites; 3) affect reproduction and growth; and, 4) tranquilization (e.g. during transit). Relatively few drugs have been approved for aquaculture. As a result, aquaculture growers may use unapproved drugs, general purpose chemicals that are not labeled for drug use, and approved drugs in a manner that deviates from the labeled instructions.

When a drug is approved by FDA's Center for Veterinary Medicine, the conditions of the approval are listed on its label. These conditions include: the species for which the drug is approved; the approved dosage; the approved route of administration; the approved frequency of use; and the approved indications for use. Only a licensed veterinarian may legally prescribe or use a drug under conditions that are not listed on the label. This restriction is more fully explained in 21 CFR 530.

Labels of approved drugs list mandatory withdrawal times, where applicable. These withdrawal times must be observed to ensure that the edible tissue is safe when it is offered for sale. Tissue residue tolerances have been established for some drugs.

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "aquaculture drugs" is a significant hazard. The criteria are:

1. Is it reasonably likely that unsafe levels of aquaculture drugs will be introduced at this processing step (e.g. do raw materials come in with unsafe levels of aquaculture drugs, or are they used at this step)?

Under ordinary circumstances, it would be reasonably likely to expect that unsafe levels of aquaculture drugs could enter the process during the receiving of any type of aquacultured fish, including:
- Fin fish;
- Crustaceans;
- Aquatic animals, such as alligator.

Under ordinary circumstances it would also be reasonably likely to expect that unsafe levels of aquaculture drugs could enter the process during the holding of live lobster (e.g. lobster pounds).

Under ordinary circumstances it would not be reasonably likely to expect that aquaculture drugs could enter the process during the receiving of wild-caught fish. Currently, FDA is not aware of drug use in the grow-out of molluscan shellfish. If the agency becomes aware of such use, this Guide, and, in particular, Table #3-2 (Chapter 3) will be updated accordingly. On a regional basis, it may be reasonable for you to conclude that aquaculture drug use is not a significant hazard for other species, because they are not used by producers in your region.

2. Can the presence of unsafe levels of aquaculture drugs, which are reasonably likely to occur, be eliminated or reduced to an acceptable level here? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12)

Continued

"Aquaculture drugs" should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level), if it reasonably likely to occur.

Preventive measures for the control of aquaculture drugs used in aquaculture operations can include:

- On-farm visits to review drug usage (other than INADs) before receipt of the product, coupled with a supplier's lot-by-lot certificate that any INADs used were used in conformance with the application requirements;
- Receipt of supplier's lot-by-lot certification of proper drug usage, coupled with appropriate verification (See Step #18 - Verification);
- Review of drug usage records (other than INADs) at receipt of the product, coupled with a supplier's lot-by-lot certificate that any INADs used were used in conformance with the application requirements;
- Drug residue testing;
- Receipt of evidence (e.g. third party certificate) that the producer operates under a third party-audited Quality Assurance Program for aquaculture drug use.

(Note: The use of Investigational New Animal Drugs (INAD) is confidential unless an exception is made by the sponsor of the drug research. Thus, review of INAD drug usage records by the processor may not be practical in certain situations. Written certification from the grower to the processor stating that any INAD drug usage is in accordance with authorizations from FDA/Center for Veterinary Medicine, will be acceptable on a lot-by-lot basis.)

Preventive measures for the control of aquaculture drugs used during the holding of live fish (e.g. lobster pounds) can include controlled application of animal drugs in a manner consistent with:

- The established withdrawal times;
- The labeled instructions for use;
- Extralabel use of FDA-approved drugs, under a veterinarian's supervision in accordance with FDA regulations and guidelines;
- The conditions specified in the FDA "low regulatory priority aquaculture drug" list;
- The conditions of an INAD application.

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s). Ordinarily this will be either the receiving step or the preharvest step. However, in the case of an integrated operation, where fish processing and grow-out, and, perhaps feed manufacture, are performed by the same firm, it may be possible and desirable to exercise preventive measures early in the process (ideally at feed manufacture), rather than at receipt of the fish at the processing plant. Such preventive measures will not be covered in this chapter. For the holding of live fish (e.g. lobster pounds) the preventive measure will usually be applied at the holding step.

If the answer to either question 1 or 2 is "Yes," the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. Except in the case of an integrated aquaculture operation, this will usually be the receiving step. If none of the criteria are met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, for aquaculture drugs, it is unlikely that the intended use will affect the significance of the hazard.

STEP #12: ***IDENTIFY THE CRITICAL CONTROL POINTS (CCP).***

For each processing step where "aquaculture drugs" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "aquaculture drugs":

Is the hazard the result of the use of aquaculture drugs during the raising of fish (i.e. aquaculture) or during the holding of live fish (e.g. lobster pounds)?

1. If it is the result of aquaculture, is your relationship with the grower one that enables you to visit the farm before receipt of the fish?

a. If you have such a relationship with the grower, then you may identify a pre-harvest step as the CCP for "aquaculture drugs." The preventive measure for this type of control is on-farm visits to review drug usage, coupled with a supplier's lot-by-lot certificate that any INADs used were used in conformance with the application requirements.

Example:
A processor of aquacultured catfish that regularly purchases from the same growers would visit the grower before the fish are harvested and review the grower's drug usage practices and records. The processor could also receive a guarantee that any INADs used were used in conformance with the application requirements. The processor could then set the critical control point for aquaculture drugs at the pre-harvest step.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the pre-harvest step. This control approach will be referred to as "Control Strategy Example 1" in Steps #14 through 18. (Note: if you have not previously identified "aquaculture drugs" as a significant hazard at the pre-harvest step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes.")

b. If you have no such relationship with the grower, then you may identify the receiving step as the CCP for "aquaculture drugs." At the receiving step you may exercise one of the following preventive measures:

- Supplier's lot-by-lot certification of proper drug usage, coupled with appropriate verification (See Step #18 - Verification).

Example:
A processor of aquacultured shrimp that purchases raw material shrimp through various brokers could receive lot-by-lot certificates from the growers. The certificates would state that all drugs were used in conformance with applicable regulations and labeled instructions. The processor combines this monitoring procedure with quarterly raw material testing for verification.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 2" in Steps #14 through 18.

- Review of drug usage records (other than INADs) at receipt of the product, coupled with a supplier's lot-by-lot certificate that any INADs used were used in conformance with the application requirements.

Example:
A processor of aquacultured shrimp that purchases raw material shrimp through various brokers could receive records of drug use (other than INADs) from the growers when the product is delivered. Additionally, the processor could receive a lot-by-lot certificate that would state that any INADs were used in conformance with the application requirements.

Continued

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 3" in Steps #14 through 18.

- Drug screening on all lots at receipt. This screening can be performed by rapid analytical methods which may indicate the presence of a family of drugs, rather than any specific drug. If the rapid screening test indicates that a family of drugs is present, further testing and/or follow-up with the supplier would be necessary.

Note: A limited number of drug screening tests for aquaculture are available. Tests are not available to assay for all drugs that might be used in all aquacultured species. Processors should be cautioned that tests that have not been validated may be unreliable. These tests may fail to detect a residue or may give a false positive. FDA has not validated any of the aquaculture screening tests; nor has the Association of Official Analytical Chemists (AOAC). Processors should assure themselves that the tests that they intend to use have otherwise been validated and are appropriate for the species and tissue to be tested.

Example:
A processor of aquacultured shrimp that purchases raw material shrimp through various brokers could screen all incoming lots of shrimp with a bank of validated rapid tests that target the families of drugs likely to be used during grow-out.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 4" in Steps #14 through 18.

- Receipt of evidence (e.g. continuing or lot-by-lot third party certificate) that the producer operates under a third party-audited Quality Assurance program for aquaculture drug use.

Example:
A processor of aquacultured trout that regularly purchases raw material trout from the same grower could obtain a third party certificate, valid for one year, that attests that the grower operates under a Quality Assurance Program which covers aquaculture drug usage.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 5" in Steps #14 through 18.

2. If the hazard is the result of live fish holding (e.g. lobster pounds), then you may identify the holding step as the CCP for "aquaculture drugs." The preventive measure for this type of control is the controlled application of animal drugs (e.g. oxytetracycline) in a manner consistent with: the established withdrawal times; the labeled instructions for use; extralabel use of an FDA-approved drug, under a veterinarian's supervision in accordance with FDA regulations and guidelines; the conditions specified in the FDA "low regulatory priority aquaculture drug" list; and, the conditions of an INAD application.

Example:
A processor that uses oxytetracycline in the holding of live lobster in a lobster pound would use the drug in accordance with the established withdrawal time and any other labeled instructions.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the holding step. This control approach will be referred to as "Control Strategy Example 6" in Steps #14 through 18.

It is important to note that you may select a control strategy that is different from those which are suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "aquaculture drugs" is identified as a significant hazard on the HACCP Plan Form, identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the critical limit at the point that if not met the safety of the product may be questionable. If you set a more restrictive critical limit you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a critical limit that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the critical limit. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the critical limit would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the critical limit.

Following is guidance on setting critical limits for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

Critical Limit: Animal drugs are used on fish only if the drugs have been:

- Approved by FDA and used in accordance with proper withdrawal times and other labeled conditions;

OR

- Approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guide lines. The regulations and guidelines are available from the FDA Center for Veterinary Medicine, HFV-230, 7500 Standish Place, Rockville, MD 20855;

OR

- Listed on the FDA "low regulatory priority aquaculture drug" list;

OR

- Permitted by FDA for use in food fish under the conditions of an INAD (as evidenced by a lot-by-lot written certificate from the grower).

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Critical Limit: Certificate indicating proper drug usage accompanying each lot of incoming aquacultured fish.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Critical Limit: Animal drugs used on fish only if the drugs have been:

- Approved by FDA and used in accordance with proper withdrawal times and other labeled conditions;

OR

- Approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guide lines. The regulations and guidelines are available from the FDA Center for Veterinary Medicine, HFV-230, 7500 Standish Place, Rockville, MD 20855;

OR

- Listed on the "low regulatory priority aquaculture drug" list;

OR

- Permitted by FDA for use in food fish under the conditions of an INAD (as evidenced by a lot-by-lot written certificate from the grower).

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

Critical Limit: No fish will be accepted that contains unapproved drug residues (other than those used within the provisions of an INAD application or used in accordance with the criteria specified in the "low regulatory priority aquaculture drug" list).

Continued

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Critical Limit: Third party certificate indicating that the producer operates under a third party-audited Quality Assurance program for aquaculture drug use, either for each lot of incoming aquacultured fish or for each producer of incoming aquacultured fish.

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

Critical Limit: Animal drugs are used on fish only if the drugs have been:

- Approved by FDA and used in accordance with proper withdrawal times and other labeled conditions;

OR

- Approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guidelines. The regulations and guidelines are available from the FDA Center for Veterinary Medicine, HFV-230, 7500 Standish Place, Rockville, MD 20855;

OR

- Listed on the FDA "low regulatory priority aquaculture drug" list;

OR

- Permitted by FDA for use in food fish under the conditions of an INAD.

- FDA-approved aquaculture drugs

FDA approved aquaculture drugs with their approved sources, species and withdrawal times are listed below. Additional details on conditions of use (e.g. disease conditions and dosage levels) can be obtained from: the Code of Federal Regulations as cited below; the labeling for the drug; the FDA Center for Veterinary Medicine (www.fda.gov/cvm/index/aquaculture); or "Guide to Drug, Vaccine, and Pesticide Use in Aquaculture," Texas Agricultural Extension Service, Publication B-5085.

- **Chorionic Gonadotropin**
  Supplied by Intervet, Inc., Millsboro, DE, may be used as an aid in improving spawning function in male and female brood finfish, (21 CFR 522.1081);
- **Formalin solution**
  Supplied by Natchez Animal Supply Co., Natchez, MS or Argent Laboratories, Redmond, WA, may only be used in salmon, trout, catfish, largemouth bass, and bluegill for the control of protozoa and monogenetic tremetodes, and on the eggs of salmon, trout and pike (esocids) for control of fungi of the family *Saprolegniacea*, (21 CFR 529.1030);
- **Formalin solution**
  Supplied by Western Chemical, Inc., Ferndale, WA, may be used to control: external protozoa and monogenetic tremetodes on all fin fish species; external protozoan parasites on shrimp; and fungi of the family *Saprolegniaceae* on the eggs of all fin fish species, (21 CFR 529.1030);
- **Tricaine methanesulfonate** (MS-222)
  Supplied by Argent Laboratories, Redmond, WA, and Western Chemical, Inc., Ferndale, WA, may only be used in the families *Ictaluridae* (catfish), *Salmonidae* (salmon and trout), *Esocidae* (pike), and *Percidae* (perch) when the fish is intended to be used for food. It may not be used within 21 days of harvesting fish for food. In other fish and in cold-blooded animals, the drug should be limited to hatchery or laboratory use, (21 CFR 529.2503);
- **Oxytetracycline**
  For feed use, supplied by Pfizer, Inc., may only be used in salmonids, catfish, and lobster. Withdrawal times are: marking in pacific salmon, 7 days; disease control in salmonids, 21 days; catfish, 21 days; lobster, 30 days (21 CFR 558.450). Oxytetracycline tolerance in the flesh is 2.0 ppm, (21 CFR 556.500).
- **Sulfamerazine**
  Supplied by Roche Vitamins, Inc., may only be used in trout. It may not be used within 21 days of harvest (21 CFR 558.582). Sulfamerazine tolerance in the flesh is zero, (21 CFR 556.660). Note: this product is currently not marketed.
- **Sulfadimethoxine/ormetoprim combination**
  Supplied by Roche Vitamins, Inc., may only be used in salmonids and catfish. Withdrawal times are: salmonids, 42 days; catfish, 3 days (21 CFR 558.575). Sulfadimethoxine/ormetoprim combination tolerance in the flesh is 0.1 ppm for both drugs, (21 CFR 556.640).

• FDA low regulatory priority aquaculture drugs

FDA's Center for Veterinary Medicine has identified a number of "low regulatory priority aquaculture drugs." The following list identifies these compounds and provides their indicated use and usage levels. These compounds have undergone review by the Food and Drug Administration and have been determined to be new animal drugs of low regulatory priority. Additional information on this subject can be obtained from: the FDA Center for Veterinary Medicine (www.fda.gov/cvm/index/aquaculture); or "Guide to Drug, Vaccine, and Pesticide Use in Aquaculture," Texas Agricultural Extension Service, Publication B-5085.

- **Acetic Acid**
  Used in a 1000 to 2000 ppm dip for 1 to 10 minutes as a parasitide for fish.
- **Calcium Chloride**
  Used to increase water calcium concentration to insure proper egg hardening. Dosages used would be those necessary to raise calcium concentration to 1-20 ppm $CaCO_3$. Used up to 150 ppm indefinitely to increase the hardness of water for holding and transporting fish in order to enable fish to maintain osmotic balance.
- **Calcium Oxide**
  Used as an external protozoacide for fingerlings to adult fish at a concentration of 2000 mg/L for 5 seconds.
- **Carbon Dioxide Gas**
  Used for anesthetic purposes in cold, cool, and warm water fish.
- **Fuller's Earth**
  Used to reduce the adhesiveness of fish eggs to improve hatchability.
- **Garlic** (whole form)
  Used for control of helminth and sea lice infestations of marine salmonids at all life stages.
- **Hydrogen Peroxide**
  Used at 250-500 mg/L to control fungi on all species and life states of fish, including eggs.
- **Ice**
  Used to reduce metabolic rate of fish during transport.
- **Magnesium Sulfate**
  Used to treat external monogenic trematode infestations and external crustacean infestations in fish at all life stages. Used in all freshwater species. Fish are immersed in a 30,000 mg $MgSO_4$/L and 7000 mg NaCl/L solutions for 5 to 10 minutes.
- **Onion** (whole form)
  Used to treat external crustacean parasites, and to deter sea lice from infesting external surface of salmonids at all life stages.
- **Papain**
  Used in a 0.2% solution to remove the gelatinous matrix of fish egg masses in order to improve hatchability and decrease the incidence of disease.
- **Potassium Chloride**
  Used as an aid in osmoregulation; relieves stress and prevents shock. Dosages used would be those necessary to increase chloride ion concentration to 10-2000 mg/L.
- **Povidone Iodine**
  Used in a 100 ppm solution for 10 minutes as an egg surface disinfectant during and after water hardening.
- **Sodium Bicarbonate**
  Used at 142 to 642 ppm for 5 minutes as a means of introducing carbon dioxide into the water to anesthetize fish.
- **Sodium Chloride**
  Used in a 0.5% to 1.0% solution for an indefinite period as an osmoregulatory aid for the relief of stress and prevention of shock; and 3% solution for 10 to 30 minutes as a parasitide.
- **Sodium Sulfite**
  Used in a 15% solution for 5 to 8 minutes to treat eggs in order to improve their hatchability.
- **Thiamine Hydrochloride**
  Used to prevent or treat thiamine deficiency in salmonids. Eggs are immersed in an aqueous solution of up to 100 ppm for up to four hours during water hardening. Sac fry are immersed in an aqueous solution of up to 1,000 ppm for up to one hour.
- **Urea & Tannic Acid**
  Used to denature the adhesive component of fish eggs at concentrations of 15g urea and 20g NaCl/5 liters of water for approximately 6 minutes, followed by a separate solution of 0.75 g tannic acid/5 liters of water for an additional 6 minutes. These amounts will treat approximately 400,000 eggs.

Continued

The Agency is unlikely to object to the use of low regulatory priority substances if the following conditions are met: 1) the substances are used for the stated indications; 2) the substances are used at the prescribed levels; 3) the substances are used according to good management practices; 4) the product is of an appropriate grade for use in food animals; and, 5) there is not likely to be an adverse effect on the environment.

The Agency's enforcement position on the use of these substances should not be considered an approval, nor an affirmation of their safety and effectiveness. The Agency reserves the right to take a different position on the use of any or all of these substances at some time in the future.

Classification of these substances as new animal drugs of low regulatory priority does not exempt facilities from complying with other Federal, State, and local environmental requirements. For, example, facilities using these substances would still be required to comply with National Pollutant Discharge Elimination System (NPDES) requirements.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "aquaculture drugs" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the critical limit is being met. That is, the monitoring process should directly measure the feature for which you have established a critical limit.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the critical limit. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a critical limit has been violated.

Following is guidance on establishing monitoring procedures for the control strategy examples discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

What: On-farm drug usage procedures;
AND
Producer certificate indicating proper INAD usage.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

What: Producer certificate indicating proper drug usage.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

What: On farm drug usage procedures;
AND
Producer certificate indicating proper INAD usage.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

What: Fish flesh for drug residues.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

What: Third party certificate indicating operation under third-party audited QA program.

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

What: Type of aquaculture drug used;
AND
Date and quantity of drug use;
AND
Any other conditions of drug use that are relevant to: the established withdrawal times; the labeled instructions for use; the extralabel use of an FDA-approved drug used under a veterinarians's supervision in accordance with FDA regulations and guidelines; the conditions specified in the FDA "low regulatory priority aquaculture drug" list; or, the conditions of the INAD application;
AND
Date of distribution of the finished product.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

How: Survey farm husbandry procedures, ask questions, and review drug usage records;
AND
Visual for presence of INAD certificate.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

How: Visual for presence of lot-by-lot certificate.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

How: Review drug records;
AND
Visual for presence of INAD certificate.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

How: Obtain samples and analyze for drugs, using rapid screening methods.

Note: A limited number of drug screening tests for aquaculture are available, and these have not been validated by FDA or AOAC. This topic is further discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

How: Visual for presence of third party certificate.

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

How: Visually observe drug use and distribution.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

Frequency: At least once per year for each aquaculture site.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Frequency: Each lot received.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Frequency: Each lot received.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

Frequency: Each lot received.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Frequency: Each lot received checked for presence of certificates. Certificates may be issued on a lot-by-lot or continuing basis, but at least annually.

Continued

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

Frequency: Every time aquaculture drugs are used during holding;
AND
Every time the product is distributed.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

Who: Field agent (employee or contractor) or any other person who has an understanding of animal drug usage and limits.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Who: Receiving employee or supervisor, production supervisor, member of the quality control staff, or any other person who has an understanding of the control procedure.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Who: Production supervisor, member of the quality control staff, or any other personnel who has an understanding of animal drug usage and limits.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

Who: Member of the quality control staff or contract laboratory.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Who: Receiving employee or supervisor, production supervisor, a member of the quality control staff, or any other person who has an understanding of the control procedure.

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

Who: Production employee or supervisor, member of the quality control staff, or any other personnel who has an understanding of drug usage and limits.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "aquaculture drugs" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the critical limit has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the critical limit deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

Corrective Action: Reject product, if the CL is not met;
AND
Discontinue use of supplier until evidence is obtained that drug treatment practices have changed.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Corrective Action: Reject lot, if the CL is not met;
AND
Discontinue use of supplier until a commitment is obtained that a certificate will accompany each lot.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Corrective Action: Reject lot, if the CL is not met;
AND
Discontinue use of supplier until evidence is obtained that drug treatment practices have changed.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

Corrective Action: Reject lot, if the CL is not met;
AND
Discontinue use of supplier until evidence is obtained that drug treatment practices have changed.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Corrective Action: Reject lot, if the CL is not met;
AND
Discontinue use of supplier until a certificate is provided.

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

Corrective Action: Hold the product until the drug residue is at or below tolerance. This may be accomplished by collecting and analyzing a representative sample of the product, using an approved method;
OR
Destroy the product;
OR
Divert the product to non-food use.
AND
Modify drug use practices

Note: If an incoming lot that fails to meet a receiving critical limit is mistakenly accepted, and the error is later detected, the following actions should be taken: 1) the lot and any products processed from that lot should be destroyed, diverted to a nonfood use or to a use in which the critical limit is not applicable, or placed on hold until a food safety evaluation can be completed; and 2) any products processed from that lot that have already been distributed should be recalled and subjected to the actions described above.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "aquaculture drugs" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

Records: On-site audit report;
AND
INAD certificate.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Records: Certificate;
AND
Receiving record showing lots received and presence/absence of certificate.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Records: Grower's drug records;
AND
INAD certificate;
AND
Receiving record showing lots received and presence/absence of certificate.

Continued

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

Records: Analytical results.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

RECORDS: Third party certificate;
AND
Receiving record showing lots received and presence/absence of certificate.

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

Records: Drug use records;
AND
Records indicating date of distribution of drug-treated product.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: ***ESTABLISH VERIFICATION PROCEDURES.***

For each processing step where "aquaculture drugs" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "aquaculture drugs"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

Verification: Review monitoring and corrective action records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Verification: Visit all new aquacultured fish suppliers within the year and all existing fish suppliers at a predetermined frequency to review the grower's drug usage procedures;
OR
Collect a representative sample of the raw material, in-process product, or finished product at least quarterly and analyze for drug residues.
AND
Review monitoring, corrective action and verification records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Verification: Review monitoring and corrective action records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

Verification: Review monitoring and corrective action records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Verification: Review monitoring and corrective action records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

Verification: Review monitoring and corrective action records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #11-1

Control Strategy Example 1 - On-farm visits

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs in farm-raised catfish, using Control Strategy Example 1 - On-farm visits. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards in this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Pre-harvest	Aquaculture drugs	Animal drugs used on fish only if the drugs have been: a) approved by FDA and used in accordance with proper withdrawal times and other labeled conditions; b) approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guidelines; c) listed on the "low regulatory priority aquaculture drug" list; or, d) permitted by FDA for use in food fish under the conditions of an INAD (as evidenced by a lot-by-lot written certificate from the grower)	• On farm drug usage procedures	• Survey farm husbandry procedures, ask questions, and review drug records	• Once per year for each aquaculture site	• Field agent	• Reject AND • Discontinue use of supplier until evidence is obtained that drug treatment practices have changed	• On-site audit report	• Review monitoring and corrective action records within one week of preparation
			• Certificate indicating proper INAD usage	• Visual	• Same	• Same	• Reject	• Certificate of INAD usage	

TABLE #11-2

Control Strategy Example 2 - Supplier's certification

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs in pond-raised shrimp, using Control Strategy Example 2 - Supplier's certification. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards in this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Receiving	Aquaculture Drugs	Certificate indicating proper drug usage accompanying all lots of incoming pond-raised shrimp	Presence of a certificate indicating proper drug usage	Visual	Each lot received	Receiving dock employee	• Reject lot AND • Discontinue use until supplier agrees to provide certificate for each lot	• Grower's drug usage certificate • Receiving record	• Visit all new pond-raised shrimp suppliers within the year and all existing suppliers at 25% per year on a rotating basis to review the grower's drug usage procedures • Review monitoring, corrective action, and verification records within one week of preparation

TABLE #11-3

Control Strategy Example 3 - Records of drug use

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs in pond-raised shrimp, using Control Strategy Example 3 - Records of drug use. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards in this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving	Aquaculture Drugs	Animal drugs used on fish only if the drugs have been: a) approved by FDA and used in accordance with proper withdrawal times and other labeled conditions; b) approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guidelines; c) listed on the "low regulatory priority aquaculture drug" list; or d) permitted by FDA for use in food fish under the conditions of an INAD (as evidence by a lot-by-lot written certificate)	• On-farm drug usage procedures • Certificate indicating proper INAD usage	• Review drug records at receipt • Visual	• Each lot received • Same	• Production supervisor • Same	• Reject lot AND • Discontinue use of supplier until evidence is obtained that drug treatment practices have changed • Same	• Grower's drug usage records • Receiving record • Certificate of INAD usage	• Review monitoring and corrective action records within one week of preparation

TABLE #11-4

Control Strategy Example 4 - Residue drug testing

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs in farm-raised catfish, using Control Strategy Example 4 - Residue drug testing. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards in this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Receiving	Aquaculture Drugs	No fish will be accepted that contains unapproved drug residues (other than those used under an INAD application or included on the "low regulatory priority aquaculture drug" list)	Fish flesh for drug residues	Obtain samples and analyze for drugs using rapid screening methods Note: A limited number of drug screening tests for aquaculture are available, and these have not been validated by FDA or AOAC. This topic is further discussed in Step #12.	Each lot received	Quality assurance personnel	• Reject lot AND • Discontinue use of supplier until evidence is obtained that drug treatment practices have changed	• Analytical results	Review monitoring and corrective action records within one week of preparation

TABLE #11-5

Control Strategy Example 5 - QA program

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs for an aquacultured trout processor, using Control Strategy Example 5 - QA program. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Receiving	Aquaculture Drugs	Third party certificate indicating that the producer operates under a third party audited Quality Assurance Program that covers aquaculture drug usage	Presence of third party certificate	Visual, for presence of certificate	Each lot checked to see if covered by certificate, which is renewed annually	Receiving dock employee	• Reject lot AND • Discontinue use until a certificate is obtained	• Third party certificate of operation • Receiving record	Review monitoring and corrective action records within one week of preparation

TABLE #11-6

Control Strategy Example 6 - Control during holding

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs for a processor that holds live lobster in a lobster pound, using Control Strategy Example 6 - Control during holding. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. natural toxins and food and color additives).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Holding	Aquaculture Drugs	• Lobster will be withheld from distribution for 30 days after treatment with oxytetracycline in accordance with the labeled directions for use • No other aquaculture drugs will be used	• Type of aquaculture drug used • Date and quantity of drug use • Date of finished product distribution	• Visual observation of drug use • Visual observation of drug use • Visual observation of drug use	• Every time aquaculture drugs are used • Every time aquaculture drugs are used • Every time aquaculture drugs are used	• Production employee • Production employee • Shipping supervisor	• Hold the product AND • Collect a sample of the finished product and have analyzed for oxytetracycline residue by contact laboratory. If 2.0 ppm or less, release. If higher than 2.0 ppm, hold product an additional 5 days and then retest AND • Destroy the lot when unapproved drugs are used AND • modify drug use practices	• Drug use record • Drug use record • Shipping record	Review monitoring and corrective action records within one week of preparation

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Pathogen growth and toxin formation as a result of time/temperature abuse of fish and fishery products can cause consumer illness. This hazard is limited to bacterial pathogens since human viral pathogens (viruses) are not able to grow in food. Temperature abuse occurs when product is allowed to remain at temperatures favorable to pathogen growth for sufficient time to result in unsafe levels of pathogens or their toxins in the product. Table #A-1 (Appendix 4) provides guidance about the conditions under which certain pathogens are able to grow. The pathogens listed are those of greatest concern in fish and fishery products.

Pathogens 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, unsafe water, and sewage, and through cross contamination between raw and cooked product.

• Strategies for controlling pathogen growth

There are a number of strategies for the control of pathogens 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 in this chapter; for *Clostridium botulinum*, in Chapter 13, and for *Staphylococcus aureus* in hydrated batter mixes in Chapter 15);

• Killing pathogens by cooking (covered in Chapter 16), pasteurizing (covered in Chapter 17), or retorting (covered by the low acid canned foods regulations, 21 CFR 113);

• 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 regulations, 21 CFR 114 for shelf-stable products; and for refrigerated acidified products in Chapter 13).

Note: The use of irradiation for fish or fishery products has not been approved by FDA. Irradiated fish and fishery products may not be distributed in the U.S.

• Managing time and temperature of exposure

The time/temperature combinations that will ensure safety in your product are dependent upon a number of factors, including:

• The types of pathogens that are expected to be present and able to grow in your product. See information contained in Step #11.

• The infective or toxic dose of these pathogens or their toxins. The infective 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 capability) of the particular strain of the pathogen.

For many of the pathogens listed in Table #A-1 (Appendix 4) the infective dose is known or suspected to be very low (from one to several hundred

Continued

organisms). These include: *Campylobacter jejuni, Escherichia coli, Salmonella* spp., *Shigella* spp., and *Yersinia enterocolitica*. The infective dose for other pathogens, such as *Vibrio vulnificus*, *Vibrio parahaemolyticus* and *Listeria monocytogenes* is not known. In the case of both of these categories of pathogens it is advisable to prevent any significant growth. Stated another way, 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 pathogens are acclimating to their environment) of the pathogen at those temperatures.

Still other pathogens (e.g. *Vibrio cholerae*) require large numbers in order to cause disease or require large numbers in order to produce toxin (e.g. *Staphylococcus aureus, Clostridium perfringens*, *Bacillus cereus*). The infective dose of *Vibrio cholerae* is suspected to be 1,000,000 total cells. *S. aureus* toxin does not normally reach levels that will cause food poisoning until the numbers of the pathogen reach 100,000 to 1,000,000/gram. *Clostridium perfringens* does not produce toxin in the human gut unless at least 100,000,000 total bacteria are consumed. Limited growth of these pathogens may not compromise the safety of the product. However, time/temperature controls must be adequate to prevent growth before the stage of the infective or toxic dose is reached. For example, the prudent processor will design controls to ensure that the numbers of *S. aureus* do not exceed 10,000/gram.

• The numbers of these pathogens that are likely to be present. This is highly dependent upon 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 pathogens is of limited importance when you calculate critical limits for pathogens that have a low infective dose. Therefore, you will be designing a critical limit that prevents any significant growth.

On the other hand, for those pathogens that have a relatively high infective dose, the initial number of pathogens may be significant.

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "pathogen growth and toxin production as a result of time/temperature abuse" is a significant hazard. The criteria are:

1. Is it reasonably likely that unsafe levels of pathogens 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 pathogens of various types, including those listed in Table #A-1 (Appendix 4), will be present on raw fish and fishery products and non-fishery ingredients. They may only be present at low levels or only sporadically, but even such occurrences warrant consideration because of the potential for growth and toxin production.

Pathogens also may be introduced during processing, even after cooking (as described in Step #10). Well designed sanitation programs (prerequisite programs) will minimize the introduction of pathogens. However, in most cases it is not reasonable to assume that they will fully prevent the introduction of pathogens. For this reason, controls should be in place to minimize the risk of pathogen growth after the cook step.

2. Is it reasonably likely that pathogens 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 pathogens that are reasonably likely to be present in your product would be able to grow if proper time/temperature controls are not maintained. Consider:

- the moisture available to support pathogen growth in the product (water activity);
- the amount of salt and preservatives in the product;
- the acidity (pH) of the product;
- the availability of oxygen (aerobic vs anaerobic) in the product;
- the presence of competing spoilage organisms in the food.

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

Certain pathogens grow well in temperature abused raw fish (e.g. raw molluscan shellfish) and others do not. Those which grow well in temperature abused raw fish include: *Vibrio vulnificus*, *Vibrio parahaemolyticus, Vibrio cholerae*, and *Listeria monocytogenes*. Those which ordinarily do not grow well, because they compete poorly with the normal spoilage bacteria, include: *Campylobacter jejuni,* pathogenic strain of *Escherichia coli, Salmonella* spp., *Shigella* spp., *Staphylococcus aureus*, and *Yersinia enterocolitica*.

Most 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. Others may grow if the natural condition of the raw fish is changed, such as through salting or reduced oxygen packaging.

Remember that you should consider the potential for time/temperature abuse in the absence of controls. You may already have controls in your process that minimize the potential for time/temperature abuse that could result in unsafe levels of pathogens or toxins. This and the following steps will help you determine whether those or other controls should be included in your HACCP plan.

Time/temperature abuse that occurs at successive processing steps (including storage steps) may be sufficient to result in unsafe levels of pathogens or toxins, even when abuse at one step alone would not result in such levels. For this reason, you should consider the cumulative effect of time/temperature abuse during the entire process. Table #A-2 (Appendix 4) provides guidance about the kinds of time/temperature abuse that may cause a product to be unsafe.

In summary, under ordinary circumstances (e.g. without data to the contrary) you should consider that it is reasonably likely that a pathogen 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 (see question 1, above);
- It is not inhibited by a condition of the food (see Table A-1 [Appendix 4]);
- If your product is raw fish (e.g. raw molluscan shellfish): it will grow in temperature abused raw fish (see information in this question, above);
- It is reasonably likely that, in the absence of controls, cumulative time/temperature abuse conditions such as those described in Table #A-2 (Appendix 4) could occur, and the processing step could contribute significantly to that cumulative abuse.

3. Can the growth to unsafe levels and/or toxin production of pathogens, which is reasonably likely to occur, be eliminated or reduced to an acceptable level at this processing step? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12.)

"Pathogen growth and toxin formation as a result of time/temperature abuse" should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate (or reduce the likelihood of occurrence to an acceptable level) the hazard, if it reasonably likely to occur.

Step #10 discusses a number of pathogen control strategies. This section covers control of pathogen growth and toxin production that occurs as a result of time/temperature abuse. Preventive measures for such growth can include:

- Maintaining product under refrigeration and controlling refrigeration temperatures;
- Proper icing;
- Controlling the amount of time that product is exposed to temperatures that would permit pathogen growth and/or toxin production;

Continued

- Rapidly cooling fish;
- Making sure that the temperature of incoming microbiologically sensitive (e.g. raw and cooked ready-to-eat fishery products) was properly controlled during transportation.

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1, 2 or 3 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If none of the criteria is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. FDA is not aware of any HACCP controls that may exist internationally for the control of pathogens in fish and fishery products that are intended to be fully cooked by the consumer or end user before consumption, other than a rigorous sanitation regime as part of either a prerequisite program or as part of HACCP itself. The Seafood HACCP Regulation requires such a regime. The proper application of sanitation controls is essential because of the likelihood that any pathogens that may be present in seafood products are introduced through poor handling practices (e.g. by the aquacultural producer, the fisherman, or the processor).

FDA is interested in information regarding any HACCP controls beyond sanitation that may be both necessary and practical for the control of pathogens in fish and fishery products that are intended to be fully cooked by the consumer or end user before consumption. However, the agency makes no recommendations in this Guide 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.

If your product is intended to be fully cooked by the consumer or end user before consumption, you should enter "No" in Column 3 of the Hazard Analysis Worksheet for each of the processing steps. For each "No" entry briefly explain in Column 4 that the hazard will be controlled by the consumer or end user cook. In this case, you need not complete Steps #12 through 18 for this hazard.

One exception to this general rule relates to the formation of heat-stable toxins, such as that which is produced by *Staphylococcus aureus*. The toxin produced by *S. aureus* is not destroyed by cooking, even 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). *Bacillus cereus* also produces a heat-stable toxin.

STEP # 12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "pathogen growth and toxin formation as a result of time/temperature abuse" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for this hazard:

Is there a cook step, a pasteurization step, or a retorting step later in your manufacturing process?

1. If there is, you may in most cases identify the cook step, pasteurization step, or retorting step as the CCP. Processing steps prior to cooking, pasteurization, or retorting will then not usually need to be identified as CCPs for this hazard.

Example:
A cooked shrimp processor could set the critical control point for "pathogen growth and toxin formation as a result of time/temperature abuse" at the cook step, and would not need to identify each of the processing steps prior to cooking as critical control points.

Guidance for this pathogen control strategy (e.g. heat treatment) is contained in: Chapter 16 (cooking); Chapter 17 (pasteurization); and, the Low Acid Canned Foods Regulations, 21 CFR 113 (retorting).

There are two important limitations to this strategy. One is that the cooking, pasteurizing, or retorting process must be sufficient to eliminate the pathogens of concern. If it is not, time/temperature control may still be necessary at the processing steps at which growth may occur.

The other limitation is that certain toxins (e.g. *Staphylococcus aureus* and *Bacillus cereus* toxins) are heat stable. Heat treatment, including retorting, may not be adequate to eliminate the toxin once it is formed. In this case time/temperature control may be necessary at the processing steps at which growth and toxin production may occur.

2. If there is no cook step, pasteurization step, or retorting step later in the process, then it may be necessary to identify each processing step at which you have identified this hazard as significant as a critical control point for the hazard. Exposure of the product to temperatures that will permit growth and/or toxin formation should be controlled at these steps.

Example:
A crab meat 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 pathogen growth and toxin formation. The processor does not subject the product to a final pasteurization process and acknowledges that it may be consumed without further cooking. The processor controls temperature during refrigerated storage, and time of exposure to unrefrigerated conditions during the processing steps. The processor identifies each of the post-cook processing and storage steps as CCPs for this hazard.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for each of those processing steps. This control approach is referred to as "Control Strategy Example 1" in Steps 14-18.

Note: Rather than identify each step as an individual CCP when the controls are the same at those steps, it may be more convenient to combine into one CCP those steps that together contribute to cumulative time/temperature exposure.

It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Continued

Following is guidance on processing steps that are likely to be identified as critical control points for this hazard because time/temperature control is necessary to control pathogen growth and/or toxin production. The guidance is divided into two finished product types, because the hazard control strategies differ. The two finished product types are cooked, ready-to-eat and raw, ready-to-eat.

• Cooked, ready-to-eat

These products are cooked by the processor and may be eaten with no further cooking by the consumer. Examples include: cooked crab meat, 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.

Cooked, ready-to-eat products, especially fabricated products, may develop pathogen hazards as a result of cross contamination and growth. Contributing factors to this risk are manual handling steps, multiple ingredients, room temperature processing, and multiple cooling steps. Cumulative exposure to temperature abuse after the cook step must be taken into consideration.

A final pasteurization step (e.g. pasteurized crabmeat) or retorting step (e.g. canned, hot-smoked salmon) may make identification of critical control points at prior processing steps unnecessary for most pathogens. However, neither pasteurization nor retorting is sufficient to inactivate *Staphylococcus aureus* toxin. *Bacillus cereus* also produces a heat-stable toxin. For this hazard you should consider the possibility that the toxin will be produced before the final heat treatment, and control toxin formation, if necessary.

In some cases cooked, ready-to-eat ingredients, such as lobster meat, pasteurized crabmeat, smoked fish, and surimi-based analog products, are received for storage, or assembly into a product that will not receive further cooking by the processor, such as a seafood salad. In these cases, the ingredient receiving and storage steps may also require time/temperature controls and be designated as CCPs (unless the ingredient is received and stored frozen). If these ingredients are to be used in a product that will be heated sufficient to kill any pathogens that may be present, these processing steps may not need to be designated as CCPs. However, in making this determination, you should consider the potential for *Staphylococcus aureus* or *Bacillus cereus* toxin formation. Remember that these toxins are not likely to be inactivated by heat.

Time/temperature controls may be required at the following steps (CCPs):

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

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

- Continuous, mechanical processing steps that are brief, such as:
  - 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/temperature exposure to unrefrigerated conditions, such as:
  - Date code stamping;
  - Case packing;
- Processing steps where the product is held in a frozen state, such as:
  - Glazing;
  - Assembly of orders for distribution;
  - Frozen product storage;
- Processing steps where the product is held at temperatures above 140^{o}F, such as:
  - Initial stage of cooling;
  - Hot holding.

In the processing of many food products, especially products that contain meat or rice, rapid cooling after cooking is important to the safety of the product. This is the case for two reasons. First, spore-forming pathogens, such as *Clostridium perfringens* and *Bacillus cereus*, may survive the cooking process and grow and/or produce toxin in the product during cooling and subsequent handling. In fact, the heat from the cooking process may actually initiate growth of the surviving spores. Second, the cooked product may be recontaminated with pathogens after cooking. Because the normally-occurring spoilage organisms are no longer present to compete with the pathogens in cooked product, rapid growth and toxin formation by the pathogens may be possible.

In deciding whether the cooling step after cooking is significant in your product, consider the following. Some cooking processes, such as the retort cooking of blue crabs (typical of the East coast processing technique) may be adequate to kill even the spores of *C. perfringens* and *B. cereus*. 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. Again, this technique is typical of East coast retort processing of blue crab. Under these conditions cooling after cooking may not need to be identified as a critical control point for this hazard. However, such a determination is dependent upon strict adherence to good sanitation practices, to further minimize the risk of recontamination with pathogens.

When significant handling occurs before or during the cooling process, when the cooked product comes into contact with equipment that was not heated along with the product, or when the cooking process is not adequate to kill the spores of *C. perfringens* and *B. cereus*, cooling after cooking may need to be identified as a critical control point for this hazard.

• Raw, ready-to-eat

These products are not heated during processing to a temperature that will kill pathogens. They are often consumed without cooking. Examples include: cold-smoked fish and raw oysters, clams, and mussels.

Like cooked, ready-to-eat products, raw ready-to-eat products may develop pathogen hazards as a result of cross contamination and growth. They may also contain pathogens that were present in the raw material, and which are capable of growth in the finished product. For example, oysters harvested during the warm weather months may contain *Vibrio vulnificus* or *Vibrio parahaemolyticus,* bacterial pathogens which are capable of growth in the raw product.

Time/temperature controls may be required at the following processing steps (CCPs):

- Receiving;
- Processing, such as:
  - Shucking;
  - Portioning;
- Packaging;
- Raw material, in-process, and finished product storage.

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

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

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

Continued

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "pathogen growth and toxin formation as a result of time/temperature abuse" is identified as a significant hazard on the HACCP Plan Form identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is some general guidance on setting critical limits for the control strategy example discussed in Step #12. More specific guidance follows.

- CONTROL STRATEGY EXAMPLE 1 - TIME/TEMPERATURE CONTROL

Critical Limit: A combination of product internal temperatures and times that will prevent growth of target pathogens to unsafe levels and/or will prevent toxin formation;

AND/OR

A combination of ambient (e.g. air, water, or brine) temperatures and times of exposure that will prevent growth of target pathogens to unsafe levels and/or will prevent toxin formation;

AND/OR

The presence of sufficient cooling media to achieve either of the above purposes (e.g. adequate ice to completely surround the product);

AND/OR

Limits for critical aspects of the process that affect the rate of cooling, as established by a cooling rate study (e.g. volume or size of product being cooled).

Refer to the data provided in Table #A-2 (Appendix 4) for assistance in establishing appropriate cumulative time/temperature exposure critical limits for the pathogens that are significant hazards in your product. The critical limits described are intended to keep the pathogens from reaching the rapid growth phase (i.e. keep them in the lag phase). In summary, the table indicates that:

- If the product is held at internal temperatures above 70˚F (21.1˚C) during processing, exposure time should ordinarily be limited to two hours (three hours if *Staphylococcus aureus* is the only pathogen of concern);

- If the product is held at internal temperatures above 50˚F (10˚C), but not above 70˚F (21.1˚C), exposure time should ordinarily be limited to six hours (twelve hours if *Staphylococcus aureus* is the only pathogen of concern);

- If the product is held at internal temperatures both above and below 70˚F (21.1˚C), exposure times above 50˚F (10˚C) should ordinarily be limited to 4 hours, as long as no more than 2 of those hours are above 70˚F (21.1˚C).

Keep in mind that pathogen 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 pathogens, although there are some exceptions. On the other hand, pathogens grow relatively fast at temperatures above 70˚F (21.1˚C).

Continued

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

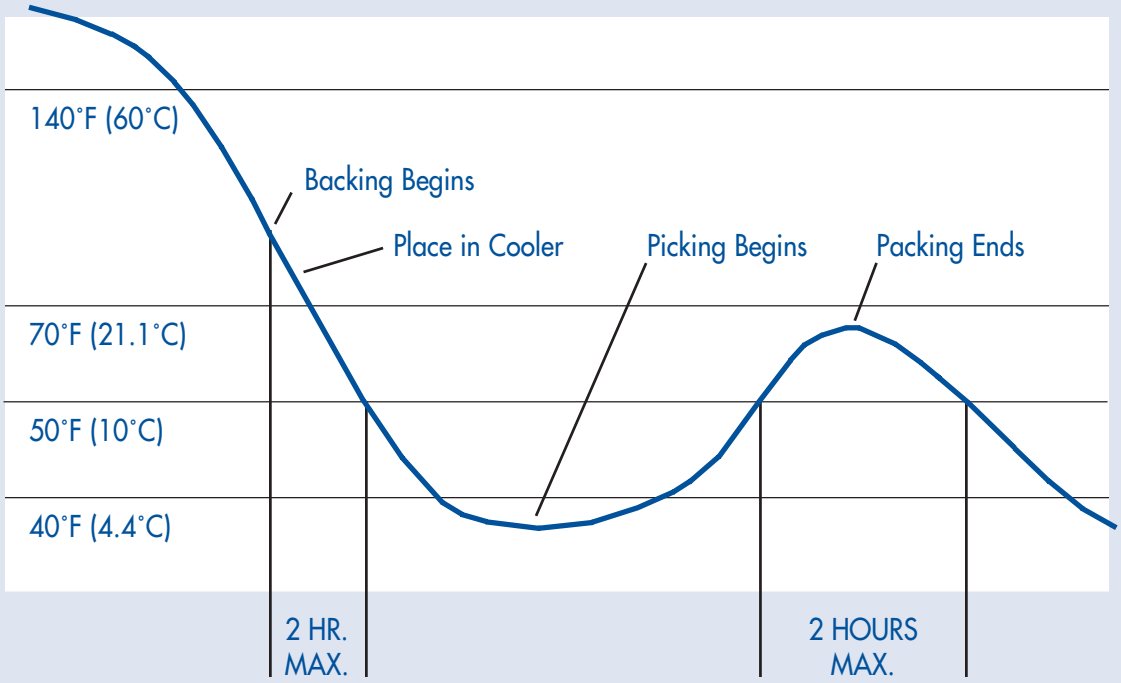
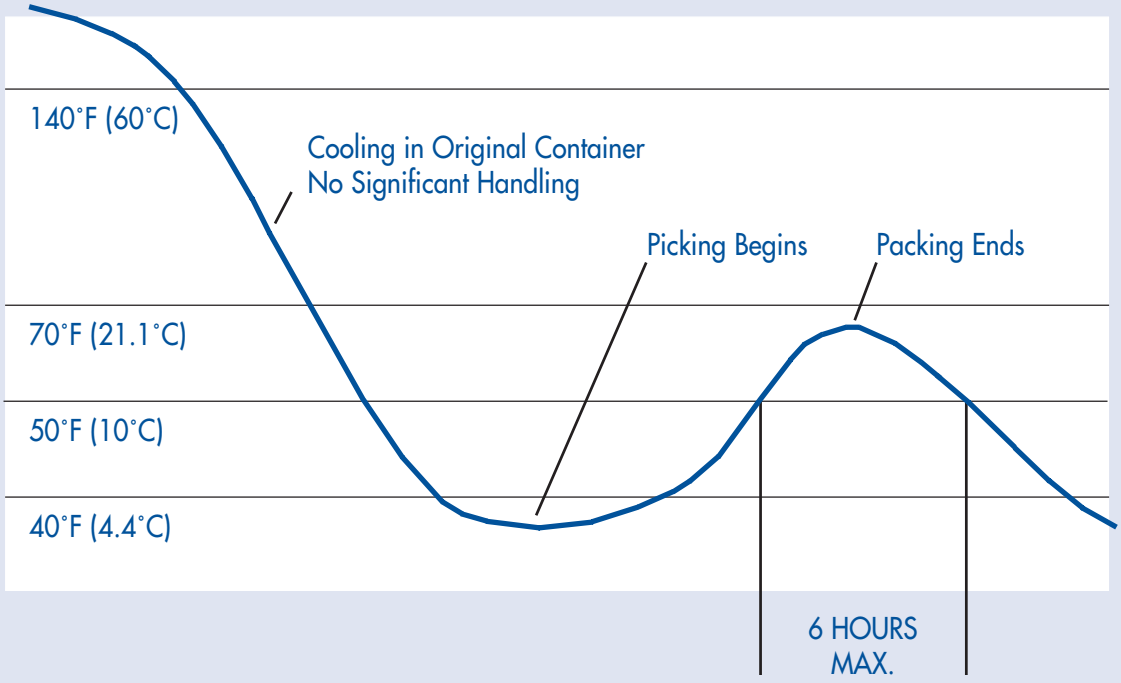


FIGURE 12-2: Internal Temperature Profile — Blue Crabmeat Processing
Cooling After Cook in Original Container With No Significant Handling During Cooling



The time/temperature relationships in the table are designed to refer to the time that your product is held at a particular internal product temperature. You may need to study temperature fluctuations in your product under normal operating conditions in order to relate the values in the table to cumulative time or exposure to unrefrigerated conditions. Drawing a graph depicting the time/temperature profile throughout your processing may help you in calculating the cumulative time/temperature exposure of your product. Figures 12-1 and 12-2 are examples of time/temperature profiles for crabmeat processing. Remember that the values provided in Table A-2 (Appendix 4) are cumulative exposure throughout processing.

For product-specific calculations you may choose to use predictive microbiology models, such as the U.S.D.A. Pathogen Modeling Program (PMP) or the United Kingdom's Food MicroModel (FMM). However, validating the reliability of predictions from such models for your food is essential.

Finished product storage critical limits should be based on the minimum growth temperatures of the pathogens of concern. You should establish a maximum storage temperature that will control pathogen growth and toxin formation throughout the shelf life of your product. It is not always necessary or practical to establish a maximum storage temperature that is below the minimum growth temperature of all of the pathogens of concern. A maximum storage temperature of 40˚F (4.4˚C) is often selected and is generally safe for most refrigerated, microbiologically sensitive products. However, where refrigeration is necessary to control the growth of nonproteolytic *Clostridium botulinum*, a maximum storage temperature of 38˚F (3.3˚C) is usually appropriate (see Chapter 13 for additional information). You should consider the same factors when you set critical limits for raw material and in-process refrigerated product storage.

Cooked, ready-to-eat products provide an additional complication. Survival of most pathogens through a cook step is unlikely if proper controls are used (see Chapter 16). Therefore, cooling after cooking that occurs before the product receives any further significant handling, or contacts any processing equipment that was not heated along with the product, need not be considered as part of the cumulative time/temperature exposure. It is advisable to fully cool product before it is further handled, in order to minimize pathogen growth and toxin formation. However, if significant handling does take place before cooling is completed, the cumulative time/temperature exposure to unrefrigerated conditions (described earlier) should be calculated from the time that the product is first handled after cooking.

If you identified cooling after cooking as a critical control point for this hazard in Step #13 (e.g., because of the potential for *Clostridium perfringens* or *Bacillus cereus* growth or toxin formation, the product should generally be cooled from 140˚F (60˚C) to 70˚F (21.1˚C) or below within two hours and to 40˚F (4.4˚C) or below within another four hours. The cooling rate critical limit is separate from the cumulative time/temperature critical limit described earlier.

Based on the type of monitoring that will be performed, it may be more convenient to state critical limits as a maximum time, a maximum temperature, or a combination of time and temperature. Generally, a critical limit that combines time and temperature is superior because it more closely approximates the actual growth characteristics of pathogens. If a critical limit references a temperature only, the temperature should ordinarily be at or near the minimum growth temperature of the target pathogen. If the critical limit references a time only, the time should ordinarily represent a safe exposure time for the target pathogen under the worst conditions that are reasonably likely to occur (i.e. nearest its optimum growth temperature).

Example:
A crab meat processor (retort process) identifies a series of post-cook processing and storage steps (e.g. backing, picking, packing, and refrigerated storage) as critical control points for pathogen growth and toxin formation. The product is packaged in a plastic container with a snap lid (aerobic). This minimizes the risk of Clostridium botulinum and Clostridium perfringens growth. However, the potential exists for

the other pathogens listed in Table #A-1 (Appendix 4) to be present and to grow, because neither the water activity, acidity, or salt content of the food will inhibit them. Initial cooling takes place in the cooking crates. The product may not be fully cooled before handling. The processor sets the following critical limits:

- *For the finished product cooler: a maximum cooler temperature of 40˚ F (4.4˚ C);*

- *For backing, picking, and packing: a maximum cumulative time of 2 hours at product internal temperatures above 50˚F (10˚C), starting when the cooked crabs are first handled. Alternatively, the processor could set a critical limit of no more than 4 hours at product internal temperatures above 50˚F (10˚C), no more than 2 of which are above 70˚F (21.1˚). These limits are necessary because the crabs are handled while still warm (e.g. above 70˚F [21.1˚C]). Cooling that takes place after the product is handled is included in the limit.*

Example:
Another crab meat processor also identifies a series of post-cook processing and storage steps (e.g. backing, picking, packing, and refrigerated storage) as critical control points. The product is packaged in the same way. However, this product is cooled fully before handling and ice is used on the product during processing to control time/temperature abuse. The processor sets the following critical limits:

- *For the finished product cooler: sufficient ice to fully cover the containers at all times;*

- *For backing, picking, and packing: a maximum product 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.*

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "pathogen growth and toxin formation as a result of time/temperature abuse" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy example discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

Continued

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - TIME/TEMPERATURE CONTROL

For receiving of refrigerated (not frozen) cooked, ready-to-eat or raw, ready-to-eat fishery products to be stored, or processed without further cooking:

What: The internal temperature of the fishery product throughout transportation;
OR
The temperature of the truck or other carrier throughout transportation;
OR
For fishery products with a transit time of four hours or less: The internal temperature of a representative number of containers in the lot at time of delivery;
OR
The adequacy of ice or chemical cooling media at time of delivery.

For raw material, in-process, or finished product refrigerated storage or for refrigerated processing:

What: The temperature of the cooler or refrigerated processing area.

For raw material, in-process, or finished product storage under ice or chemical cooling media:

What: The adequacy of ice or chemical cooling media.

For cooling after cooking:

What: The internal temperature of the product, and the length of time between the end of the cook (or the time that the product internal temperature fell below 140˚F [60˚C]) and the time that measurement was made;
OR
The critical aspects 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 product being cooled).

For unrefrigerated processing and packaging:

What: The length of time of exposure of the product to unrefrigerated conditions, and either the internal temperature of the product or the ambient temperature;
OR
The length of time of exposure of the product to unrefrigerated conditions when the critical limit assumes a temperature greater than 70˚F (21.1˚C);
OR
The length of time of exposure of the product to unrefrigerated conditions when a study demonstrates that under ordinary conditions product does not exceed 70˚F (21.1˚C) when exposed for the length of time specified by the critical limits and that time/temperature combination is adequate to control the growth of the pathogens of concern;
OR
The internal temperature of the product (where temperatures are held below a temperature at which growth is minimized [e.g. 50˚F (10˚C) for *Salmonella* spp.] or held above 140˚F [60˚C] during processing);
OR
The ambient air temperature (where ambient air temperature is low enough to control microbial growth [e.g. 50˚F (10˚C) for *Salmonella* spp.]).

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - TIME/TEMPERATURE CONTROL

For receiving of refrigerated (not frozen) cooked, ready-to-eat or raw, ready-to-eat products to be stored, or processed without further cooking:

How: Use a time/temperature integrator for product internal temperature monitoring during transit;
OR
Use a maximum indicating thermometer for ambient air temperature monitoring during transit;

OR
Use a digital time/temperature data logger for product internal temperature or ambient air temperature monitoring during transit;
OR
Use a recorder thermometer for ambient air temperature monitoring during transit;
OR
Use a dial or digital thermometer for internal product temperature monitoring at receipt;
OR
Make visual observations of the adequacy of ice or other cooling media in a sufficient number of containers to represent all of the product.

For raw material, in-process, or finished product refrigerated storage or for refrigerated processing:

How: Use a digital time/temperature data logger;
OR
Use a recorder thermometer;
OR
Use a high temperature alarm with 24-hour monitoring.

For raw material, in-process, or finished product storage under ice or chemical cooling media:

How: Make visual observations of the adequacy of ice or chemical cooling media in a sufficient number of containers to represent all of the product.

For cooling after cooking:

How: Use a dial or digital thermometer and visual check on time of cooling;
OR
Use a digital time/temperature data logger;
OR
Use appropriate instruments (e.g. dial thermometer, digital time/temperature data logger) and/or visual observations as necessary to measure the critical aspects of the process that affect the rate of cooling, as established by a cooling rate study.

Example:
A crayfish processor has identified cooling after the cook step as a critical control point for pathogen growth and toxin formation. The processor established a cooling critical limit of no more than two hours from 140˚ F (60˚ C) to 70˚F (21.1˚ C) and no more than four 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 two hours after cooking and four more hours after cooking is monitored with a dial thermometer.

Example:
Another crayfish processor has similarly identified cooling as a critical control point and has established the same critical limit. The processor uses a digital time/temperature data logger to monitor the cooling rate of the cooked product.

Example:
Another crayfish processor has similarly identified cooling as a critical control point. This processor has performed a cooling rate study that determined that a cooling rate of no more than two hours from 140˚ F (60˚ C) to 70˚ F (21.1˚ C) and no more than four 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 two hours of cooling and no more than 40˚ F (4.4˚ C) during the remainder of cooling; and, no more than 1000 lbs of crayfish in the cooler. The processor monitors the cooler temperature with a recorder thermometer and monitors the weight of product at receiving with a scale.

For unrefrigerated processing and packaging:

How: Use a dial or digital thermometer for product or ambient air temperature;
AND/OR
Make visual observations of length of exposure to unrefrigerated conditions.

Continued

Example:
A crab meat processor has identified a series of processing steps (e.g. backing, picking, and packing) as critical control points for pathogen growth. The processor established a critical limit of no more than two cumulative hours of exposure to unrefrigerated temperature during these processing steps. 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 visually.

Example:
Another crabmeat processor with identical CCPs, has established a more complex set of critical limits - no more than two cumulative hours with product internal temperatures above 70˚ F (21.1˚ C), and no more than six cumulative hours with product internal temperatures above 50˚ F (10˚ C). This processor also uses marked containers to monitor the progress of the product through the process. However, in addition to monitoring time, the processor also monitors product internal temperature for the marked containers. This monitoring technique provides the processor more flexibility in processing but requires more monitoring effort.

Example:
Another crabmeat processor that fully cools the product before handling has identified the same CCPs. The processor has determined through study that, under ordinary circumstances, in 3 1/2 hours of exposure to ambient (room) temperature the product will remain below 70^{O}F (21.1^{O}C). The processor has set a critical limit of 3 1/2 hours out of refrigeration. The processor monitors visually the time that picking begins after each batch of crabs is brought into the processing room and the time that the last of the containers of crabmeat from this batch has been placed on ice.

Example:
A lobster meat processor has identified the meat removal process as a critical control point for pathogen growth. The operation is performed under near refrigeration conditions (50˚F [10˚C]). The processor has determined that exposure time sufficient to jeopardize the safety of the product at these temperatures is not reasonably likely to occur. The processor only monitors ambient air temperature with a digital data logger.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - TIME/TEMPERATURE CONTROL

For receiving of refrigerated (not frozen) cooked, ready-to-eat or raw, ready-to-eat products to be stored, or processed without further cooking:

Frequency: Each shipment.

For raw material, in-process, or finished product refrigerated storage or for refrigerated processing:

Frequency: Continuous monitoring by the instrument itself, with visual check of the instrument at least once per day.

For raw material, in-process, or finished product storage under ice or chemical cooling media:

Frequency: At least twice per day;
OR
For finished product storage, at least immediately prior to shipment.

For cooling after cooking:

Frequency: At least every two hours;
OR
For critical aspects of the cooling process, as often as necessary to ensure control of the process.

For unrefrigerated processing and packaging:

Frequency: At least every two hours;
OR
Each batch.

Who Will Perform the Monitoring??

- CONTROL STRATEGY EXAMPLE 1 - TIME/TEMPERATURE CONTROL

Who: With recorder thermometers, time/temperature integrators, high temperature alarms, maximum indicating thermometers, and digital data loggers, monitoring is performed by the equipment itself. However, anytime that such instrumentation is used, a visual check should be made at least once per day in order to ensure that the critical limits have consistently been met. These checks, as well as dial thermometer checks, time of expo sure checks, and adequacy of ice or other cooling media checks may be performed by the receiving employee, the equipment operator, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the process and the monitoring procedure.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "pathogen growth and toxin formation as a result of time/temperature abuse" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - TIME/TEMPERATURE CONTROL

For receiving of refrigerated (not frozen) cooked, ready-to-eat or raw, ready-to-eat products to be stored, or processed without further cooking:

Corrective Action: Reject shipment, if the CL is not met;
OR
Hold the product until it can be evaluated based on its total time/temperature exposure;
AND
Discontinue use of supplier or carrier until evidence is obtained that transportation practices have changed.

Note: If an incoming lot that fails to meet a receiving critical limit is mistakenly accepted, and the error is later detected, the following actions should be taken: 1) the lot and any products processed from that lot should be destroyed, diverted to a nonfood use or to a use in which the critical limit is not applicable, or placed on hold until a food safety evaluation can be completed; and 2) any products processed from that lot that have already been distributed should be recalled and subjected to the actions described above.

For other critical control points:

Corrective Action: Take one or several of the following actions as necessary to regain control over the operation after a CL deviation:
- Add ice to the affected product;

OR
- Make repairs or adjustments to the malfunctioning cooler;

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

OR
- Return the affected in-process product to the cooler;

Continued

OR
- Freeze the affected product;

OR
- Modify the process as needed to reduce the time/temperature exposure;

AND

Take one of the following actions to product involved in the critical limit deviation:
- Destroy the product;

OR
- Hold the product until it can be evaluated based on its total time/temperature exposure;

OR
- Cook or recook the product. In this case, special attention must be paid to the fact that any *Staphylococcus aureus* or *Bacillus 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). In this case, special attention must be paid to the fact that any *Staphylococcus aureus* or *Bacillus cereus* toxin that may be present may not be inactivated by heat;

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

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "pathogen growth and toxin formation as a result of time/temperature abuse" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - TIME/TEMPERATURE CONTROL

For receiving of refrigerated (not frozen) cooked, ready-to-eat or raw, ready-to-eat products to be stored or processed without further cooking:

Records: Receiving record showing the results of the time/temperature integrator checks;

OR

Printout from digital time/temperature data logger;

OR

Recorder thermometer chart;

OR

Receiving record showing the results of the maximum indicating thermometer checks;

OR

The results of internal product temperature monitoring at receipt;

AND

The date and time of departure and arrival of the vehicle;

OR

Receiving record showing the results of the ice or other cooling media checks.

For raw material, in-process, or finished product refrigerated storage or refrigerated processing:

Records: Printout from digital time/temperature data logger;

OR

Recorder thermometer chart;

OR

Storage record showing the results of the high temperature alarm checks.

For raw material, in-process, or finished product storage under ice or chemical cooling media:

Records: Storage record showing the results of the ice or other cooling media checks.

For cooling after cooking:

Records: Processing record showing the results of the time/temperature checks;
OR
Printout from digital time/temperature data logger;
OR
Appropriate records (e.g. processing record showing the results of the time and temperature checks and/or volume of product in cooler, printout from digital time/temperature data logger) as necessary to document the monitoring of the critical aspects of the process that affect the rate of cooling, as established by a cooling rate study.

For unrefrigerated processing and packaging:

Records: Processing records showing the results of time and/or temperature checks;
OR
Printout from digital time/temperature data logger.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "pathogen growth and toxin formation as a result of time/temperature abuse" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - TIME/TEMPERATURE CONTROL

Verification: Review monitoring, corrective action, and verification records within one week of preparation;
AND
When digital time/temperature data loggers, recorder thermometers, or high temperature alarms are used for in-plant monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) at least once per day;
AND
When digital time/temperature data loggers or recorder thermometers are used for monitoring of transport conditions at receiving, check for accuracy against a known accurate thermometer (NIST-traceable). Verification should be conducted on new suppliers' vehicles and at least quarterly for each supplier thereafter. Additional verifications may be warranted based on observations at receipt (e.g. refrigeration units appear to be in poor repair, or readings appear to be erroneous);
AND
When visual checks of ice or cooling media are used to monitor the adequacy of coolant, periodically measure internal temperatures of fish to ensure that the ice or cooling media is sufficient to maintain product temperatures at 40˚F (4.4˚C) or less;
AND
When dial or digital thermometers or maximum indicating thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter. (Note: optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.)

Enter the verification procedures in Column 10 of the HACCP Plan Form.

Continued

TABLE #12-1

Control Strategy Example 1 - Time/temperature control - Version 1

This table is an example of a portion of a HACCP plan relating to the control of pathogen growth and toxin formation as a result of time/temperature abuse for a processor of blue crabmeat (typical of Gulf Coast boiling processing method), using Control Strategy Example 1 - Time/temperature control. It is provided for illustrative purposes only. Pathogen growth and toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. Chemical contaminants, pathogen survival through cooking, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Backing	Pathogen growth and toxin formation	No more than 2 hrs. cumulative time during backing, picking and packing Note: This CL is necessary because the crabs are handled at internal temperatures above 70˚F during backing	Time of product exposure to unrefrigerated conditions	Visual observation of marked containers	Start marked container every two hours during backing	Production supervisor	• Immediately ice product or move to cooler • Hold and evaluate based on total time/ temperature exposure	Production record	Review monitoring and corrective action records within one week of preparation
Backed crab cooler	Pathogen growth and toxin formation	Cooler maintained at or below 40˚F	Cooler temperature	Digital time/ temperature data logger	Continuous with visual check once per day	Production supervisor	• Move to alternate cooler and/or add ice • Hold and evaluate based on total time/ temperature exposure	Data logger printout	• Check accuracy of data logger against a standard thermometer once per day; • Review monitoring, corrective action, and verification records within one week of preparation

TABLE #12-1, continued

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring What	(5) Monitoring How	(6) Monitoring Frequency	(7) Monitoring Who	(8) Corrective Action(s)	(9) Records	(10) Verification
Picking	Pathogen growth and toxin formation	No more than 2 hrs. cumulative time during backing, picking, and packing	Time of product exposure to unrefrigerated conditions	Visual observation of marked containers	Start marked container appx. every two hours during picking	Production supervisor	• Immediately ice product or move to cooler • Hold and evaluate based on total time/ temperature exposure	Production record	Review monitoring and corrective action records within one week of preparation
Packing	Pathogen growth and toxin formation	No more than 2 hrs. cumulative time during backing, picking, and packing	Time of product exposure to unrefrigerated conditions	Visual observation of marked containers	Start marked container appx. every two hours during picking	Production supervisor	• Immediately ice product or move to cooler • Hold and evaluate based on total time/ temperature exposure	Production record	Review monitoring and corrective action records within one week of preparation
Finished product cooler	Pathogen growth and toxin formation	Cooler maintained at or below 40°F	Cooler temperature	Digital time/ temperature data logger	Continuous with visual check once per day	Production employee	• Move to alternate cooler and/or add ice • Hold and evaluate based on total time/ temperature exposure	Data logger printout	• Check accuracy of data logger against a standard thermometer once per day; • Review monitoring, corrective action, and verification records within one week of preparation

TABLE #12-2

Control Strategy Example 1 - Time/temperature control - Version 2

This table is an example of a portion of a HACCP plan relating to the control of pathogen growth and toxin formation as a result of time/temperature abuse for a processor of blue crabmeat (typical of the East coast retort processing method), using Control Strategy Example 1 - Time/temperature control. It is provided for illustrative purposes only. Pathogen growth and toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, pathogen survival through cooking, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Cooked crab cooler	Pathogen growth and toxin formation Note: Control is necessary at this step because the processor has not established that the cook step is adequate to kill the spores of *Clostridium perfringens* or *Bacillus cereus*	• Crabs cooled from 140°F to 70°F in 2 hrs. and 70°F to 40°F in 4 more hrs.	• Cooked crab internal temperature	• Dial thermometer in marked batches of cooked crabs	• Start marked batch approx. every two hours during cooking	• Production supervisor	• Move part of load to alternate cooler and/or add ice • Hold and evaluate based on total time/ temperature exposure	• Production record	• Check accuracy of data logger against a standard thermometer once per day; • Check accuracy of digital thermometer against a standard once per day
		• Cooler maintained at or below 40°F after cooling completed	• Cooler temperature	• Digital time/ temperature data logger	• Continuous with visual check once per day	• Production supervisor	• Same	• Data logger printout	• Review monitoring, corrective action, and verification records within one week of preparation

TABLE #12-2, continued

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Picking/boning/ packing	Pathogen growth and toxin formation	No more than 3 1/2 hours cumulative time during picking, boning, and packing (beginning when cooked crabs are first handled in picking room) Note: This critical limit is based on a study that demonstrates that, under ordinary circumstances, the product does not exceed 70°F in 3 1/2 hours exposure to ambient temperature	Time of product exposure to unrefrigerated conditions	• Visual observation of time that picking begins for each batch of cooked crabs that is brought into the picking room • Visual observation of time that the last container of crabmeat from the batch is packed on ice	• Every batch • Every batch	• Picking room supervisor • Packing room employee	• Pasteurize or freeze the product • Hold and evaluate based on total time/ temperature exposure	• Cooked crab record • Packing record	• Review monitoring and corrective action records within one week of preparation • Study showing temperature profile of product during processing
Finished product storage	Pathogen growth and toxin formation	Finished product containers completely surrounded with ice	Adequacy of ice	Visual observation	Each case immediately before shipping	Shipping employee	• Re-ice • Hold and evaluate based on total time/ temperature exposure	Shipping record	• Review monitoring and corrective action records within one week of preparation

Notes:

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Clostridium botulinum toxin formation can result in consumer illness and death. This chapter covers the potential for *C. botulinum* growth and toxin formation as a result of time/temperature abuse during processing, storage and distribution. The growth of other pathogens and the formation of other toxins as a result of time/temperature abuse during processing are covered in Chapters 7 (histamine formation), 12 (pathogen growth during processing other than *C. botulinum*), and 15 (*Staphylococcus aureus* toxin formation in hydrated batter mixes). Additionally, the prevention of *C. botulinum* toxin formation during storage and distribution of the finished product by drying is covered in Chapter 14. The prevention of *C. botulinum* toxin formation during storage and distribution of the finished product by specialized cooking and hot filling procedures is covered in Chapter 16. The prevention of *C. botulinum* toxin development during storage and distribution of the finished product by pasteurization in the finished product container is covered in Chapter 17.

When *C. botulinum* grows it can produce a potent toxin, which can cause death by preventing breathing. It is one of the most poisonous naturally occurring substances known. The toxin can be destroyed by heat (e.g. boiling for 10 minutes), but processors cannot rely on this as a means of control.

There are two major groups of *C. botulinum*, the proteolytic group (i.e. those that break down proteins) and the nonproteolytic group (i.e. those that do not break down proteins). The proteolytic group includes *C. botulinum* type A and some of types B and F. The nonproteolytic group includes *C. botulinum* type E and some of types B and F.

The vegetative cells of all types are easily killed by heat. *C. botulinum* is able to produce spores. In this state the pathogen is very resistant to heat. The spores of the proteolytic group are much more resistant to heat than are those of the nonproteolytic group. Table A-4 (Appendix 4) provides guidance about the conditions under which the spores of the most heat resistant form of nonproteolytic *C. botulinum*, type B, are killed. However, there are some indications that substances that may be naturally present in some products, such as lysozyme, may enable nonproteolytic *C. botulinum* to more easily recover after heat damage, resulting in the need for a considerably more aggressive process to ensure destruction.

Temperature abuse occurs when product is exposed to temperatures favorable for *C. botulinum* growth for sufficient time to result in toxin formation. Table #A-1 (Appendix 4) provides guidance about the conditions under which *C. botulinum* and other pathogens are able to grow.

Packaging conditions that reduce the amount of oxygen present in the package (e.g. vacuum packaging) extend the shelf life of product by inhibiting the growth of aerobic spoilage bacteria. The safety concern with these products is the increased potential for the formation of *C. botulinum* toxin before spoilage makes the product unacceptable to consumers.

C. botulinum forms toxin more rapidly at higher temperatures than at lower temperatures. The minimum temperature for growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F is 38˚F (3.3˚C). For type A and proteolytic types B and F, the minimum temperature for growth is 50˚F (10˚C). As the shelf life of refrigerated foods is increased, more time is available for *C. botulinum* growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened. Processors should expect that at some point during storage, distribution,

Continued

display or consumer handling of refrigerated foods, proper refrigeration temperatures will not be maintained (especially for the nonproteolytic group). Surveys of retail display cases indicate that temperatures of 45-50˚F (7-10˚C) are not uncommon. Surveys of home refrigerators indicate that temperatures can exceed 50˚F (10˚C).

In reduced oxygen packaged products in which the spores of nonproteolytic *C. botulinum* are inhibited or destroyed (e.g., smoked fish, pasteurized crabmeat, pasteurized surimi), normal refrigeration temperatures of 40˚F (4.4˚C) are appropriate because they will limit the growth of proteolytic *C. botulinum* and other pathogens that may be present. Even in products where nonproteolytic *C. botulinum* is the target organism for the pasteurization process and vegetative pathogens, such as *Listeria monocytogenes,* are not likely to be present (e.g. pasteurized crabmeat, pasteurized surimi), a storage temperature of 40˚F (4.4˚C) is still appropriate because of the potential survival through the pasteurization process and recovery of spores of nonproteolytic *C. botulinum* aided by naturally occurring substances, such as lysozyme. In this case refrigeration serves as a prudent second barrier.

In reduced oxygen packaged products in which refrigeration is the sole barrier to outgrowth of nonproteolytic *C. botulinum* and the spores have not been destroyed (e.g. vacuum packaged raw fish, unpasteurized crayfish meat), the temperature must be maintained at 38˚F (3.3˚C) or below from packing to consumption. Ordinarily processors can ensure that temperatures are maintained at or below 38˚F (3.3˚C) while the product is in their control. However, current distribution channels do not ensure the maintenance of these temperatures after the product leaves their control. The use of time temperature integrators on each consumer package may be an appropriate means of enabling temperature control throughout distribution. Alternatively, products of this type may be safely marketed frozen, with appropriate labeling. For some products, control of *C. botulinum* can be achieved by breaking the vacuum seal before the product leaves the processor's control.

• Sources of *C. botulinum*

C. botulinum can enter the process on raw materials. The spores of *C. botulinum* are very common in nature. They have been found in the gills and viscera of fin fish, crabs, and shellfish. *C. botulinum* type E is the most common form found in fresh water and marine environments. Types A and B are generally found on land, but may also be occasionally found in water. It should be assumed that *C. botulinum* will be present in any raw fishery product, particularly in the viscera.

• Reduced oxygen packaging

There are a number of conditions that can result in the creation of a reduced oxygen packaging environment. They include:

• Vacuum packaging or modified or controlled atmosphere packaging. These packaging methods directly reduce the amount of oxygen in the package;

• Packaging in hermetically sealed containers (e.g. double seamed cans, glass jars with sealed lids, heat sealed plastic containers), or packing in deep containers from which the air is expressed (e.g. caviar in large containers), or packing in oil. These and similar processing/packaging techniques prevent the entry of oxygen into the container. Any oxygen present at the time of packaging may be rapidly depleted by the activity of spoilage bacteria, resulting in the formation of a reduced oxygen environment.

Packaging that provides an oxygen transmission rate of 10,000 cc/m^2/24hrs (e.g. 1.5 mil polyethylene) can be regarded as an oxygen-permeable packaging material for fishery products. This can be compared to an oxygen-impermeable package which might have an oxygen transmission rate as low as or lower than 100 cc/m^2/24hr (e.g. 2 mil polyester). An oxygen permeable package should provide sufficient exchange of oxygen to allow aerobic spoilage organisms to grow and spoil the product before toxin is produced under moderate abuse temperatures. However, use of an oxygen permeable package will not compensate for the restriction to oxygen exchange created by practices such as packing in oil or in deep containers from which the air is expressed.

• Control of *C. botulinum* in the finished product

There are a number of strategies to prevent *C. botulinum* toxin formation during storage and distribution of finished fishery products. They include:

For products that do not require refrigeration (i.e. shelf-stable products):

• Heating the finished product in its final container sufficiently by retorting to destroy the spores of *C. botulinum* types A,B,E, and F (e.g. canned fish) (covered by the low acid canned foods regulations, 21 CFR 113). Note: these controls are not required to be included in your HACCP plan;

• Controlling the level of acidity (pH) in the finished product sufficient to prevent the growth of *C. botulinum* types A,B,E, and F (4.6 or below) (e.g. shelf-stable acidified products) (covered by the acidified foods regulations, 21 CFR 114). Note: these controls are not required to be included in your HACCP plan;

• Controlling the amount of moisture that is available in the product (water activity) sufficient to prevent the growth of *C. botulinum* types A,B,E, and F and other pathogens that may be present in the product (i.e. 0.85 or below) (e.g. shelf-stable dried products) (covered by Chapter 14);

• Controlling the amount of salt in the product sufficient to prevent the growth of *C. botulinum* types A, B, E, and F and other pathogens that may be present in the product (i.e. 20% salt or more)(e.g. shelf-stable salted products)(covered in this chapter).

For products that require refrigeration:

• Heating the finished product in its final container sufficiently by pasteurization to destroy the spores of *C. botulinum* type E and nonproteolytic types B and F (covered in Chapter 17); and then controlling the growth of the surviving *C. botulinum* type A and proteolytic types B and F in the finished product with refrigerated storage (e.g. pasteurized crabmeat, some pasteurized surimi-based products) (covered in this chapter and Chapter 12);

• Heating the product sufficiently to destroy the spores of *C. botulinum* type E and nonproteolytic types B and F (covered in Chapter 16); and then minimizing the risk of recontamination by hot filling the product into the final container in a continuous filling system (covered in Chapter 18); and then controlling the growth of the surviving *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (covered in this chapter and Chapter 12);

• Controlling the amount of moisture that is available in the product (water activity) sufficient to inhibit the growth of *C. botulinum* type E and nonproteolytic types B and F by drying (covered in Chapter 14); and then controlling the growth of *C. botulinum* type A, and proteolytic types B and F, and other pathogens that may be present in the finished product through refrigerated storage (covered in this chapter and Chapter 12);

• Controlling the level of acidity (pH), salt, moisture (water activity), or some combination of these barriers, in the finished product sufficiently to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F by formulation (i.e. pH 5 or below; salt 5% or more; or water activity below 0.97) (covered in this chapter); and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g. refrigerated acidified ["pickled"] products) (covered in this chapter and Chapter 12);

• Controlling the amount of salt and preservatives, such as sodium nitrite, in the finished product, in combination with other barriers, such as smoke, heat damage and competitive bacteria, sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F (covered in this chapter); and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g. salted, smoked, or smoke-flavored fish) (covered in this chapter and Chapter 12);

Continued

• Controlling the amount of salt in the finished product, in combination with heat damage from pasteurization in the finished product container, sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F (covered in this chapter); and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g. some pasteurized surimi-based products) (covered in this chapter and Chapter 12);

• Control of *C. botulinum* during processing and storage

There are a number of strategies to prevent *C. botulinum* toxin formation during the processing and storage of fishery products. They include:

• Managing the amount of time that food is exposed to temperatures that are favorable for *C. botulinum* growth and toxin formation during finished product storage (covered in this chapter).

Note: The guidance in this chapter emphasizes preventive measures for the control of *C. botulinum* in products that are contained in reduced oxygen packaging. As was previously described, this is because such an environment extends the shelf life of the product in a way that favors *C. botulinum* growth and toxin formation over aerobic spoilage. It is also possible for *C. botulinum* to grow and produce toxin in unpackaged or aerobically packaged product. This is because of the development within the product of microenvironments that support its growth. However, toxin formation under these circumstances requires the type of severe temperature abuse that is not reasonably likely to occur in most food processing environments. Nonetheless, the Good Manufacturing Practice Regulations, 21 CFR 110, require refrigeration of foods that support the growth of pathogenic microorganisms. In addition Chapter 12 provides recommendations for storage controls for pathogens other than *C. botulinum*.

• Evisceration of fish before processing. Because spores are known to be present in the viscera of fish, any product that will be preserved by salting, drying, pickling, or fermentation must be eviscerated prior to processing (see Compliance Policy Guide sec. 540.650). Without evisceration, toxin formation is possible during the process even with strict control of temperature. Evisceration must be thorough and performed to minimize contamination of the fish flesh. If even a portion of the viscera or its contents is left behind, the risk of toxin formation by *C. botulinum* remains. Small fish, less than 5 inches in length (e.g. anchovies and herring sprats), that are processed in a manner that prevents toxin formation, and that reach a water phase salt content of 10 percent in refrigerated products, or a water activity of below 0.85 (Note: this value is based on the minimum water activity for growth of *S. aureus*) or a pH of 4.6 or less, in shelf-stable products are exempt from the evisceration requirement.

Examples of *C. botulinum* Control in Specific Products:

• Control in refrigerated, reduced oxygen packaged smoked and smoke-flavored fish

Achieving the proper concentration of salt and nitrite in the flesh of refrigerated, reduced oxygen packaged smoked and smoke-flavored fish is necessary to prevent the formation of toxin by *C. botulinum* type E and nonproteolytic types B and F during storage and distribution. Salt works along with smoke and any nitrites that are added to prevent growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F (Note: nitrites may only be used in salmon, sable, shad, chubs, and tuna - FDA Compliance Policy Guide sections 540.500 and 540.200).

In hot-smoked products, heat damage to the spores of *C. botulinum* type E and nonproteolytic types B and F also helps prevent toxin formation. In these products, control of the heating process is critical to the safety of the finished product. It is important to note, however, that this same heating process also reduces the numbers of naturally occurring spoilage organisms. The spoilage organisms would otherwise have competed with, and inhibited the growth of, *C. botulinum*.

In cold-smoked fish, it is important that the product does not receive so much heat that the number of spoilage organisms are significantly reduced. This is because spoilage organisms must be present to inhibit the growth and toxin formation of *C. botulinum* type E and nonproteolytic types B and F. This inhibition is important in cold-smoked fish because the heat applied during this process is not adequate to weaken the *C. botulinum* spores. Control of the temperature during the cold-smoking process to ensure survival of the spoilage organisms is, therefore, critical to the safety of the finished product.

The interplay of these inhibitory effects (i.e. salt, temperature, smoke, nitrite) is complex. Control of the brining or dry salting process is clearly critical to ensure that there is sufficient salt in the finished product. However, preventing toxin formation by *C. botulinum* type E and nonproteolytic types B and F is made even more complex by the fact that adequate salt levels are not usually achieved during brining. Proper drying is also critical in order to achieve the finished product water phase salt level (i.e. the concentration of salt in the water portion of the fish flesh) needed to inhibit the growth and toxin formation of *C. botulinum*.

The above described control procedures are covered in this chapter.

Processors should ordinarily restrict brining, dry salting, and smoking loads to single species and to fish portions of approximately uniform size. This minimizes the complexity of controlling the operation.

The combination of inhibitory effects that are present in smoked and smoke-flavored fish are not adequate to prevent toxin formation by *C. botulinum* type A and proteolytic types B and F. Strict refrigeration control (i.e. at or below 40˚F [4.4˚C]) during storage and distribution must be maintained to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in these products (covered in this chapter and Chapter 12).

• Control in refrigerated, reduced oxygen packaged, pasteurized fishery products

Refrigerated, reduced oxygen packaged, pasteurized products fall into two categories: 1) those which are pasteurized in the final container); and 2) those which are pasteurized in a kettle (i.e. cooked) and then hot filled into the final container (e.g."heat and fill" soups and sauces). In both cases, ordinarily the heating process must be sufficient to destroy the spores of *C. botulinum* type E and nonproteolytic types B and F. In neither case is it likely that the heating process will be sufficient to destroy the spores of *C. botulinum* type A and proteolytic types B and F. Therefore, strict refrigeration control (i.e. at or below 40˚F [4.4˚C]) must be maintained during storage and distribution to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F, and because of the potential survival through the pasteurization process and recovery of spores of nonproteolytic *C. botulinum* aided by naturally occurring substances, such as lysozyme. In the case of the lysozyme effect, refrigeration serves as a prudent second barrier.

In the second category of products, filling the product into the final container while it is still hot in a continuous filling system (i.e. "hot filling") is also critical to the safety of the finished product, because it minimizes the risk of recontamination of the product with pathogens, including *C. botulinum* type E and nonproteolytic types B and F. This strategy applies to products such as soups and sauces that are filled directly from the cooking kettle, where the risk of recontamination is minimized. It does not apply to products such as crabmeat, lobster meat, or crayfish meat, or other products that are handled between cooking and filling. Control of hot filling is covered in Chapter 18. Chapter 18 also covers other controls that may be necessary to prevent recontamination, including controlling container sealing and controlling contamination of container cooling water. These controls may be critical to the safety of both categories of products.

Examples of properly pasteurized products are: blue crabmeat pasteurized to a cumulative lethality of $F_{185^{\circ}F}$ ($F_{85^{\circ}C}$) = 31 min., z=16˚F (9˚C); surimi-based products, soups, or sauces pasteurized at an internal temperature of 194˚F (90˚C) for at least 10 minutes.

Continued

In some pasteurized surimi-based products, salt in combination with a milder pasteurization process in the finished product container work to prevent growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F. Control of the formulation process is clearly critical in these products to ensure that there is sufficient salt in the finished product. The formulation controls discussed in this chapter for the production of "pickled" fishery products are also suitable for the control of surimi-based product formulation. Control of the in-container pasteurization process is also critical. An example of a properly pasteurized surimi-based product in which 2.5% salt is present is one that has been pasteurized at an internal temperature of 185˚F (85˚C) for at least 15 minutes. This process may not be suitable for other types of products, because of the unique formulation and processing involved in the manufacture of surimi-based products.

In-container pasteurization is covered in Chapter 17. Cooking is covered in Chapter 16. Control of refrigerated storage is covered in this chapter and in Chapter 12.

• Control in refrigerated, reduced oxygen packaged "pickled" fish, caviar, and similar products

In "pickled" fish, caviar, and similar products that have not been preserved sufficiently for them to be shelf-stable, growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F is controlled by either:

- Adding sufficient salt to produce a water phase salt level (i.e. the concentration of salt in the water-portion of the fish flesh) of at least 5 percent;

- Adding sufficient acid to reduce the acidity (pH) to 5.0 or below;

- Reducing the amount of moisture that is available for growth (water activity) to below 0.97 (e.g., by adding salt or other substances that "bind" the available water); or

- Making a combination of salt, pH, and/or water activity adjustments that, when combined, prevent the growth of *C. botulinum* type E and nonproteolytic types B and F (to be established by a scientific study).

Much like smoked products, in some of these products the interplay of these inhibitory effects (i.e. salt, water activity, and pH) can be complex. Control of the brining, pickling, or formulation steps is, therefore, critical to ensure that there are sufficient barriers in the finished product to prevent the growth and toxin formation of *C. botulinum* type E and nonproteolytic type B and F during storage and distribution. These control procedures are covered in this chapter.

Processors should ordinarily restrict brining and pickling loads to single species and to fish portions of approximately uniform size. This minimizes the complexity of controlling the operation.

The above discussed controls are not sufficient to prevent toxin formation by *C. botulinum* type A and proteolytic types B and F. Strict refrigeration control (i.e. at or below 40˚F [4.4˚C]) during storage and distribution must, therefore, be maintained to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F, and other pathogens that may be present in these products (covered in this chapter).

• Control in refrigerated, reduced oxygen packaged raw, unpreserved fish and unpasteurized, cooked fishery products

For refrigerated, reduced oxygen packaged raw, unpreserved fish (e.g. vacuum packaged fresh fish fillets) and unpasteurized, cooked fishery products (e.g. vacuum packaged, unpasteurized crabmeat, lobstermeat, or crayfish meat), the sole barrier to toxin formation by *C. botulinum* type E and nonproteolytic types B and F during finished product storage and distribution is refrigeration. These types of *C. botulinum* will grow at temperatures as low as 38˚F (3.3C). As was previously stated, maintenance of temperatures at or below 38˚F (3.3˚C) after the product leaves the processor's control cannot normally be ensured. Time temperature integrators on each consumer package may be an appropriate means of providing such control. If you intend to use a reduced oxygen packaging technique for these products and you intend to market the products refrigerated without time temperature integrators on each consumer package, you will need to evaluate the effectiveness of other preventive measures, either

singularly, or in combination. Such evaluation will usually necessitate the performance of inoculated pack studies under moderate abuse conditions. A suitable protocol for the performance of such studies is contained in a 1992 publication by the National Advisory Committee on Microbiological Criteria for Foods, "Vacuum or modified atmosphere packaging for refrigerated, raw fishery products.

- Control in frozen, reduced oxygen packaged fishery products

If your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important, keep frozen until used, thaw under refrigeration immediately before use"), then formation of *C. botulinum* toxin may not be a significant hazard.

- Control in unrefrigerated (shelf-stable), reduced oxygen packaged fishery products

Examples of shelf-stable, reduced oxygen packaged fishery products are dried fish, acidified fish, canned fish and salted fish. Because these products are marketed without refrigeration, either: 1) the spores of *Clostridium botulinum* types A,B, E and F must be destroyed after the product is placed in the finished product container (covered by the low acid canned foods regulations, 21 CFR 113); or 2) a barrier, or combination of barriers, must be in place that will prevent growth and toxin formation by *Clostridium botulinum* types A,B, E and F, and other pathogens that may be present in the product. Suitable barriers include:

- Sufficient salt is added to produce a water phase salt level (the concentration of salt in the water-portion of the fish flesh) of at least 20 percent (Note: this value is based on the maximum salt level for growth of *S. aureus*.) (covered in this chapter)

- Sufficient salt is added to reduce the water activity to 0.85 or below (covered in this chapter);

- Sufficient acid is added to reduce the pH to 4.6 or below (covered by the acidified foods regulations, 21 CFR 114);

- The product is dried sufficiently to reduce the water activity to 0.85 or below (Note: this value is based on the minimum water activity for growth and toxin formation of *S. aureus,*)(covered in Chapter 14).

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "*C. botulinum* toxin formation" is a significant hazard. The criteria are:

1. Is it reasonably likely that *C. botulinum* will grow and produce toxin during finished product storage and distribution?

The factors that make *C. botulinum* toxin formation during finished product storage and distribution reasonably likely are those that may result in the formation of a reduced oxygen packaging environment. These are discussed in Step #10, under the heading, "Reduced oxygen packaging."

2. Can the growth and/or toxin production of *C. botulinum,* which is reasonably likely to occur, be eliminated or reduced to an acceptable level at this processing step? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12.)

"*C. botulinum* toxin formation" should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate (or reduce the likelihood of occurrence to an acceptable level) the hazard, if it is reasonably likely to occur.

Preventive measures for *C. botulinum* toxin formation during processing can include:

- controlling refrigeration temperatures;
- proper icing;
- controlling the amount of time that the product is exposed to temperatures that would permit *C. botulinum* toxin formation;
- rapidly cooling the fish.

Continued

Preventive measures for *C. botulinum* toxin formation during finished product distribution and storage are discussed in Step #10, under the heading, "Control of *C. botulinum* in the finished product."

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

Preventive measures of the type just described should be available to most of the "at risk" products described above (i.e. vacuum packaged fish, modified atmosphere packaged fish, fish packaged in hermetically sealed containers, fish packed in oil, fish packed in deep containers in which the air is expressed). Notable products for which these preventive measures are not available include: refrigerated, reduced oxygen packaged raw, unpreserved fish (e.g. vacuum packaged, fresh fish fillets) and reduced oxygen packaged, unpasteurized, cooked fishery products (e.g. vacuum packaged, unpasteurized crabmeat, lobstermeat, or crayfish meat). For these products, the sole barrier to toxin formation by *C. botulinum* type E and nonproteolytic types B and F during finished product storage and distribution is refrigeration. These types of *C. botulinum* will grow at temperatures as low as 38˚F (3.3C). As was previously stated, maintenance of temperatures at or below 38˚F (3.3˚C) after the product leaves the processor's control cannot normally be ensured. Time temperature integrators on each consumer package may be an appropriate means of providing such control. If you intend to use a reduced oxygen packaging technique for these products and you intend to market the products refrigerated without time temperature integrators on each consumer package, you will need to evaluate the effectiveness of other preventive measures, either singularly, or in combination. Such evaluation will usually necessitate the performance of inoculated pack studies under moderate abuse conditions.

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If none of the criteria is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No" or where noted above.

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use and method of distribution and storage

In determining whether a hazard is significant you should also consider the intended use and method of distribution and storage of the product, which you developed in Step #4. Due to the extremely toxic nature of *C. botulinum* toxin, it is unlikely that the significance of the hazard will be affected by the intended use of your product.

However, if your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important, keep frozen until used, thaw under refrigeration immediately before use"), then formation of *C. botulinum* toxin may not be a significant hazard.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "*C. botulinum* toxin formation" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for *C. botulinum* toxin formation:

1. Is there an acidification step (equilibrium pH of 4.6 or below), a drying step or an in-package pasteurization step (target organism *C. botulinum* type E and nonproteolytic types B and F) a combination of cook and hot-fill steps (target organism *C. botulinum* type E and nonproteolytic types B and F), or a retorting step (commercial sterility) in the process?

   a. If there is, you may in most cases identify the acidification step, drying step, pasteurization step, cook and hot-fill steps or retorting step as

the CCP(s) for this hazard. Other processing steps where you have identified "*C. botulinum* toxin formation" as a significant hazard will then not require control and will not need to be identified as CCPs for the hazard. However, the following products require control of temperature during finished product storage and distribution: products pasteurized in the final container to kill *C. botulinum* type E and nonproteolytic types B and F and refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present (e.g. pasteurized crabmeat, pasteurized surimi); 2) products cooked to kill *C. botulinum* type E and nonproteolytic types B and F, and then hot filled into the final container, and then refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F, and other pathogens that may be present; and 3) products dried to control the growth of *C. botulinum* type E and nonproteolytic types B and F and refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present. In these cases, you should also identify the finished product storage step as a CCP for the hazard. Such control is covered in this chapter and in Chapter 12. Additionally, some pasteurized surimi-based products rely on a combination of salt and a relatively mild pasteurization process in the finished product container for the control of *C. botulinum* type E and nonproteolytic types B and F. In these products, you should also identify the formulation step as a CCP for the hazard. Such control is covered in this chapter under Control Strategy Example 2 – "Pickling."

Guidance for these *C. botulinum* toxin control strategies is contained in the following locations:

- Chapters 16 and 18, for control of cooking and hot-filling;
- Chapters 17 and 18, for control of pasteurization;
- Chapter 14, for control of drying;
- Acidified foods regulations, 21 CFR 114, for control of acidification;
- Low acid canned foods regulations, 21 CFR 113, for control of retorting.

Note: acidification and retorting controls required by 21 CFR 113 and 114 need not be included in your HACCP plan.

b. If there is no acidification step, drying step, pasteurization step, cooking and hot-filling, or retorting step(s) in the process, then decide which of the following categories best describes your product:
   - smoked or smoke-flavored fish;
   - "pickled" fish, salted fish and similar products;
   - other products for which *C. botulinum* toxin formation is a significant hazard.

If your product fits into the third category (other products), you will have to establish other preventive measures, either singularly, or in combination that are effective in controlling the hazard, and develop a HACCP plan accordingly.

If your product fits into the first category (smoked or smoke-flavored fish), you should follow the guidance contained in the rest of this chapter contained under the heading "Control Strategy Example 1 – Salting/smoking."

If your product fits into the second category ("pickled" fish), you should follow the guidance in the rest of this chapter contained under the heading "Control Strategy Example 2 - Pickling."

• CONTROL STRATEGY EXAMPLE 1 – SALTING/SMOKING

The following questions apply to salted, smoked, and smoke-flavored fish:

1. Is the temperature of the heating/smoking process important to the safety of the product?

For both cold-smoked and hot-smoked fish products the temperature of heating/smoking is critical. The heating/smoking step for hot-smoked fish must be sufficient to damage the spores and make them more susceptible to inhibition by salt. The smoking step for cold-smoked fish must not be so severe that it kills the natural spoilage bacteria. These bacteria are necessary so that the product will spoil before toxin production occurs. It is likely that they will also

Continued

produce acid, which will further inhibit *C. botulinum* growth and toxin formation.

For these products you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the heating/ smoking step.

2. Is the water phase salt level and, when permitted, the nitrite level, important to the safety of the product?

For all products in this category the water phase salt level is critical to the safety of the product. Nitrite, when permitted, allows a lower level of salt to be used. Salt, and nitrite are the principal inhibitors to *C. botulinum* type E and nonproteolytic types B and F toxin formation in these products. The water phase salt level needed to inhibit toxin formation is partially achieved during brining or dry salting, and partially achieved during drying. Control must be exercised over both operations.

You should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the brining or dry salting step and the drying step.

3. Is the finished product storage temperature important to the safety of the product?

Toxin formation by *C. botulinum* type A and proteolytic B and F is not inhibited by salt levels below 10%, nor by the combination of inhibitors present in most smoked or smoke-flavored fish. *B. cereus* can grow and form toxin at salt concentrations as high as 18%. Therefore, in these products, finished product storage temperature must be controlled.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the finished product storage step.

In some cases smoked or smoke-flavored fish are received as ingredients for assembly into another product, such as a salmon pate. In other cases, they are received simply for storage and further distribution (e.g. by a warehouse). In these cases, the receiving and storage steps may also require time/ temperature controls, and should be designated as CCPs.

The above described control approach is referred to as "Control Strategy Example 1" in Steps #14-18. It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

• CONTROL STRATEGY EXAMPLE 2 – PICKLING

The following questions apply to "pickled" fish and similar products (and to some pasteurized surimi-based products that rely on a combination of salt and a relatively mild pasteurization process in the finished product container for the control of *C. botulinum* type E and nonproteolytic types B and F):

1. Is the water phase salt level, water activity, and/or pH level important to the safety of the product?

For all products in this category the water phase salt level, water activity, and/or pH level is critical to the safety of the product, because they are the principle inhibitors to growth and toxin formation by *C. botulinum* type E and nonproteolytic type B and F. The levels of these inhibitors needed to inhibit toxin formation are achieved during the pickling, brining, or formulation step. Control must be exercised over the relevant step.

You should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the pickling, brining, or formulation step, as appropriate.

2. Is the finished product storage temperature important to the safety of the product?

Unless pickling, brining, or formulation results in a water phase salt level of at least 20% (Note: this value is based on the maximum salt concentration for growth of *S. aureus*), a pH of 4.6 or below, or a water activity of 0.85 or below (Note: this value is based on the minimum water activity for growth of *S. aureus*), storage and distribution temperature will be critical to ensure the safety of the product.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the finished product storage step.

In some cases "pickled" fish or similar products are received as ingredients for assembly into another product, such as receipt of bulk "pickled" herring for repackaging into retail-size containers. In other cases, they are received simply for storage and further distribution (e.g. by a warehouse). In these cases, the receiving and storage steps may also require time/temperature controls, and should be designated as CCPs.

The above described control approach is referred to as Control Strategy Example 2" in Steps #14-18. It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "*C. botulinum* toxin formation" is identified as a significant hazard on the HACCP Plan Form, identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met, the safety of the product is questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - SMOKING

For controlling toxin formation by cold smoking:

Critical Limit: The smoker temperature must not exceed 90˚F (32.2˚C).

For controlling toxin formation by hot smoking:

Critical Limit: The internal temperature of the fish must be maintained at or above 145˚F (62.8˚C) throughout the fish for at least 30 minutes.

For controlling toxin formation by brining, dry salting, and/or drying:

Critical Limit: The minimum or maximum values for the critical factors of the brining/dry salting, and/or drying processes established by a scientific study. The critical factors are those that are necessary to assure that the finished product has:

- For refrigerated, reduced oxygen packaged (e.g. vacuum or modified atmosphere packaged) smoked fish or smoke-flavored fish, not less than 3.5 percent water phase salt, or, where permitted, the combination of 3.0 percent water phase salt and not less than 100 ppm nitrite.

The critical factors may include: brine strength; brine to fish ratio; brining time; brining temperature; thickness, texture, fat content, quality, and species of fish; drying time; input/output air temperature, humidity, and velocity; smoke density; drier loading.

- CONTROL STRATEGY EXAMPLE 2 - PICKLING

For controlling toxin formation by pickling, brining, or formulation:

Critical Limit: The minimum or maximum values for the critical factors of the pickling, brining, or formulation process established by a scientific study. The critical factors are those that are necessary to assure that the finished product has:

Continued

For refrigerated, reduced oxygen packaged fishery products:

- A water phase salt level of at least 5 percent;

OR

- A pH of 5.0 or below;

OR

- A water activity of below 0.97;

OR

- a water phase salt level of at least 2.5% in surimi-based products, when combined with a pasteurization process in the finished product container of 185˚F (85˚C) for at least 15 minutes (covered in Chapter 17);

OR

- A combination of water phase salt, pH, and/or water activity that, when combined, have been demonstrated to prevent the growth of *C. botulinum* type E and nonproteolytic type B and F.

For unrefrigerated (shelf-stable), reduced oxygen packaged products:

- A water phase salt level of at least 20 percent (based on the maximum salt level for growth of *S. aureus*;

OR

- A pH of 4.6 or below;

OR

- A water activity of 0.85 or below (based on the minimum water activity for growth and toxin formation of *S. aureus*).

The critical factors may include: brine strength; acid strength; brine/acid to fish ratio; brining/pickling time; brining/pickling temperature; thickness, texture, fat content, quality, and species of fish.

- CONTROL STRATEGY EXAMPLES 1 & 2

For controlling toxin formation during refrigerated (not frozen) finished product storage:

Critical Limit: The product must not be exposed to a combination of times and temperatures that will allow growth or toxin formation by *C. botulinum* or other pathogens that may be present in the product. Refer to the guidance for the control of pathogens other than *C. botulinum* provided in the critical limits section (Step #14) of Chapter 12, which is also adequate for the control of *C. botulinum*.

For controlling toxin formation at receipt of "pickled," smoked or smoke-flavored fish for storage or further processing:

Critical Limit: The product must not be exposed to a combination of times and temperatures that will allow growth or toxin formation by *C. botulinum* or other pathogens that may be present in the product. Refer to the guidance for the control of pathogens other than *C. botulinum* provided in the critical limits section (Step #14) of Chapter 12, which is also adequate for the control of *C. botulinum*.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "*C. botulinum* toxin formation" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements, the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy examples discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

• CONTROL STRATEGY EXAMPLE 1 - SMOKING

For controlling toxin formation by cold smoking:

What: The smoker temperature.

For controlling toxin formation by hot smoking:

What: The internal temperature at the thickest portion of three of the largest fish in the smoking chamber.

For controlling toxin formation by brining, dry salting, and/or drying:

What: The critical aspects of the established brining, dry salting, and/or drying processes. These may include: brine strength; brine to fish ratio; brining time; brining temperature; thickness, texture, fat content, quality, and species of fish; drying time; input/output air temperature, humidity, and velocity; smoke density; drier loading.
OR
The water phase salt and, where appropriate, nitrite level of the finished product.

• CONTROL STRATEGY EXAMPLE 2 - PICKLING

For controlling toxin formation by pickling, brining, or formulation:

What: The critical aspects of the established pickling, brining, or formulation process. These may include: brine/acid strength; brine/acid to fish ratio; brining/pickling time; brine/acid temperature; thickness, texture, fat content, quality, and species of fish;
OR
The water phase salt, pH, and/or water activity of the finished product.

• CONTROL STRATEGY EXAMPLES 1 & 2

For controlling toxin formation during refrigerated (not frozen) finished product storage:

What: The temperature of the cooler;
OR
The adequacy of ice or other cooling media.

For controlling toxin formation at receipt of refrigerated (not frozen) "pickled," smoked or smoke-flavored fish for storage or further processing:

What: The internal temperature of the fish throughout transportation;
OR
The temperature of the truck or other carrier throughout transportation;
OR
For fishery products with a transit time of four hours or less: The internal temperature of a representative number of containers in the lot at time of delivery;
OR
The adequacy of ice or other cooling media at time of delivery.

How Will Monitoring Be Done?

• CONTROL STRATEGY EXAMPLE 1 - SMOKING

For controlling toxin formation by cold smoking:

How: Use a digital time/temperature data logger;
OR
Use a recorder thermometer;
OR
Use a maximum indicating thermometer;
OR
Use a high temperature alarm.

Continued

For controlling toxin formation by hot smoking:

How: Use a digital time/temperature data logger with three probes.

For controlling toxin formation by brining. dry salting, and/or drying:

How: Monitor the drying time and the input/output air temperature (as specified by the study) with a temperature recording device or digital time/temperature data logger. The device should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the input/output air temperature;
AND
Monitor brine strength with a salinometer;
AND
Monitor the brine temperature with a dial or digital thermometer;
AND
Monitor all other critical factors specified by the study with equipment appropriate for the measurement;
OR
Collect a representative sample of finished product and conduct water phase salt analysis, and, when appropriate, nitrate analysis.

• CONTROL STRATEGY EXAMPLE 2 – PICKLING

For controlling toxin formation by pickling, brining, or formulation:

How: Monitor brine strength with a salinometer;
AND
Monitor acid strength with a pH meter or by titration;
AND
Monitor brine/acid temperature with a dial or digital thermometer;
AND
Monitor all other critical factors specified by the study with equipment appropriate for the measurement;
OR
Collect a representative sample of finished product and conduct water phase salt, pH, and/or water activity analysis.

• CONTROL STRATEGY EXAMPLES 1 & 2

For controlling toxin formation during refrigerated (not frozen) finished product storage:

How: Use a digital time/temperature data logger;
OR
Use a recorder thermometer;
OR
Use a high temperature alarm with 24-hour monitoring;
OR
Make visual observations of the adequacy of ice or other cooling media in a sufficient number of containers to represent all of the product.

For controlling toxin formation at receipt of refrigerated (not frozen) "pickled," smoked or smoke-flavored fish for storage or further processing:

How: Use a time/temperature integrator for product internal temperature monitoring during transit;
OR
Use a digital time/temperature data logger for product internal temperature or ambient air temperature monitoring during transit;
OR
Use a recorder thermometer for ambient air temperature monitoring during transit;
OR
Use a maximum indicating thermometer for ambient air temperature monitoring during transit;
OR
Use a dial or digital thermometer for internal product temperature monitoring at receipt;
OR
Make visual observations of the adequacy of ice or other cooling media in a sufficient number of containers to represent all of the product.

How Often Will Monitoring Be Done (Frequency)?

• CONTROL STRATEGY EXAMPLE 1 - SMOKING

For controlling toxin formation by cold smoking:

Frequency: Continuous monitoring by the instrument itself, with visual check of the monitoring instrument at least once per batch.

For controlling toxin formation by hot smoking:

Frequency: Continuous monitoring by the instrument itself, with visual check of the monitoring instrument at least once per batch.

For controlling toxin formation by brining, dry salting, and/or drying:

Frequency: Temperature requirements of the drying process should be monitored continuously by the instrument itself, with visual check of the monitoring instrument at least once per batch;
AND
Time requirements of the drying process should be monitored for each batch;
AND
Monitor brine strength at least at the start of the brining process;
AND
Monitor the brine temperature at the start of the brining process and at least every two hours thereafter;
AND
Monitor the brine to fish ratio at the start of the brining process;
AND
Monitor all other critical factors specified by the study as often as necessary to maintain control.
OR
Water phase salt and, when appropriate, nitrite should be determined for each lot or batch of finished product.

• CONTROL STRATEGY EXAMPLE 2 - PICKLING

For controlling toxin formation by pickling, brining, or formulation:

Frequency: Monitor brine/acid strength at the start of the brining/pickling/formulation process;
AND
Monitor the brine/acid temperature at the start of the brining/pickling/formulation process and at least every two hours thereafter;
AND
Monitor the brine/acid to fish ratio at the start of the brining/pickling/formulation process;
AND
Monitor all other critical factors specified by the study as often as necessary to maintain control;
OR
Water phase salt, pH, and/or water activity analysis should be determined for each batch of finished product.

• CONTROL STRATEGY EXAMPLES 1 & 2

For controlling toxin formation during refrigerated (not frozen) finished product storage:

Frequency: Continuous monitoring by the instrument itself, with visual check of the monitoring instrument at least once per day;
OR
For ice or other cooling media, check at least twice per day, or immediately prior to shipment.

For controlling toxin formation at receipt of refrigerated (not frozen) "pickled," smoked or smoke-flavored fish for storage or further processing:

Frequency: Each shipment.

Continued

Who Will Perform the Monitoring?

• CONTROL STRATEGY EXAMPLES 1 & 2

Who: With recorder thermometers, time/temperature integrators, high temperature alarms, maximum indicating thermometers, and digital time/temperature data loggers, monitoring is performed by the equipment itself. However, anytime that such instruments are used, a visual check should be made at least once per day (at least once per batch, as appropriate) in order to ensure that the critical limits have consistently been met. These checks, as well as dial thermometer checks, salinometer checks, pH meter checks, titrations and adequacy of ice or other cooling media checks may be performed by the receiving employee, the equipment operator, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the process, the monitoring procedure, and the critical limits.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "*C. botulinum* toxin formation" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy examples discussed in Step #12.

• CONTROL STRATEGY EXAMPLE 1 - SMOKING

For controlling toxin formation by cold smoking:

Corrective Action: Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:

- Make repairs or adjustments to the smoking/drying chamber;

OR

- Move some or all of the product to another smoking/drying chamber;

AND

Take one of the following actions to the product involved in the critical limit deviation:

- Destroy the product;

OR

- Hold the product until its safety can be evaluated;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. packaging that is not hermetically sealed, or low acid canned food [LACF] or frozen product);

OR

- Divert the product to a non-food use.

For controlling toxin formation by hot smoking:

Corrective Action: Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:

- Make repairs or adjustments to the heating chamber;

OR

- Move some or all of the product to another heating chamber;

AND

Take one of the following actions to the product involved in the critical limit deviation:

- Destroy the product;

OR

- Hold the product until its safety can be evaluated;

OR

- Reprocess the product;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. packaging that is not hermetically sealed, or LACF or frozen product);

OR

- Divert the product to a non-food use.

For controlling toxin formation by brining, dry salting, and/or drying:

Corrective Action: Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:

- Adjust the brine and/or nitrite concentration;

OR

- Adjust the air velocity or input air temperature to the drying chamber;

OR

- Extend the drying process to compensate for a reduced air velocity or temperature or elevated humidity;

OR

Adjust the brine strength or brine to fish ratio;

OR

- Extend the brining time to compensate for an improper brine temperature;

AND

Take one of the following actions to the product involved when there has been a failure to maintain specified critical factors of the brining, dry salting or drying process:

- Destroy the product;

OR

- Hold the product until it can be evaluated based on its water phase salt and/or nitrate level;

OR

- Reprocess the product;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. packaging that is not hermetically sealed, or LACF or frozen product);

OR

- Divert the product to a non-food use.

AND

Take one of the following actions to the product involved when finished product testing shows that the water phase salt level and/or nitrite level is below the critical limit:

- Destroy the product

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. packaging that is not hermetically sealed, or LACF or frozen product);

OR

- Divert to a non-food use.

- CONTROL STRATEGY EXAMPLE 2 - PICKLING

For controlling toxin formation by pickling, brining, or formulation:

Corrective Action: Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:

- Adjust the brine/acid strength or brine/acid to fish ratio;

OR

- Extend the brining/pickling time to compensate for an improper brine/acid temperature;

AND

Take one of the following actions to the product involved when there has been a failure to maintain the specified critical factors of the pickling, brining, or formulation process:

- Destroy the product;

OR

- Hold the product until it can be evaluated based on its water phase salt, pH, and/or water activity level;

OR

- Reprocess the product;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. packaging that is not hermetically sealed, or LACF or frozen product);

OR

- Divert the product to a non-food use.

Continued

AND

Take one of the following actions to the product involved when finished product testing shows that water phase salt is below 5 percent, or the pH is above 5.0, or the water activity is 0.97 or above, or the intended combination of water phase salt, pH, and/or water activity has not been achieved, as appropriate:

- Destroy the product;

OR

- Divert the product to a use in which the critical limit is not applicable because *C. botulinum* growth in the finished product will be controlled by some other means (e.g. packaging that is not hermetically sealed, or LACF or frozen product);

OR

- Reprocess the product (if reprocessing does not jeopardize the safety of the product);

OR

- Divert to a non-food use.

- CONTROL STRATEGY EXAMPLES 1 & 2

For controlling toxin formation during refrigerated (not frozen) finished product storage:

Corrective Action: Take one or several of the following actions as necessary to regain control over the operation after a CL deviation:

- Add ice to the affected product

OR

- Make repairs or adjustments to the malfunctioning cooler;

OR

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

OR

- Freeze the product;

AND

Take one of the following actions to the product involved in the critical limit deviation:

- Destroy the product;

OR

- Hold the product until it can be evaluated based on its total time/temperature exposure;

OR

- Divert the product to a non-food use.

For controlling toxin formation at receipt of refrigerated (not frozen) "pickled," smoked or smoke-flavored fish for storage or further processing:

Corrective Action: Reject products that do not meet the time/temperature or adequacy of ice or other cooling media critical limit at receiving;

OR

Hold the product until it can be evaluated based on its total time/temperature exposure.

AND

Discontinue use of supplier or carrier until evidence is obtained that transportation practices have changed.

Note: If an incoming lot that fails to meet a receiving critical limit is mistakenly accepted, and the error is later detected, the following actions should be taken: 1) the lot and any products processed from that lot should be destroyed, diverted to a nonfood use or to a use in which the critical limit is not applicable, or placed on hold until a food safety evaluation can be completed; and 2) any products processed from that lot that have already been distributed should be recalled and subjected to the actions described above.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "*C. botulinum* toxin formation" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy examples discussed in Step #12.

• CONTROL STRATEGY EXAMPLE 1 - SMOKING

For controlling toxin formation by cold smoking:

Records: Printout from digital time/temperature data logger;
OR
Recorder thermometer chart;
OR
Record showing the results of the maximum indicating thermometer checks;
OR
Record showing the results of the high temperature alarm checks.

For controlling toxin formation by hot smoking:

Records: Printout from digital time/temperature data logger;
AND
Smoking log showing the time that the product reached 145˚F (62.8˚C) and the time that the heating process ended.

For controlling toxin formation by brining, dry salting, and/or drying:

Records: Temperature recorder chart or data logger printout for drier input/output air temperature;
AND
Appropriate records (e.g. processing record showing the results of the brine strength and temperature, brine to fish ratio, size and species of fish, time of brining) as necessary to document the monitoring of the critical factors of the brining, dry salting, and/or drying process, as established by a study;
OR
Results of the finished product water phase salt determination, and, when appropriate, nitrite determination.

• CONTROL STRATEGY EXAMPLE 2 - PICKLING

For controlling toxin formation by pickling, brining, or formulation:

Records: Appropriate records (e.g. processing record showing the results of the brine/acid strength and temperature, brine/acid to fish ratio, size and species of fish, time of brining/pickling) as necessary to document the monitoring of the critical factors of the brining/pickling process, as established by a study;
OR
Results of the finished product water phase salt, pH, or water activity determinations.

• CONTROL STRATEGY EXAMPLES 1 & 2

For controlling toxin formation during refrigerated (not frozen) finished product storage:

Records: Printout from digital time/temperature data logger;
OR
Recorder thermometer chart;
OR
Storage record showing the results of the high temperature alarm checks.

For controlling toxin formation at receipt of refrigerated (not frozen) "pickled," smoked or smoke-flavored fish for storage or further processing:

Records: Receiving record showing the results of the time/temperature integrator checks;
OR
Printout from digital time/temperature data logger;
OR
Recorder thermometer chart;
OR
Receiving record showing the results of the maximum indicating thermometer checks;
OR
The results of internal product temperature monitoring at receipt;
AND
The date and time of departure and arrival of the vehicle;
OR
Receiving record showing the results of the ice or other cooling media checks.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

Continued

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "*C. botulinum* toxin formation" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of *C. botulinum* toxin production; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step #12.

• CONTROL STRATEGY EXAMPLE 1 - SMOKING

Verification: Review monitoring, corrective action, and verification records within one week of preparation;

AND

Process establishment (except where finished product water phase salt analysis and, where appropriate, nitrite analysis is the monitoring procedure): The adequacy of the brining/dry salting and/or drying process should be established by a scientific study. It should be designed to consistently achieve a water phase salt level of: 3.5 percent or 3.0 percent with not less than 100 ppm nitrite for refrigerated, reduced oxygen packaged (e.g. vacuum or modified atmosphere packaged) smoked fish or smoke-flavored fish. Expert knowledge of salting and/or drying processes is required to establish such a process. Such knowledge can be obtained by education or experience or both. Establishment of brining/dry salting and drying processes requires access to adequate facilities and the application of recognized methods. The drying equipment must be designed, operated and maintained to deliver the established drying process to every unit of product. In some instances, brining/dry salting and/or drying studies will be required to establish minimum processes. In other instances, existing literature, which establish minimum processes or adequacy of equipment, are available. Characteristics of the process, product, and/or equipment that affect the ability of the established minimum salting and/or drying process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

When digital time/temperature data loggers, recorder thermometers, or high temperature alarms are used for in-plant monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) at least once per day;

AND

When digital time/temperature data loggers or recorder thermometers are used for monitoring of transport conditions at receiving, check for accuracy against a known accurate thermometer (NIST-traceable). Verification should be conducted on new suppliers' vehicles and at least quarterly for each supplier thereafter. Additional verifications may be warranted based on observations at receipt (e.g. refrigeration units appear to be in poor repair, or readings appear to be erroneous);

AND

When dial or digital thermometers or maximum indicating thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter (Note: Optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument);

AND

Other calibration procedures as necessary to ensure the accuracy of the monitoring instruments;

AND

Finished product sampling and analysis to determine water phase salt and, where appropriate, nitrite analysis at least once every three months (except where such testing is performed as part of monitoring).

• CONTROL STRATEGY EXAMPLE 2 - PICKLING

Verification: Review monitoring, corrective action, and verification records within one week of preparation;

AND

Process establishment (except where finished product water phase salt, pH, or water activity analysis is the monitoring procedure): The adequacy of the pickling/brining/formulation process should be established by a scientific study. For refrigerated, reduced oxygen packaged products it should be designed to consistently achieve: a water phase salt level of at least 5 percent; a pH of 5.0 or below; a water activity of below 0.97; a water phase salt level of at least 2.5% in surimi-based products, when combined with a pasteurization process in the finished product container of 185˚F (85˚C) for at least 15 minutes; or, a combination of salt, pH, and/or water activity that, when combined, prevent the growth of *C. botulinum* type E and nonproteolytic types B and F (established by scientific study). For unrefrigerated (shelf-stable), reduced oxygen packaged products, it should be designed to consistently achieve: a water phase salt level of at least 20% (based on the maximum water phase salt level for growth of *S. aureus*); a pH of 4.6 or below; or a water activity of 0.85 or below (based on the minimum water activity for growth of *S. aureus*. Expert knowledge of pickling/brining/formulation processes is required to establish such a process. Such knowledge can be obtained by education or experience or both. Establishment of pickling/brining/formulation processes requires access to adequate facilities and the application of recognized methods. In some instances, pickling/brining/formulation studies will be required to establish minimum processes. In other instances, existing literature, which establish minimum processes, are available. Characteristics of the process and/or product that affect the ability of the established minimum pickling/brining/formulation process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

When digital time/temperature data loggers, recorder thermometers, or high temperature alarms are used for in-plant monitoring, check for accuracy against a known accurat thermometer (NIST-traceable) at least once per day;

AND

When digital time/temperature data loggers or recorder thermometers are used for monitoring of transport conditions at receiving, check for accuracy against a known accurate thermometer (NIST-traceable). Verification should be conducted on new suppliers' vehicles and at least quarterly for each supplier thereafter. Additional verifications may be warranted based on observations at receipt (e.g. refrigeration units appear to be in poor repair, or readings appear to be erroneous);

AND

When visual checks of ice or cooling media are used to monitor the adequacy of coolant, periodically measure internal temperatures of the product to ensure that the ice or cooling media is sufficient to maintain product temperatures at or below 40˚F (4.4˚C);

AND

When dial thermometers or maximum indicating thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter (Note: Optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument);

AND

Daily calibration of pH meters against standard buffers;

AND

Other calibration procedures as necessary to ensure the accuracy of the monitoring instruments;

AND

Finished product sampling and analysis to determine water phase salt, pH, or water activity level, as appropriate, at least once every three months (except where such testing is performed as part of monitoring).

Enter the verification procedures in Column 10 of the HACCP Plan Form.

Continued

TABLE #13-1

Control Strategy Example 1 – Smoking

This table is an example of a portion of a HACCP plan relating to the control of *C. botulinum* toxin formation for a processor of vacuum packaged hot-smoked salmon, using Control Strategy Example 1 - Smoking. It is provided for illustrative purposes only. *C. botulinum* toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. aquaculture drugs, chemical contaminants, parasites, growth of other pathogens, survival of other pathogens through the cook step, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Brining	• *C. botulinum* toxin formation in finished product	• Minimum brining time 6 hours	• Length of brining process	• Visual	• Start and end of brining process	• Brine room employee	• Extend brining process	• Production record	• Documentation of brining/ drying process establishment
		• Minimum salt concentration of brine at start of brining 60° salimeter	• Salt concentration of brine	• Salinometer	• Start of brining process	• Brine room employee	• Add salt	• Production record	• Review monitoring, corrective action, and verification records within one week of preparation
		• Minimum ratio of brine:fish 2:1	• Weight of brine (as determined by volume)	• Visual to mark on tank	• Start of brining process	• Brine room employee	• Add brine	• Production record	
			• Weight of fish	• Scale	• Each batch	• Brine room employee	• Remove some fish and reweigh	• Production record	• Monthly calibration of scale
		• Maximum fish thickness 1 1/2" (Note: To produce a minimum water phase salt level in the loin muscle of 3.5%)	• Fish thickness	• Caliper	• Each batch (10 fish)	• Brine room employee	• Hold and evaluate based on finished product water phase salt analysis	• Production record	• Quarterly water phase salt analysis

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

TABLE #13-1, continued

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring: What	(5) Monitoring: How	(6) Monitoring: Frequency	(7) Monitoring: Who	(8) Corrective Action(s)	(9) Records	(10) Verification
Smoking/drying/ heating	• *C. botulinum* toxin formation in finished product	• Minimum time open vent 2 hours • Internal temperature of fish held at or above 145˚F for at least 30 minutes	• Time of open vent • Internal temperature of fish and time at that temperature	• Visual • Digital data logger with probes in 3 of thickest fish in cold spot of oven	• Each batch • Continuous with visual at end of batch	• Smoker employee • Smoker employee	• Extend drying process, and • Hold and evaluate • Extend heating process, and • Make repairs or adjustments to the smoking chamber, and • Hold and evaluate	• Production record • Data logger printout • Smoking log	• Documentation of brining/ drying process establishment • Review monitoring, corrective action, and verification records within one week of preparation • Daily calibration of data logger • Quarterly water phase salt analysis
Finished product storage	• *C. botulinum* toxin formation during finished product storage	• Maximum cooler temperature 40˚F (based on growth of vegetative pathogens)	• Cooler air temperature	• Digital data logger	• Continuous, with visual once per day	• Production employee	• Adjust or repair cooler, and • Hold and evaluate based on time/ temperature of exposure	• Data logger printout	• Review monitoring, corrective action, and verification records within one week of preparation • Daily check of data logger accuracy

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

TABLE #13-2

Control Strategy Example 2 – Pickling

This table is an example of a portion of a HACCP plan relating to the control of *Clostridium botulinum* for a processor of pickled herring, using Control Strategy Example 2 - Pickling. It is provided for illustrative purposes only. *C. botulinum* toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. histamine, chemical contaminants, parasites, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Pickling	*C. botulinum* toxin formation in finished product	Maximum finished product pH in the loin muscle of 5.0	Finished product pH in the loin muscle	Collect sample of product from each pickling tank at the end of each pickling cycle and analyze for pH using a pH meter	Each pickling tank, each cycle	QC personnel	Continue pickling process until pH meets the CL	Analytical results	• Daily calibration of pH meter • Review monitoring, corrective action, and verification records within one week of preparation
Finished product storage	*C. botulinum* toxin formation during finished product storage	Maximum cooler temperature 40°F (based on growth of vegetative pathogens)	Cooler air temperature	High temperature alarm with 24-hour monitoring	Continuous, with visual check of operation once per day	Production employee	• Adjust or repair cooler, and • Hold and evaluate based on time/ temperature of exposure	Production record with daily alarm check	• Daily accuracy check of high temperature alarm • Review monitoring, corrective action, and verification records within one week of preparation

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Pathogen growth in the finished product as a result of inadequate drying of fishery products can cause consumer illness. Examples of dried fish products are: salmon jerky; octopus chips; dried shrimp; and, stock fish.

- Control of drying

Dried products are usually considered shelf stable and are, therefore, often stored and distributed unrefrigerated. The characteristic of dried foods that makes them shelf stable is their low water activity (A_W). Water activity is the measure of the amount of water in a food that is available for the growth of microorganisms, including pathogens. A water activity of 0.85 or below will prevent the growth and toxin production of all pathogens, including *Staphylococcus aureus* and *Clostridium botulinum*, and is necessary for a shelf-stable dried product. *S. aureus* grows at a lower water activity than other pathogens, and should, therefore, be considered the target pathogen for drying for shelf-stable products.

Some dried products that are reduced oxygen packaged (e.g. vacuum packaged, modified atmosphere packaged) are dried only enough to control growth and toxin production by *C. botulinum* type E and nonproteolytic types B and F, and are then refrigerated to control growth and toxin formation by *C. botulinum* type A and proteolytic types B and F, and other pathogens that may be present in the product, including *S. aureus*. A water activity of below 0.97 will prevent the growth of *C. botulinum* type E and nonproteolytic types B and F, and is necessary for these refrigerated, partially dried products. More information on *C. botulinum* and reduced oxygen packaging is contained in Chapter 13.

This chapter covers the control of the drying process to prevent the growth and toxin production of pathogens, including *S. aureus* and *C. botulinum* in the finished product. Such control is critical to product safety.

This chapter does not cover the growth of pathogens, including *S. aureus*, that may occur as a result of time/temperature abuse during processing, including before or during the drying process. That hazard is covered in Chapter 12. It also does not cover the control of *C. botulinum* type A and proteolytic types B and F, and other pathogens that may be present, including *S. aureus,* during refrigerated storage of reduced oxygen packaged, partially dried products. That hazard is covered in Chapters 12 and 13.

Controlling pathogen growth and toxin formation by drying is best accomplished by:

- Scientifically establishing a drying process that reduces the water activity to 0.85 or below, if the product will be stored and distributed unrefrigerated (shelf-stable);

- Scientifically establishing a drying process that reduces the water activity to below 0.97, if the product will be stored refrigerated (not frozen) in reduced oxygen packaging;

- Designing and operating the drying equipment so that every unit of product receives at least the established minimum process;

- Packaging the finished product in a container that will prevent rehydration.

You should select a packaging material that will prevent rehydration of the product under the expected conditions of storage and distribution. Additionally, finished product package closures should be free of gross defects that could expose the product to moisture during storage and distribution.

Continued

Pathogen growth is not a concern in dried products that are stored, distributed, displayed and sold frozen, and are so labeled. These products need not meet the control measures outlined in this chapter since drying in this case is not critical to product safety. Similarly, drying may not be critical to the safety of dried products that are stored refrigerated, unless they are reduced oxygen packaged, since refrigeration may be sufficient to prevent pathogen growth in aerobically packaged products.

The drying operation used in the production of smoked or smoke-flavored fish is not designed to result in a finished product water activity of 0.85 or below. Drying controls for these products are described in Chapter 13.

Because spores of *Clostridium botulinum* are known to be present in the viscera of fish, any product that will be preserved by salting, drying, pickling, or fermentation must be eviscerated prior to processing (see Compliance Policy Guide sec. 540.650). Without evisceration, toxin formation is possible during the process even with strict control of temperature. Evisceration must be thorough and performed to minimize contamination of the fish flesh. If even a portion of the viscera or its contents is left behind, the risk of toxin formation by *C. botulinum* remains. Small fish, less than 5 inches in length, that are processed in a manner that prevents toxin formation, and that reach a water phase salt content of 10 percent in refrigerated products, or a water activity of below 0.85 (Note: this value is based on the minimum water activity for growth of *S. aureus*) or a pH of 4.6 or less in shelf-stable products, are exempt from the evisceration requirement.

- Strategies for controlling pathogen growth

Pathogens 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, unsafe water, and sewage. There are a number of strategies for the control of pathogens in fish and fishery products. They include:

- Controlling the amount of moisture that is available for pathogen growth, water activity, in the product by drying (covered in this chapter);

- 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 regulations, 21 CFR 114 for shelf-stable acidified products; and for refrigerated acidified products in Chapter 13);

- Managing the amount of time that food is exposed to temperatures that are favorable for pathogen growth and toxin production (covered in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15);

- Killing pathogens by cooking (covered in Chapter 16), pasteurizing (covered in Chapter 17), or retorting (covered by the low acid canned foods regulations, 21 CFR 113).

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "pathogen growth and toxin formation as a result of inadequate drying" is a significant hazard. The criteria are:

1. For shelf-stable products, is it reasonably likely that *S. aureus* will grow and form toxin in the finished product if the product is inadequately dried?

Table #A-1 (Appendix 4) provides information on the conditions under which *S. aureus* will grow. If your food meets these conditions before drying, then drying will usually be important to the safety of the product, because it provides the barrier to *S. aureus* growth. Under ordinary circumstances, it would be reasonably likely that *S. aureus* will grow and form toxin in such products during finished product storage and distribution, if drying is not properly performed. However, see also the information contained in "Intended use and method of distribution and storage," below.

2. For shelf-stable products, can *S. aureus* toxin formation, which is reasonably likely to occur, be eliminated or reduced to an acceptable level at this processing step? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12.)

"Pathogen growth and toxin formation as a result of inadequate drying" should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate (or reduce the likelihood of occurrence to an acceptable level) the hazard, if it is reasonably likely to occur.

3. For refrigerated (not frozen), reduced oxygen packaged products, is it reasonably likely that *C. botulinum* type E and nonproteolytic types B and F will grow and form toxin in the finished product if the product is inadequately dried?

Table #A-1 (Appendix 4) provides information on the conditions under which *C. botulinum* type E and nonproteolytic types B and F will grow. If your refrigerated (not frozen), reduced oxygen packaged food meets these conditions before drying, then drying will usually be important to the safety of the product, because it provides the barrier to growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F. Under ordinary circumstances, it would be reasonably likely that *C. botulinum* type E and nonproteolytic types B and F will grow and form toxin in such products during finished product storage and distribution, if drying is not properly performed. However, see also the information contained in "intended use and method of distribution and storage," below.

4. For refrigerated (not frozen), reduced oxygen packaged products, can *C. botulinum* type E and nonproteolytic types B and F toxin formation, which is reasonably likely to occur, be eliminated or reduced to an acceptable level at this processing step? (Note: If you are not certain of the answer to this question at this time, you may answer "no." However, you may need to change this answer when you assign critical control points in Step #12.)

"Pathogen growth and toxin formation as a result of inadequate drying" should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate (or reduce to the likelihood of occurrence to an acceptable level) the hazard, if it is reasonably likely to occur.

Step #10 discusses a number of pathogen control strategies. This chapter covers control of pathogens by drying. Delivering a properly designed drying process can be an effective preventive measure for the control of pathogens. If this preventive measure is applied list it in Column 5 of the Hazard Analysis Worksheet at the drying step.

If the answer to question 1, 2, 3 or 4 is "Yes" the potential hazard is significant at the drying step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use and method of distribution and storage

In determining whether a hazard is significant you should also consider the intended use and method of distribution and storage of the product, which you developed in Steps #4 and 3, respectively. Because of the highly stable nature of *S. aureus* toxin and the extremely toxic nature of *C. botulinum* toxin, it is unlikely that the intended use will affect the significance of the hazard.

However, the hazard may not be significant if: 1) the product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important, keep frozen until used, thaw under refrigeration immediatley before use"); or 2) the product is

Continued

unpackaged or aerobically packaged, and is distributed refrigerated throughout the chain of commerce, and is labeled to be kept refrigerated. In both of these cases, the hazard of pathogen growth is controlled by the control of temperature, rather than by the drying of the product. In these cases, you may enter "No" in Column 3 of the Hazard Analysis Worksheet for each of the processing steps. In addition, for each "No" entry briefly explain in Column 4 that the hazard is controlled by freezing or refrigeration. In this case, you need not complete Steps #12 through 18 for this hazard. However, refer to Chapter 12 for the control of pathogen growth by refrigeration.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "pathogen growth and toxin formation as a result of inadequate drying" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

You should identify the drying step as the critical control point for this hazard. Therefore, you should answer "Yes" in Column 6 of the Hazard Analysis Worksheet at the drying step and "No" in that column for the other processing steps for which the hazard was identified as a significant hazard. In addition, for each "No" entry make sure that Column 5 indicates that the hazard is controlled at the drying step. (Note: if you have not previously identified "pathogen growth and toxin formation as a result of inadequate drying" as a significant hazard at the drying step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".)

This control approach is referred to as "Control Strategy Example 1" in Steps #14-18. It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Example:

A salmon jerky processor could set the critical control point for controlling the hazard of "pathogen growth and toxin formation as a result of inadequate drying" at the drying step. The processor would not need to identify the processing steps prior to drying as critical control points for that hazard. However, these steps may be CCPs for the control of other hazards, such as the growth of pathogens as a result of time/temperature abuse during processing, covered by Chapter 12.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For the drying step, identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product is questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the drying step.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF DRYING

Critical Limit: The minimum or maximum values for the critical factors established by a scientific study (i.e. for shelf-stable products, those which must be met in order to ensure that the finished product has a water activity of 0.85 or less; for refrigerated [not frozen], reduced oxygen packaged products, those which must be met in order to ensure that the finished product has a water activity of less than 0.97). These will likely include drying time, input/output air temperature, humidity, and velocity, and flesh thickness. Other critical factors that affect the rate of drying of the product may also be established by the study;
OR
The minimum percent weight loss established by a scientific study (i.e. for shelf-stable products, those which must be met in order to ensure that the finished product has a water activity of 0.85 or less; for refrigerated [not frozen], reduced oxygen packaged products, those which must be met in order to ensure that the finished product has a water activity of less than 0.97);
OR
For shelf-stable products: Maximum finished product water activity of 0.85 or less;
OR
For refrigerated (not frozen), reduced oxygen packaged products: Maximum finished product water activity of less than 0.97.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For the drying step, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the drying step. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF DRYING

What: Critical factors of the established drying process that affect the ability of the process to ensure the desired finished product water activity (i.e. 0.85 or below for shelf stable products, less than 0.97 for refrigerated [not frozen], reduced oxygen packaged products). These may include drying time, air temperature, humidity, and velocity, and flesh thickness;
OR
Percent weight loss;
OR
Water activity.

Continued

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF DRYING

For batch drying equipment:

How: Monitor the drying time and the input/output air temperature (as specified by the study) with a temperature recording device or digital time/temperature data logger. The device should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the air input/output temperature;
AND
Monitor all other critical factors specified by the study with equipment appropriate for the measurement;
OR
Using all or a portion of the batch, determine the percent weight loss by weighing the product before and after drying;
OR
Collect a representative sample of finished product and conduct water activity analysis.

For continuous drying equipment:

How: Monitor the input/output air temperature (as specified by the study) with a temperature recording device or digital time/temperature data logger. The device should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the air input/output temperature;
AND
Monitor the time by measuring either:
- The RPM of the belt drive wheel, using a stop watch or tachometer;
  OR
- The time necessary for a test unit or belt marking to pass through the equipment, using a stop watch;

AND
Monitor all other critical factors specified by the study with equipment appropriate for the measurement;
OR
Using all or a portion of the lot, determine the percent weight loss by weighing the product before and after drying;
OR
Collect a representative sample of finished product and conduct water activity analysis.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF DRYING

For batch drying equipment:

Frequency: Temperature requirements of the drying process should be monitored continuously by the instrument itself, with visual check of the monitoring instrument at least once per batch;
AND
Time requirements of the drying process should be monitored for each batch;
AND
Monitor all other critical factors specified by the study as often as necessary to maintain control;
OR
Percent weight loss should be determined for each batch of finished product;
OR
Water activity should be determined for each batch of finished product.

For continuous drying equipment:

Frequency: Temperature requirements of the drying process should be monitored continuously by the instrument itself, with visual check of the monitoring instrument at least once per day;
AND
Time requirements of the drying process should be monitored at least once per day, and whenever any changes in belt speed are made;
AND
Monitoring of all other critical factors specified by the study as often as necessary to maintain control;

OR

Percent weight loss should be determined for each lot of finished product;

OR

Water activity should be determined for each lot of finished product.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF DRYING

For batch drying equipment:

Who: Time and temperature monitoring is performed by the equipment itself. However, a visual check should be made of the recorded data at least once at the end of each cycle in order to ensure that the critical limits have consistently been met. These checks, as well as the monitoring of the other critical factors in the drying process, the percent weight loss, or the water activity may be performed by the equipment operator, a production supervisor, a member of the quality control staff, a member of the maintenance or engineering staff, or any other person who has an understanding of the operation of the equipment and the critical limit. In assigning responsibility for monitoring you should consider the complexity of the monitoring equipment. For example, accurately performing water activity analyses requires considerable training.

For continuous drying equipment:

Who: Temperature monitoring is performed by the equipment itself. However, a visual check should be made of the recorded data at least daily in order to ensure that the critical limits have consistently been met. These checks, as well as the monitoring of the drying time and the other critical factors in the drying process, the percent weight loss, or the water activity may be performed by the equipment operator, a production supervisor, a member of the quality control staff, a member of the maintenance or engineering staff, or any other person who has an understanding of the operation of the equipment and the critical limit. In assigning responsibility for monitoring you should consider the complexity of the monitoring equipment. For example, accurately performing water activity analyses requires considerable training.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For the drying step, describe the procedures that you will use when your monitoring indicates that the CL has not been met. These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the drying step.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF DRYING

Corrective Action: Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:

- Adjust the air temperature or velocity;

OR

- Adjust the length of the drying cycle to compensate for a temperature or velocity drop, humidity increase, or inadequate percent weight loss;

OR

- Adjust the belt speed to increase the length of the drying cycle;

AND

When there has been a failure to maintain specified critical factors of the drying process, or when the prescribed minimum percent weight loss is not met, take one of the following actions to the product involved in the deviation:

- Destroy the product;

Continued

OR

- Redry the product (provided that redrying does not present an unacceptable opportunity for pathogen growth);

OR

- Segregate and hold the product (under refrigerated conditions) for an evaluation of the adequacy of the drying process. The evaluation may involve water activity determi nation on a representative sample of the finished product. If the evaluation shows that the product has not received an adequate drying process the product should be destroyed, diverted to a non-food use, or redried;

OR

- Divert the product to a use in which the critical limit is not applicable because pathogen growth in the finished product will be controlled by means other than drying (e.g. divert inadequately dried fish to a frozen fish operation);

OR

- Divert the product to a non-food use.

AND

When finished product testing shows that the water activity is above 0.85, take one of the following actions to the product involved in the deviation:

- Destroy the product;

OR

- Re-dry the product (where re-drying does not create a hazard for pathogen growth);

OR

- Divert the product to a use in which the critical limit is not applicable because pathogen growth in the finished product will be controlled by means other than drying (e.g. divert inadequately dried fish to a frozen fish operation);

OR

- Divert the product to a non-food use.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For the drying step, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring. Following is guidance on establishing a recordkeeping system for the drying step.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF DRYING

For batch drying equipment:

Records: Temperature recorder charts or digital time/temperature data logger printout;
AND
Records that are appropriate for the other critical factors (e.g. drying log that indicates input/output air humidity and/or velocity);

OR

Records of weight before and after drying;

OR

Records of water activity analysis for each lot of product.

For continuous drying equipment:

Records: Temperature recorder charts or digital time/temperature data logger printout;
AND
Drying log that indicates the RPM of the belt drive wheel or the time necessary for a test unit or belt marking to pass through the drier;
AND
Records that are appropriate for the other critical factors (e.g. drying log that indicates input/output air humidity and/or velocity);

OR

Records of weight before and after drying;

OR

Records of water activity analysis for each lot of product.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For the drying step, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "pathogen growth and toxin formation as a result of inadequate drying; and, 2) consistently being followed. Following is guidance on establishing verification procedures for the drying step.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF DRYING

Verification: Process establishment (except where finished product water activity analysis is the monitoring procedure): The adequacy of the drying process should be established by a scientific study. For shelf-stable products, it should be designed to ensure the production of a shelf stable product with a water activity of 0.85. For refrigerated (not frozen), reduced oxygen packaged products, it should be designed to ensure a finished water activity of less than 0.97. Expert knowledge of drying process calculations and the dynamics of mass transfer in processing equipment is required to establish such a drying process. Such knowledge can be obtained by education or experience or both. Establishment of drying processes requires access to adequate facilities and the application of recognized methods. The drying equipment must be designed, operated and maintained to deliver the established drying process to every unit of product. In some instances, drying studies will be required to establish the minimum process. In other instances, existing literature which establish minimum processes or adequacy of equipment, are available. Characteristics of the process, product and/or equipment that affect the ability of the established minimum drying process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

Finished product sampling and analysis to determine water activity at least once every three months (except where such testing is performed as part of monitoring);

AND

Check the accuracy of the temperature recording device or digital time/temperature data loggers against a known accurate thermometer (NIST-traceable) at least once per day;

AND

Calibrate other instruments as necessary to ensure their accuracy;

AND

Review monitoring, corrective action, and verification records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #14-1

Control Strategy Example 1 - Control of drying

This table is an example of a portion of a HACCP plan relating to the control of pathogen growth and toxin formation as a result of inadequate drying for a processor of shelf-stable salmon jerky, using Control Strategy Example 1 - Control of drying. It is provided for illustrative purposes only. Pathogen growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. aquaculture drugs, chemical contaminants, parasites, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5) Monitoring	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Drying (forced convection oven)	Pathogen growth and toxin formation	• Maximum product thickness 1/4"	• Product thickness	• Preset slicer to just less than 1/4"	• Once per day before operations	• Slicer operator	• Readjust slicer	• Processing log	• Documentation of drying process establishment
		• Minimum drying time 5 hours	• Drying time	• Digital time/ temperature data logger	• Continuous, with visual check each batch	• Oven operator	• Continue drying	• Data logger printout	• Review monitoring, verification and corrective action records within one week of preparation
		• Minimum oven temperature 140°F	• Oven air input temperature	• Digital time/ temperature data logger	• Continuous, with visual check each batch	• Oven operator	• Extend drying process	• Data logger printout	• Check the accuracy of the data logger daily.
		To achieve a final water activity of 0.85 or less					• Segregate product and hold for evaluation. Evaluate by performing water activity analysis on finished product. Re-dry if more than 0.85		• Analyze finished product sample once every 3 months for water activity

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

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Staphylococcus aureus toxin formation in hydrated batter mixes can cause consumer illness. This toxin in particular is a concern because the toxin cannot be destroyed by heating steps that may be performed by the processor or the consumer. Pathogens other than *S. aureus*, such as those described in Chapter 12, are, in many cases, less likely to grow in hydrated batter mixes, and are likely to be killed by the heating steps that follow.

• Control of *Staphylococcus aureus* in batter mixes

S. aureus can enter the process on raw materials. It can also be introduced into foods during processing from unclean hands and insanitary utensils and equipment.

The hazard develops when a batter mix is exposed to temperatures favorable for *S. aureus* growth for sufficient time to permit toxin development. *S. aureus* toxin does not normally reach levels that will cause food poisoning until the numbers of the pathogen reach 100,000 to 1,000,000/gram. *S. aureus* will grow at temperatures as low as 41-43˚F (5.0-6.1˚C) and at a water activity as low as .85 (additional information on conditions favorable to *S. aureus* growth are provided in Table #A-1 (Appendix 4). However, toxin formation is not likely at temperatures lower than 50˚F (10˚C). For this reason, toxin formation can be controlled by minimizing exposure of hydrated batter mixes to temperatures above 50˚F (10˚C). Exposure times greater than 12 hours for temperatures between 50˚F (10˚C) and 70˚F (21.1˚C) could result in toxin formation. Exposure times greater than 3 hours for temperatures above 70˚F (21.1˚C) could also result in toxin formation.

• Strategies for controlling pathogen growth

There are a number of strategies for the control of pathogens 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 in this chapter for *S. aureus* in hydrated batter mix; Chapter 13 for *C. botulinum*; and Chapter 12 for other pathogens and conditions);

- Killing pathogens by cooking (covered in Chapter 16), pasteurizing (covered in Chapter 17), or retorting (covered by the low acid canned foods regulations, 21 CFR 113);

- 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 regulations, 21 CFR 114 for shelf-stable acidified products; and for refrigerated acidified products in Chapter 13).

Continued

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "*S. aureus* toxin formation in hydrated batter mixes" is a significant hazard. The criteria are:

1. Is it reasonably likely that *S. aureus* will grow and form toxin in the hydrated batter mix at the hydrated batter mix storage/recirculation step?

Remember that you should consider the potential for time/temperature abuse in the absence of controls. You may already have controls at the hydrated batter mix storage/recirculation step that minimize the potential for time/temperature abuse that could result in *S. aureus* growth and toxin formation. This and the following steps will help you determine whether those or other controls should be included in your HACCP plan.

Step #10 provides information to help you decide if the time/temperature conditions of your hydrated batter mix storage/recirculation step are significant for this hazard.

2. Can *S. aureus* growth and toxin formation, which is reasonably likely to occur, be eliminated or reduced to an acceptable level at this processing step?
(Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12.)

"*S. aureus* toxin formation in hydrated batter mixes" should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate (or reduce the likelihood of occurrence to an acceptable level) the hazard, if it is reasonably likely to occur.

Step #10 discusses a number of pathogen control strategies. This chapter covers control of *S. aureus* toxin formation that occurs as a result of time/temperature abuse at the hydrated batter mix storage/recirculation step. A preventive measure for toxin formation can include controlling the amount of time that batter mixes are exposed to temperatures above 50˚F (10˚C).

List this preventive measure in Column 5 of the Hazard Analysis Worksheet at the batter mix storage/recirculation step.

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If none of the criteria is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where the critical control point is located.

• Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, because of the highly stable nature of *S. aureus* toxin, it is unlikely that the intended use will affect the significance of the hazard.

STEP #12: *IDENTIFY CRITICAL CONTROL POINTS (CCP).*

For each processing step where "*S. aureus* growth and toxin formation in hydrated batter mixes" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

You should identify the hydrated batter mix storage/recirculation step as the critical control point for this hazard. For hand battering operations, where hydrated batter mix is stored at each hand battering station, each station should be identified as a CCP.

This control approach will be referred to as "Control Strategy Example 1" in Steps #14-18. It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

You should answer "Yes" in Column 6 of the Hazard Analysis Worksheet at the hydrated batter mix storage/recirculation step and "No" in that column for the other processing steps for which the hazard was identified as a significant hazard. In addition, for each "No" entry make sure that Column 5 indicates that the hazard is controlled at the hydrated batter mix storage/recirculation step. (Note: if you have not previously identified "*S. aureus* growth and toxin formation in hydrated batter mixes" as a significant hazard at the hydrated batter mix storage/recirculation step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".)

Example:
A breaded fish processor could set the critical control point for controlling the hazard of "S. aureus growth and toxin formation in hydrated batter mixes" at the hydrated batter mix storage/recirculation step. The processor would not need to identify other processing steps as critical control points for that hazard.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For the hydrated batter mix storage/recirculation step, identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the hydrated batter mix storage/recirculation step.

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

Critical Limit: Hydrated batter mix temperatures should not exceed 50˚F (10˚C) for more than twelve hours, cumulatively;
AND
Hydrated batter mix temperatures should not exceed 70˚F (21.1˚C) for more than three hours, cumulatively.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

Continued

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For the hydrated batter mix storage/recirculation step, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the hydrated batter mix storage/recirculation step. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

What: The temperature of the hydrated batter mix.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

How: Use a digital time/temperature data logger;
OR
Use a recorder thermometer;
OR
Use a maximum indicating thermometer;
OR
Use a high temperature alarm;
OR
Use an indicating thermometer.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

Frequency: Continuous monitoring, with visual check at least once per day;
OR
For indicating thermometers: at least every two hours.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

Who: With recorder thermometers, high temperature alarms, maximum indicating thermometers, and digital data loggers, monitoring is performed by the equipment itself. However, when such instruments are used, a visual check should be made at least once per day in order to ensure that the critical limits have consistently been met. These checks, as well as indicating thermometer checks, may be performed by a production employee, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the process and the monitoring procedure.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For the hydrated batter mix storage/recirculation step, describe the procedures that you will use when your monitoring indicates that the CL has not been met. These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the hydrated batter mix storage/recirculation step.

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

Corrective Action: Take one or more of the following actions to regain control over the operation after a CL deviation:

- Add ice to the hydrated batter mix storage/recirculation tank;

OR

- Make repairs or adjustments to the hydrated batter mix refrigeration equipment;

AND

Take one of the following actions to product involved in the critical limit deviation:

- Destroy the product and the remaining hydrated batter mix;

OR

- Divert the product and the remaining hydrated batter mix to a non-food use;

OR

- Hold the product and hydrated batter until it can be evaluated based on its total time/temperature exposure;

OR

- Hold the product and hydrated batter mix until the hydrated batter mix can be sampled and analyzed for the presence of staphylococcal enterotoxin.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For the hydrated batter mix storage/recirculation step, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the hydrated batter mix storage/recirculation step.

- CONTROL STRATEGY EXAMPLE 1 - HYDRATED BATTER MIX CONTROL

Records: Printout from digital time/temperature data logger;
OR
Recorder thermometer chart;
OR
Record showing the results of the maximum indicating thermometer checks;
OR
Record showing the results of the high temperature alarm checks;
OR
Record showing the results of the indicating thermometer checks.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

Continued

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For the hydrated batter mix storage/recirculation step, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "*S. aureus* growth and toxin formation in hydrated batter mixes"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the hydrated batter mix storage/ recirculation step.

- CONTROL STRATEGY EXAMPLE 1 -

HYDRATED BATTER MIX CONTROL

Verification: Review monitoring, corrective action, and verification records within one week of preparation;

AND

When digital time/temperature data loggers, recorder thermometers, or high temperature alarms are used, check for accuracy against a known accurate thermometer (NIST-traceable) at least once per day;

AND

When indicating thermometers or maximum indicating thermometers are used, check for accuracy against a known accurate thermometer (NIST-traceable) when first used and at least once per year thereafter. (Note: optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.)

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #15-1

Control Strategy Example 1 - Hydrated batter mix control

This table is an example of a portion of a HACCP plan relating to the control of *S. aureus* toxin formation in hydrated batter mixes for a breaded fish processor, using Control Strategy Example 1 - Hydrated batter mix control. It is provided for illustrative purposes only. *S. aureus* toxin formation in the hydrated batter mix may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5) Monitoring	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Batter mix recirculation	*S. aureus* growth and toxin formation	Hydrated batter mix temperature not to exceed 50°F for more than 12 hrs, nor 70°F for more than 3 hrs, cumulative	Hydrated batter mix temperature	Recorder thermometer	Continuous with visual check once per day	Production employee	• Adjust hydrated batter mix refrigeration equipment • Destroy hydrated batter mix and any product produced during deviant period	Recorder thermometer chart	• Check accuracy of recorder thermometer once per day; • Review monitoring, corrective action and verification records within one week of preparation

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

Notes:

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Pathogen survival through a cook step can cause consumer illness. Cooking is a relatively severe heat treatment, usually performed before the product is placed in the finished product container.

Generally, after cooking, fishery products are referred to as cooked, ready-to-eat. Examples of cooked, ready-to-eat products are: crab meat, lobster meat, crayfish meat, cooked shrimp, surimi-based analog products, seafood salads, seafood soups and sauces and hot-smoked fish.

• Goal of cooking — most products

One of the purposes of cooking products that will be aerobically packaged is to eliminate vegetative cells of pathogens (or reduce them to an acceptable level) that may have been introduced to the process by the raw materials or by processing that occurs before the cook step. Selection of the target pathogen is critical. Generally, *Listeria monocytogenes* is selected, because it is regarded as the most heat tolerant, foodborne pathogen that does not form spores. Cooking processes are not usually designed to eliminate spores of pathogens. Determining the degree of destruction of the target pathogen is also critical. Generally, a reduction of six orders of magnitude (six logarithms) in the level of contamination is suitable. This is called a "6D" process. FDA's draft *L. monocytogenes* risk assessment indicates that approximately 7% of raw fish are contaminated with from 1 to 10^3 CFU/g, and that approximately 92% are contaminated at less than 1 CFU/g. Less than 1% of raw fish are contaminated at levels greater than 10^3 CFU/g, and none at levels greater than 10^6 CFU/g. FDA's action level for *L. monocytogenes* in ready-to-eat products, nondetectable, corresponds to a level of less than 1 CFU/25g.

Table #A-3 provides 6D process times for a range of cooking temperatures, with *L. monocytogenes* as the target pathogen.

Lower degrees of destruction may be acceptable if supported by a scientific study of the normal innoculum in the food. It is also possible that higher levels of destruction may be necessary in some foods, if there is an especially high normal innoculum.

• Goal of cooking — refrigerated, reduced oxygen packaged products

When cooking is performed immediately before reduced oxygen packaging (e.g. vacuum packaging, modified atmosphere packaging), for product that will be marketed under refrigeration, it may be necessary for the cooking process to be sufficient to eliminate the spores of *Clostridium botulinum* type E and nonproteolytic types B and F. This is the case when the product does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen (e.g. many refrigerated, vacuum packaged hot-filled soups and sauces). Generally, a 6D process is suitable. However, lower degrees of destruction may be acceptable if supported by a scientific study of the normal innoculum in the food. It is also possible that higher levels of destruction may be necessary in some foods, if there is an especially high normal innoculum. Table #A-4 provides 6D process times for a range of cooking temperatures, with *C. botulinum* type B (the most heat resistant form of nonproteolytic *C. botulinum*) as the target pathogen. An example of a product that is properly cooked to eliminate nonproteolytic *C. botulinum* is a soup or sauce that is pasteurized at an internal temperature of 194˚F (90˚C) for at least 10 minutes. The lethal rates and process times provided in the table may not be sufficient for the destruction of nonproteolytic *C. botulinum* in soups or sauces containing dungeness crabmeat, because of the potential that naturally occuring substances, such as lysozyme, may enable the pathogen to more easily recover after damage.

Continued

Reduced oxygen packaged soups or sauces that are cooked immediately before packaging to control nonproteolytic *C. botulinum*, but not proteolytic *C. botulinum,* and that do not contain barriers to its growth, must be refrigerated or frozen to control proteolytic *C. botulinum.* Control of refrigeration is critical to the safety of these products. Further information on *C. botulinum* and reduced oxygen packaging is contained in Chapter 13.

Cooking processes that target nonproteolytic *C. botulinum* have much in common with pasteurization processes, which are discussed in Chapter 17. Like products that are pasteurized in the final container, products that are cooked and then placed in the final container also are at risk for recontamination after they are placed in the finished product container. Controls, such as container seal integrity and protection from contamination by cooling water, are critical to the safety of these products. They are covered in Chapter 18. Additionally, because these products are cooked before they are packaged, they are at risk for recontamination between cooking and packaging. The risk of this recontamination must be minimized by filling the container in a continuous filling system while the product is still hot (i.e. hot filling), another critical step for the safety of these products. This control strategy is suitable for products that are filled directly from the cooking kettle, where the risk of recontamination is minimized. It is not ordinarily suitable for products such as crabmeat, lobster meat, or crayfish meat, or other products that are handled between cooking and filling. Hot filling is also covered in Chapter 18.

• Control of cooking

Controlling pathogen survival through the cook step is accomplished by:

- Scientifically establishing a cooking process that will eliminate pathogens of public health concern or reduce their numbers to acceptable levels; and,

- Designing and operating the cooking equipment so that every unit of product receives at least the established minimum process.

• Strategies for controlling pathogen growth

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

- Killing pathogens by cooking (covered in this chapter), pasteurizing (covered in Chapter 17), or retorting (covered by the low acid canned foods regulations, 21 CFR 113);

- Managing the amount of time that a food is exposed to temperatures that are favorable for pathogen growth and toxin production (covered in Chapter 12; and for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15);

- 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 regulations, 21 CFR 114 for shelf-stable acidified products; and for refrigerated acidified products in Chapter 13).

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "pathogen survival through cooking" is a significant hazard. The criteria are:

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

It is reasonable to assume that pathogens of various types, including those listed in Table #A-1 (Appendix 4), will be present on raw fish and fishery products. They may only be present at low levels or only occasionally, but even such occurrences warrant consideration because of the potential for growth and toxin production.

Pathogens may also be introduced during processing, as described in Step #10. Well designed sanitation programs will minimize the introduction of pathogens. Such sanitation controls need not be part of your HACCP plan if they are monitored under your sanitation program (prerequisite program). In most cases it is not reasonable to assume that they will fully prevent the introduction of pathogens. For this reason, you should consider it reasonably likely that low numbers of pathogens will be present in the product, even after a cook step. Remember, control of pathogen growth (e.g. after a cook step) is covered in Chapter 12.

2. Can unsafe levels of pathogens that were introduced at an earlier processing step be eliminated or reduced to an acceptable level at this processing step? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12).

"Pathogen survival through cooking" should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate (or reduce the likelihood of occurrence to an acceptable level) the hazard, if it is reasonably likely to occur.

Step #10 discusses a number of pathogen control strategies. This section covers the control of pathogens during a cook step. Delivering a properly designed cooking process can be an effective preventive measure for the control of pathogens. If this preventive measure is applied list it in Column 5 of the Hazard Analysis Worksheet at the cooking step.

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use and method of storage and distribution

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, for cooked, ready-to-eat fishery products, it is unlikely that the intended use will affect the significance of the hazard.

However, if your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important, keep frozen until used, thaw under refrigeration immediately before use"), then formation of *C. botulinum* toxin may not be a significant hazard.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINT (CCP).*

For each processing step where "pathogen survival through cooking" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "pathogen survival through cooking":

Continued

Will the finished product be pasteurized in the final container?

1. If it will be, you may identify the pasteurization step as the CCP. In this case you will not need to identify the cook step as a CCP for the hazard of "pathogen survival through cooking."

Example:
A crabmeat processor cooks, picks, packs, and pasteurizes the crabmeat. The processor sets the critical control point for "pathogen survival through cooking" at the pasteurization step, and does not identify the cooking step as a critical control point for this hazard.

In this case, you should identify the pasteurization processing step as the critical control point for this hazard. Therefore, you should answer "Yes" in Column 6 of the Hazard Analysis Worksheet at the pasteurization step, and "No" in that column at the other processing steps for which the hazard was identified as a significant hazard. (Note: if you have not previously identified "pathogen survival though cooking" as a significant hazard at the pasteurization step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes.") If you choose to follow this approach you should refer to Chapter 17, Pathogen survival through pasteurization, for further guidance. In particular, you should note that, if the cook step is not identified as a CCP, the pasteurization step must be effective in eliminating pathogens that may be present in an improperly cooked product.

2. If the product will not be pasteurized, you should identify the cooking step as the CCP. Therefore, you should answer "Yes" in Column 6 of the Hazard Analysis Worksheet at the cooking step, and "No" in that column at the other processing steps for which the hazard was identified as a significant hazard. (Note: if you have not previously identified "pathogen survival though cooking" as a significant hazard at the cooking step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes").

This control approach will be referred to as "Control Strategy Example 1" in Steps #14-18. It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For the cook step identify the minimum or maximum value to which a feature of the process must be controlled in order to control the hazard.

The CL will be the minimum or maximum parameters established by a scientific study (see Step #18 - Verification) as necessary for adequate cooking (e.g. time and temperature of the cooking process). If you set a more restrictive CL (e.g. 2˚F higher/2 minutes longer) you could be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the cook step:

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

Critical Limit: The minimum or maximum values for the critical factors established by a scientific study. These will likely include length of the cook cycle (speed of the belt for a continuous cooker), and temperature of the steam or water used for cooking (or visual observation of minutes at a boil). Other critical factors that affect the rate of heating of the product may also be established by the study. Product internal temperatures at the end of the cooking cycle are not ordinarily suitable CLs, because of variability from unit to unit.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For the cook step, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the critical limit is being met. That is, the monitoring process should directly measure the feature for which you have established a critical limit.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the critical limit. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a critical limit has been violated.

Following is guidance on establishing monitoring procedures for cooking. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

What: Critical factors of the established cooking process. These may include:
- Time and temperature of the cooking process;

AND
- Other critical factors that affect the rate of heating of the product, as specified by the study, including, but not limited to, initial temperature and size of product.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

For batch cooking equipment:

How: Monitor the cooking time and temperature with a temperature recording device or a digital time/temperature data logger. The device should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the coldest temperature of the cooking equipment (cold spot to be determined by study). Where cooking is performed at the boiling point, visual observation of minutes at a boil may be an acceptable alternative;

AND

The start and end of each cooking cycle should be determined visually;

AND

Monitor other critical factors with equipment appropriate to the critical factor (e.g. initial temperature with a dial thermometer or equivalent).

Continued

For continuous cooking equipment:

How: Monitor the cooking temperature with a temperature recording device or a digital time/temperature data logger. The device should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the coldest temperature of the cooking equipment (cold spot to be determined by study). Due to the extended time of operation of such equipment, it is unlikely that visual observation of boiling will be an acceptable alternative, even if cooking is performed at the boiling point;

AND

Monitor the time by measuring either:

- The RPM of the belt drive wheel, using a stop watch or tachometer;

OR

- The time necessary for a test unit or belt marking to pass through the equipment, using a stop watch;

AND

Monitor other critical factors with equipment appropriate to the critical factor (e.g. initial temperature with a dial thermometer or equivalent).

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

For batch cooking equipment:

Frequency: Monitor the cooking temperature continuously by the instrument itself, with a visual check of the monitoring instrument at least once per batch;

AND

The start and end of each cooking cycle should be determined visually;

AND

Monitor other critical factors with sufficient frequency to achieve control.

For continuous cooking equipment:

Frequency: Monitor the cooking temperature continuously by the instrument itself, with a visual check of the monitoring instrument at least once per day;

AND

Monitor the time at least once per day, and whenever any changes in belt speed are made;

AND

Monitor other critical factors with sufficient frequency to achieve control.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

For batch cooking equipment:

Who: Monitoring of cooking temperature is performed by the equipment itself, except in the case of visual observation of minutes at a boil. However, a visual check should be made of the recorded data at least once at the end of each cycle in order to ensure that the critical limits have consistently been met. These checks, as well as the monitoring of the cooking time, visual observations of boiling, where applicable, and monitoring of other critical factors may be performed by the equipment operator, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the equipment and the monitoring procedure.

For continuous cooking equipment:

WHO: Monitoring of cooking temperature is performed by the equipment itself. However, a visual check should be made at least once per day in order to ensure that the critical limits have consistently been met. These checks, as well as the monitoring of the cooking time and of other critical factors may be performed by the equipment operator, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the equipment and the monitoring procedure.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *Establish corrective action procedures.*

For the cook step, describe the procedures that you will use when your monitoring indicates that the critical limit has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for cooking:

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

Corrective Action: Take one or more of the following actions, as necessary, to regain control over the operation after a CL deviation:
- Adjust the steam supply to increase the processing temperature;

OR
- Extend the length of the cooking cycle to compensate for a temperature drop;

OR
- Adjust the belt speed to increase the length of the cook cycle;

AND

Take one of the following actions to the product involved in the critical limit deviation:
- Destroy the product;

OR
- Reprocess the product;

OR
- Segregate and hold the product for an evaluation of the adequacy of the cooking process. If the product has not received an adequate cook, the product should be destroyed, diverted to a non-food use, or reprocessed to eliminate potential pathogens of public health concern;

OR
- Divert the product to a use in which the critical limit is not applicable (e.g. divert improperly cooked shrimp to a shrimp canning operation);

OR
- Divert to a non-food use.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For the cook step, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for cooking.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

For batch cooking equipment:

Records: Either:
- Temperature recorder chart or a digital time/temperature data logger printout;

OR
- Cooking log that indicates visual observation of boiling, where cooking is performed at the boiling point;

AND

Cooking log that indicates the start and end of each cooking cycle;

For continuous cooking equipment:

Records: Temperature recorder chart or a digital time/temperature data logger printout;

AND

Cooking log that indicates the RPM of the belt drive wheel or the time necessary for a test unit or belt marking to pass through the tank.

Continued

For all cooking equipment:

Records: Records that are appropriate for the other critical factors (e.g. cooking log that indicates the initial temperature).

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For the cook step, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "pathogen survival through cooking"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for cooking.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF COOKING

Verification: Process establishment: The adequacy of the cooking process should be established by a scientific study. It should be designed to ensure an appropriate reduction in the numbers of pathogens of public health concern. Selecting the target organism is critical. In most cases it will be a relatively heat tolerant vegetative pathogen, such as *Listeria monocytogenes*. However in some cases where outgrowth of spore-forming pathogens, such as *Clostridium perfringens* and *Bacillus cereus*, during the post-cook cooling step must be prevented by eliminating these pathogens during the cook (e.g., because cooling after cooking is not controlled – see Chapter 12) then they will be the target organisms. Additionally, when cooking is performed immediately before reduced oxygen packaging (e.g. vacuum packaging, modified atmosphere packaging), for product that will be marketed under refrigeration, it may be necessary for the cooking process to be sufficient to eliminate the spores of *Clostridium botulinum* type E and nonproteolytic types B and F. This is the case when the product does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen (e.g. refrigerated, vacuum packaged hot-filled soups and sauces). Generally, a 6D process is suitable, regardless of the target pathogen. However, lower degrees of destruction may be acceptable if supported by a scientific study of the normal innoculum in the food. Tables #A-3 and A-4 provide 6D process times for a range of internal product temperatures, with *L. monocytogenes* and *C. botulinum* type B (the most heat resistant form of nonproteolytic *C. botulinum*) as the target pathogens, respectively. The values provided in Table #A-4 may not be sufficient for the destruction of nonproteolytic *C. botulinum* in products containing dungeness crabmeat, because of the potential protective effect of naturally occuring substances, such as lysozyme. Expert knowledge of thermal process calculations and the dynamics of heat transfer in processing equipment is required to establish such a cooking process. Such knowledge can be obtained by education or experience, or both. Establishing cooking processes requires access to suitable facilities and the application of recognized methods. The cooking equipment should be designed, operated, and maintained to deliver the established process to every unit of product. In some cases, thermal death time, heat penetration, temperature distribution and inoculated pack studies will be required to establish the minimum process. In many cases, establishing the minimum process may be simplified by repetitively determining the process needed to reach an internal product temperature that will assure the inactivation of all vegetative pathogens of public health concern under the most difficult heating conditions likely to be encountered during processing. In other instances, existing literature or federal, state or local regulations which establish minimum processes or adequacy of equipment, are available. Characteristics of the process, product and/or equipment that affect the ability of the established minimum cooking process should be taken into consideration in the establishment of the process. A record of process establishment should be maintained;

AND

Check the accuracy of the temperature recording device or digital time/temperature data logger by comparing it to a mercury-in-glass thermometer (or equivalent instrument) at least once per day. The recording device should be adjusted to agree as nearly as possible, but never higher than the thermometer;

AND

Calibrate the mercury-in-glass thermometer (or equivalent instrument) at the cooking temperature against a known accurate standard thermometer (NIST-traceable). This should be done when the thermometer is installed and at least once per year after that (Note: optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument);

AND

Calibrate other instruments as necessary to ensure their accuracy;

AND

Review monitoring, corrective action and verification records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #16-1

Control Strategy Example 1 - Control of cooking

This table is an example of a portion of a HACCP plan relating to the control of pathogen survival through cooking for a processor of wild-caught cooked shrimp, using a continuous steam cooker, using Control Strategy Example 1 - Control of cooking. It is provided for illustrative purposes only. Pathogen survival through cooking may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, pathogen growth and toxin formation during processing, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Cooking	Pathogen survival	• Minimum time: 2.5 min.	• Length of the cook cycle	• Belt speed measurement with stopwatch	• Once per day and after any adjustment	• Cooker operator	• Extend process or elevate temperature to compensate for deviation from CL AND	• Cooking record	• Documentation of process establishment • Review monitoring, verification, and corrective action records within one week of preparation
		• Minimum temperature: 210°F (Note: To achieve a 6D reduction of *L. monocytogenes*)	• Temperature of steam in the cooker	• Digital time/ temperature data logger	• Continuous. Visual check once per day	• Cooker operator	• Segregate and hold for evaluation.	• Data logger printout	• Check the accuracy of the data logger against the mercury-in-glass thermometer daily • Calibrate the mercury-in-glass thermometer yearly
		• Maximum shrimp size: 40 count/pound	• Shrimp size	• Scale	• Hourly and after every raw material lot change or grader adjustment	• Grader operator		• Grading record	• Calibrate the scale monthly

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

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Survival of pathogens through the pasteurization process can cause illness to the consumer. Pasteurization is a mild or moderate heat treatment, usually performed on fishery products after the product is placed in the hermetically sealed finished product container. The purpose of pasteurization is to either: 1) make the product safe for an extended refrigerated shelf-life, which, in most cases, involves eliminating the spores of *Clostridium botulinum* type E and nonproteolytic B and F (the types of *C. botulinum* most commonly found in fish); or 2) eliminate or reduce the numbers of other target pathogens (e.g. *Listeria monocytogenes*, *Vibrio vulnificus*).

Selection of the target pathogen is critical. If a target pathogen other than *C. botulinum* type E and nonproteolytic types B and F is selected, you must consider the potential that *C. botulinum* type E or nonproteolytic types B and F will survive the pasteurization process and grow under normal storage conditions or moderate abuse conditions. Ordinarily, the potential exists if the product is reduced oxygen packaged (e.g. vacuum packaged, modified atmosphere packaged), does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen, and is stored or distributed refrigerated (not frozen). For example, vacuum packaged lobster meat that is pasteurized to kill *L. monocytogenes* but not *C. botulinum* type E or nonproteolytic types B and F must be frozen to prevent growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F. Surveys of retail display cases and home refrigerators indicate that temperatures above the minimum growth temperature of *C. botulinum* type E and nonproteolytic types B and F (38˚F [3.3˚C]) are not uncommon. Therefor, refrigeration alone cannot be relied upon for control of the *C. botulinum* hazard.

For pasteurization processes that target nonproteolytic *C. botulinum*, generally a reduction of six orders of magnitude (six logarithms, e.g. from 10^3 to 10^{-3}) in the level of contamination is suitable. This is called a "6D" process. However, lower degrees of destruction may be acceptable if supported by a scientific study of the normal innoculum in the food. It is also possible that higher levels of destruction may be necessary in some foods, if there is an especially high normal innoculum. Table #A-4 provides 6D process times for a range of cooking temperatures, with *C. botulinum* type B (the most heat resistant form of nonproteolytic *C. botulinum*) as the target pathogen. The lethal rates and process times provided in the table may not be sufficient for the destruction of nonproteolytic *C. botulinum* in dungeness crabmeat, because of the potential that naturally occuring substances, such as lysozyme, may enable the pathogen to more easily recover after heat damage.

Examples of properly pasteurized products are: blue crabmeat pasteurized to a cumulative lethality of $F_{185˚F}$ ($F_{85˚C}$) = 31 min., z=16˚F (9˚C); surimi-based products pasteurized at an internal temperature of 194˚F (90˚C) for at least 10 minutes.

In some pasteurized surimi-based products, salt in combination with a milder pasteurization process in the finished product container work to prevent growth and toxin formation by *C. botulinum* type E and nonproteolytic types B and F. An example of a properly pasteurized surimi-based product in which 2.5% salt is present is one that has been pasteurized at an internal temperature of 185˚F (85˚C) for at least 15 minutes. This process may not be suitable for other types of products, because of the unique formulation and processing involved in the manufacture of surimi-based products.

Reduced oxygen packaged foods that are pasteurized to control nonproteolytic *C. botulinum*, but not proteolytic *C. botulinum,* and that do not contain barriers to its growth, must be refrigerated or frozen to control proteolytic *C. botulinum.* Control of

Continued

refrigeration is critical to the safety of these products. Further information on *C. botulinum* and reduced oxygen packaging is contained in Chapter 13.

In cases where *Listeria monocytogenes* is selected, a 6D process is also generally suitable. FDA's draft *L. monocytogenes* risk assessment indicates that approximately 7% of raw fish are contaminated with from 1 to 10^3 CFU/g, and that approximately 92% are contaminated at less than 1 CFU/g. Less than 1% of raw fish are contaminated at levels greater than 10^3 CFU/g, and none at levels greater than 10^6 CFU/g. FDA's action level for *L. monocytogenes* in ready-to-eat products, nondetectable, corresponds to a level of less than 1 CFU/25g. Table #A-3 provides 6D process times for a range of pasteurization temperatures, with *L. monocytogenes* as the target pathogen.

Lower degrees of destruction may be acceptable if supported by a scientific study of the normal innoculum in the food. It is also possible that higher levels of destruction may be necessary in some foods, if there is an especially high normal innoculum.

Products that are pasteurized in the finished product container are at risk for recontamination after pasteurization. Controls, such as container seal integrity and protection from contamination by cooling water, are critical to the safety of these products. They are covered in Chapter 18.

• Control of pasteurization

In order to ensure that the targeted pathogens are eliminated, it is critical that the pasteurization process be scientifically established. The pasteurization equipment must also be designed and operated so that every unit of product receives at least the established minimum process.

• Strategies for controlling pathogen growth

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

- Killing pathogens by pasteurization (covered in this chapter), cooking (covered in Chapter 16), or retorting (covered by the low acid canned foods regulation, 21 CFR 113);
- Controlling the introduction of pathogens after the pasteurization process (covered in Chapter 18);
- Controlling the level of acidity, pH, in the product (covered by the acidified foods regulation, 21 CFR 114 for shelf-stable acidified products; and for refrigerated acidified products in Chapter 13);
- Controlling the amount of moisture that is available for pathogen growth, water activity, in the product by drying (covered in Chapter);
- 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);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogen growth and toxin production (covered in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mix, in Chapter 15).

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "pathogen survival through pasteurization" is a significant hazard. The criteria is:

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

It is reasonable to assume that pathogens of various types, including those listed in Table #A-1 (Appendix 4), will be present on raw fish and fishery products. They may only be present at low levels or only occasionally, but even such occurrences warrant consideration because of the potential for growth and toxin production.

Pathogens may also be introduced during processing, from the air, unclean hands, insanitary utensils and

equipment, unsafe water, and sewage. Well designed sanitation programs will minimize the introduction of pathogens. Such sanitation controls need not be part of a HACCP plan if they are monitored under your sanitation program (prerequisite program). In most cases it is not reasonable to assume that they will fully prevent the introduction of pathogens. For this reason, you should consider it reasonably likely that low numbers of pathogens will be present in the product, even after a cook step.

2. Can unsafe levels of pathogens, which were introduced at an earlier processing step, be eliminated or reduced to an acceptable level here? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12.)

"Pathogen survival through pasteurization" should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate (or reduce the likelihood of occurrence to an acceptable level) the hazard, if it is reasonably likely to occur.

Step #10 discusses a number of pathogen control strategies. This section covers the control of pathogens by pasteurization. Delivering a properly designed pasteurization process can be an effective preventive measure for the control pathogens. If this preventive measure is applied, list it in Column 5 of the Hazard Analysis Worksheet at the pasteurization step.

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If none of the criteria is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use and method of storage and distribution

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, for most fishery products which are currently pasteurized, it is unlikely that the intended use will affect the significance of the hazard.

However, if your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important, keep frozen until used, thaw under refrigeration immediately before use"), then formation of *C. botulinum* toxin may not be a significant hazard.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "pathogen survival through pasteurization" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

You should identify the pasteurization processing step as the critical control point for this hazard. Therefore, you should answer "Yes" in Column 6 of the Hazard Analysis Worksheet at the pasteurization step, and "No" in that column at the other processing steps for which the hazard was identified as a significant hazard. (Note: if you have not previously identified "pathogen survival through pasteurization" as a significant hazard at the pasteurization step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes").

This control approach is referred to as "Control Strategy Example 1" in Steps #14-18. It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

Continued

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For the pasteurization step identify the minimum or maximum value to which a feature of the process must be controlled in order to control the hazard.

The CL will be the minimum or maximum parameters established by a scientific study (see Step #18 - Verification) as necessary for adequate pasteurization (e.g. time and temperature of the pasteurization process, container size). If you set a more restrictive CL (e.g. 2˚F higher/2 minutes longer) you could be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action.

You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the pasteurization step:

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

Critical Limit: The minimum or maximum values for the critical factors established by a scientific study. These may include length of the pasteurization cycle (speed of the belt for a continuous pasteurizer), temperature of the water bath, initial temperature of the product, container size (e.g. can dimensions, pouch thickness), and product formulation. Product internal temperatures during the pasteurization cycle are not ordinarily suitable CLs because of variability from container to container.

As described in Step #10, the critical limits must be established for the target pathogen. In most cases this will be *C. botulinum* type E and nonproteolytic types B and F. However, in certain cases the target pathogen may be a vegetative pathogen such as *L. monocytogenes* or *V. vulnificus*.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For the pasteurization step, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the critical limit is being met. That is, the monitoring process should directly measure the feature for which you have established a critical limit.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the critical limit. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a critical limit has been violated.

Following is guidance on establishing monitoring procedures for pasteurization. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

WHAT: Critical factors established by a scientific study. These may include length of the pasteurization cycle (speed of the belt for a continuous pasteurizer), temperature of the water bath, initial temperature of the product, container

size (e.g. can dimensions, pouch thickness), and product formulation.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

For batch pasteurizers:

How: Monitor the pasteurization time and temperature with a temperature recording device or a digital time/temperature data logger. The device should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the coldest temperature of the pasteurizing equipment (cold spot to be determined by study);
AND
The start and end of each pasteurization cycle should be determined visually;
AND
Monitor other critical factors with equipment appropriate to the critical factor (e.g. initial temperature with a dial thermometer or equivalent).

For continuous pasteurizers:

How: Monitor the pasteurization temperature with a temperature recording device or a digital time/temperature data logger. The device should be installed where it can be easily read and the sensor for the device should be installed to ensure that it accurately measures the coldest temperature of the pasteurizing equipment (cold spot to be determined by study);
AND
Monitor the time by measuring either:
- The RPM of the belt drive wheel, using a stop watch or tachometer;

OR
- The time necessary for a test unit or belt marking to pass through the tank, using a stop watch;

AND
Monitor other critical factors with equipment appropriate to the critical factor (e.g. initial temperature with a dial thermometer or equivalent).

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

For batch pasteurizers:

Frequency: Monitor the pasteurization temperature continuously, with a visual check at least once per batch;
AND
The start and end of each pasteurization cycle should be determined visually;
AND
Monitor other critical factors with sufficient frequency to achieve control.

For continuous pasteurizers:

Frequency: Monitor the pasteurization temperature continuously, with a visual check at least once per day;
AND
Monitor the time at least once per day, and whenever any changes in belt speed are made;
AND
Monitor other critical factors with sufficient frequency to achieve control.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

For batch pasteurizers:

Who: Monitoring of pasteurization temperature is performed by the equipment itself. However, a visual check should be made at least once at the end of each cycle in order to ensure that the critical limits have consistently been met. These checks, as well as the monitoring of the pasteurization time and other critical factors may be performed by the equipment operator, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the equipment and the monitoring procedure.

Continued

For continuous pasteurizers:

Who: Monitoring of pasteurization temperature is performed by the equipment itself. However, a visual check should be made at least once per day in order to ensure that the critical limits have consistently been met. These checks, as well as the monitoring of the pasteurization time and other critical factors may be performed by the equipment operator, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the equipment and the monitoring procedure.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For the pasteurization step, describe the procedures that you will use when your monitoring indicates that the critical limit has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for pasteurization.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

Corrective Action: Take one or more of the following actions as necessary to regain control over the operation after a CL deviation:

- Adjust the steam supply to increase water bath temperature;

OR

- Extend the length of the pasteurization cycle to compensate for a temperature drop or a low initial temperature;

OR

- Process at a higher temperature to compensate for a low initial temperature;

OR

- Adjust the belt speed to increase the length of the pasteurization cycle;

AND

Take one of the following actions to the product involved in the critical limit deviation:

- Destroy the product;

OR

- Reprocess the product;

OR

- Segregate and hold the product for an evaluation of the adequacy of the pasteurization process. If the product has not received adequate pasteurization, the product should be destroyed, diverted to a non-food use, or reprocessed to eliminate potential pathogens of public health concern;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. divert improperly pasteurized crabmeat to a crabmeat canning operation);

OR

- Divert to a non-food use.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For the pasteurization step, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for pasteurization.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

For batch pasteurizers:

Recods: Temperature recorder chart or a digital time/temperature data logger printout;

AND

Pasteurization log that indicates the start and end of each pasteurization cycle;

AND

Records that are appropriate for the other critical factors (e.g. pasteurization log that indicates the initial temperature).

For continuous pasteurizers:

Recods: Temperature recorder chart or a digital time/temperature data logger printout;

AND

Pasteurization log that indicates the RPM of the belt drive wheel or the time necessary for a test unit or belt marking to pass through the tank;

AND

Records that are appropriate for the other critical factors (e.g. pasteurization log that indicates the initial temperature).

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For the pasteurization step, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of pathogen survival through pasteurization; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for pasteurization.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF PASTEURIZATION

Verification: Process establishment: The adequacy of the pasteurization process should be established by a scientific study. It should be designed to ensure an appropriate reduction in the numbers of the target pathogen. Expert knowledge of thermal process calculations and the dynamics of heat transfer in processing equipment is required to determine the target pathogen and to establish such a pasteurization process. Such knowledge can be obtained by education or experience, or both. Establishing pasteurization processes requires access to suitable facilities and the application of recognized methods. The pasteurization equipment should be designed, operated, and maintained to deliver the established process to every unit of product. In some cases, thermal death time, heat penetration, temperature distribution and inoculated pack studies will be required to establish the minimum process. In other instances, existing literature or federal, state or local regulations which establish minimum processes or adequacy of equipment, are available. Characteristics of the process, product and/or equipment that affect the adequacy of the established minimum pasteurization process should be taken into consideration in the establishment of the process. A record of process establishment should be maintained;

AND

Check the accuracy of the temperature recording device or time/temperature data logger by comparing it to a mercury-in-glass thermometer (or equivalent instrument) at least once per day. The recording device should be adjusted to agree as nearly as possible, but never higher than the thermometer.

AND

Calibrate the mercury-in-glass thermometer (or equivalent instrument) at the pasteurization temperature against a known accurate standard thermometer (NIST-traceable). This should be done when the thermometer is installed and at least once per year after that. (Note: optimal calibration frequency is dependent upon the type, condition, and past performance of the monitoring instrument.)

AND

Calibrate other instruments as necessary to ensure their accuracy.

AND

Review monitoring, corrective action and verification records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #17-1

Control Strategy Example 1 - Control of pasteurization

This table is an example of a portion of a HACCP plan relating to the control of pasteurization for pasteurized, refrigerated blue crab meat, using Control Strategy Example 1 - Control of pasteurization. It is provided for illustrative purposes only. Pathogen survival through pasteurization may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, pathogen growth and toxin formation during processing, recontamination after pasteurization, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Batch Pasteurization	Pathogen survival	• Minimum initial product temperature 37°F	• Initial temperature	• Dial thermometer	• Coldest can entering each batch	• Pasteurizer operator	• Extend process or elevate temperature to compensate for deviation from CL AND	• Pasteurization log	• Documentation of process establishment
		• Minimum length of pasteurization cycle 120 minutes	• Time up to 189°F and time cycle ends	• Wall clock/ temperature recording device	• Each batch	• Pasteurizer operator		• Pasteurization log	• Review monitoring, verification, and corrective action records within one week of preparation
		• Minimum water bath temperature 189°F	• Temperature of water bath	• Temperature recording device	• Continuously, each batch. Visual check at end of batch.	• Recorder thermometer with visual by pasteurizer operator	• Segregate and hold for evaluation.	• Recorder thermometer chart	• Check the accuracy of the temperature recording device against the mercury-in-glass thermometer daily • Calibrate the mercury-in-glass thermometer yearly

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

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

The introduction of pathogens after pasteurization and certain cooking processes can cause consumer illness.

Pasteurization is a mild or moderate heat treatment, usually performed on fishery products after the product is placed in the hermetically sealed finished product container. The purpose of pasteurization is to either: 1) make the product safe for an extended refrigerated shelf-life, which, in most cases, involves eliminating the spores of *Clostridium botulinum* type E and nonproteolytic B and F (the types of *C. botulinum* most commonly found in fish); or 2) eliminate or reduce the numbers of other target pathogens (e.g. *Listeria monocytogenes*, *Vibrio vulnificus*, *Vibrio parahaemolyticus*).

In addition to eliminating pathogens, the pasteurization process also greatly reduces the number of spoilage bacteria present in the fishery product. These bacteria normally restrict the growth of pathogens through competition. Rapid growth of pathogens that may be introduced after pasteurization is, therefore, a concern. This chapter covers control of recontamination after pasteurization.

For some products that are marketed refrigerated, cooking is performed immediately before reduced oxygen packaging (e.g. vacuum packaging, modified atmosphere packaging). For these products, the cooking process is targeted to eliminate the spores of *Clostridium botulinum* type E and nonproteolytic types B and F, particularly when the product does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen (e.g. many refrigerated, vacuum packaged hot-filled soups and sauces). These cooking processes, which are discussed in Chapter 16, have much in common with pasteurization processes, which are discussed in Chapter 17. For example, control of recontamination after they are placed in the finished product container is critical to the safety of these products. Additionally, because these products are cooked before they are packaged, they are at risk for recontamination between cooking and packaging. The risk of this recontamination is minimized by filling the container in a continuous filling operation while the product is still hot (i.e. hot filling), another critical step for the safety of these products. This control strategy is suitable for products that are filled directly from the cooking kettle, where the risk of recontamination is minimized. It is not ordinarily suitable for products such as crabmeat, lobster meat, or crayfish meat, or other products that are handled between cooking and filling. Hot filling is covered in this chapter.

- Control of pathogen introduction after pasteurization and after cooking that is performed immediately before reduced oxygen packaging

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

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

Poorly formed or defective container closures can increase the risk of pathogens entering the container, especially during container cooling performed in a water bath. Contaminated cooling water can enter through the container closure, especially when the closure is defective. Container closure can be controlled by adherence to seal guidelines that are provided by the container or sealing machine manufacturer. Control is accomplished through periodic seal inspection.

Continued

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

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

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

• Strategies for controlling pathogen growth

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

• Controlling the introduction of pathogens after the pasteurization process and after cooking process performed immediately before reduced oxygen packaging (covered in this chapter);

• Killing pathogens by cooking (covered in Chapter 16), pasteurizing (covered in Chapter 17), or retorting (covered by the low acid canned foods regulations, 21 CFR 113);

• Controlling the level of acidity, pH, in the product (covered by the acidified foods regulations, 21 CFR 114 for shelf-stable acidified products; and for refrigerated acidified products in Chapter 13);

• 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);

• Managing the amount of time that food is exposed to temperatures that are favorable for pathogen growth and toxin production (covered in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in batter mix, in Chapter 15).

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step determine whether "introduction of pathogens after pasteurization" is a significant hazard. The criteria are:

1. Is it reasonably likely that pathogens will be introduced at this processing step (consider post-pasteurization processing steps, only)?

It is reasonable to assume that, in the absence of controls, pathogens of various types may enter the finished product container during a water bath cooling process or between cooking and reduced oxygen packaging.

2. Can the introduction of pathogens after pasteurization be eliminated or reduced to an acceptable level here? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12)

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

Step #10 discusses a number of pathogen control strategies. This section covers control of pathogen introduction that can occur after the pasteurization process and between cooking and reduced oxygen packaging. Preventive measures for the introduction of pathogens at these times can include:

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

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use and method of storage and distribution

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, for those fishery products which are currently pasteurized, it is unlikely that the intended use will affect the significance of the hazard.

However, if your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important, keep frozen until used, thaw under refrigeration immediately before use"), then formation of *C. botulinum* toxin may not be a significant hazard.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "introduction of pathogens after pasteurization" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

You should identify the container sealing step, the water bath container cooling step, and the hot filling step (where applicable) as the critical control points for this hazard. Therefore, you should answer "Yes" in Column 6 of the Hazard Analysis Worksheet for the container sealing, water bath container cooling, and hot filling steps. (Note: if you have not previously identified "pathogen introduction after pasteurization" as a significant hazard at the container sealing, water bath container cooling, and hot filling steps in Column 3 of the Hazard Analysis Worksheet, you should change the entries in Column 3 to "Yes").

This control approach is referred to as "Control Strategy Example 1" in Steps #14-18. It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

Continued

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

At each processing step where "introduction of pathogens after pasteurization" is identified as a significant hazard on the HACCP Plan Form (e.g. container sealing, water bath container cooling and hot filling) identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy example identified in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF RECONTAMINATION

For container sealing:

Critical Limit: Container or sealing machine manufacturer's seal guidelines.

For container cooling:

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

For hot filling:

Critical Limit: Product temperature of 185˚F (85˚C) or higher as the product enters the final container.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "introduction of pathogens after pasteurization" is identified as a significant hazard on the HACCP Plan Form (e.g. container sealing, container cooling tank and hot filling), describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control option discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF RECONTAMINATION

For container sealing:

What: Container integrity

For container cooling:

What: Residual chlorine, or other approved water treatment chemical, in the cooling water;
OR
Intensity of UV light;
AND
Cooling water flow rate.

For hot filling:

What: Product temperature as the product enters the final container.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF RECONTAMINATION

For container sealing:

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

OR
  - For pouches: Visual examination should be sufficient to detect gross closure defects, including: cuts, fractures, non-bonding, malformation, puncture, abrasion, blister, contaminated seal, delamination, seal creep, wrinkle, flex cracks, crushed package or other obvious defects;

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

AND
Detailed examination of containers (destructive):
- Recommendations for seal evaluation measurements that ensure a reliable hermetic seal should be obtained from the container or sealing machine manufacturer. They should include:
  - For double seamed metal and plastic cans: The examination should include a teardown examination of the can. If the micrometer method is used, three (3) measurements, approximately 120˚ apart around the double seam, should be made. Measurements should include: cover hook, body hook, width, tightness, and thickness. If the optical method (seamscope or projector) is used, cuts should be made at at least two (2) different locations, excluding the side seam juncture. Measurements should include body hook, overlap, tightness, and thickness;

OR
  - For pouches: The examination should include: burst testing or vacuum or bubble testing. It may also include: drop testing, peel testing (tensile strength), residual gas testing, electroconductivity testing, and dye testing;

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

Continued

For container cooling:

How: Measure residual of chlorine, or other approved water treatment chemical, at the discharge point of the container cooling tank;
OR
Use a UV light meter;
AND
Use a flow rate meter.

For hot filling:

How: Use a digital time/temperature data logger;
OR
Use a recorder thermometer.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF RECONTAMINATION

For container sealing:

Frequency: Visual examination of containers: At least one container from each sealing head at least every 30 minutes of sealing machine operation. At a minimum this should include visual examinations made at the beginning of production, and immediately following a jam in the sealing machine, or machine adjustment, repair, or prolonged shut down;
AND
Detailed examination of containers: At least one container from each sealing head at least every four hours of sealing machine operation. At a minimum this should include examinations made at the beginning of production and immediately following a jam in the sealing machine, or machine adjustment, repair, or prolonged shut down.

For container cooling:

Frequency: For residual water treatment chemical: Sufficient frequency to assure control, but no less frequently than once every four hours of use;
OR
For UV light meter and flow rate meter: at least daily.

For hot filling:

Frequency: Continuous monitoring by the instrument itself, with visual check of the instrument at least once per batch of cooked product.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF RECONTAMINATION

For container sealing:

Who: Monitoring may be performed by the sealing machine operator, a production supervisor, a member of the quality control staff, or any person who is trained and qualified to conduct container examinations.

For container cooling:

Who: Monitoring may be performed by the equipment operator, a production supervisor, a member of the quality control staff or any other person who has an understanding of the testing procedure and the critical limits.

For hot filling:

Who: With recorder thermometers and digital data loggers, monitoring is performed by the equipment itself. However, when such instruments are used a visual check should be performed at least once per batch of cooked product in order to ensure that the critical limits have consistently been met. These checks may be performed by a production employee, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the process and the monitoring procedure.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

At each processing step in which "introduction of pathogens after pasteurization" is identified as a significant hazard in the HACCP Plan Form (e.g. container sealing, water bath container cooling and hot filling), describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control option discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF RECONTAMINATION

For container sealing:

Corrective Action: Identify and correct the source of the defect after a CL deviation;
AND
Evaluate the seriousness of the defects, and, if necessary, identify, segregate, and hold the affected product for appropriate follow-up action. That may include, but is not limited to, 100% visual inspection of all affected containers to remove the defective containers;
OR
Repack the affected product.

For container cooling:

Corrective Action: If no measurable residual chlorine, or other approved water treatment chemical, is detected, add chlorine or adjust the chlorine metering system and recheck for chlorine residual;
OR
If UV intensity is inadequate, replace or clean the bulbs or shields;
AND
If flow exceeds the critical limit, adjust or replace the pump.

For hot filling:

Corrective Action: Take one or more of the following actions to regain control over the operation after a CL deviation:

- Adjust the cooking equipment to increase the processing temperature;

OR

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

AND
Take one of the following actions to the product involved in the critical limit deviation:

- Destroy the product;

OR

- Recook the product;

OR

- Segregate and hold the product for a safety evaluation. If the product is found to be unsafe, it should be destroyed, diverted to a non-food use, or recooked to eliminate potential pathogens of public health concern;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g. divert to a canning operation);

OR

- Divert to a non-food use.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

Continued

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

At each processing step in which "introduction of pathogens after pasteurization" is identified as a significant hazard and critical control point in the HACCP Plan Form (e.g. container sealing, water bath container cooling and hot filling), list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control option discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF RECONTAMINATION

For container sealing:

Records: Record of visual examination of containers;
AND
Record of detailed examination of containers.

For container cooling:

Records: Record of residual chlorine, or other approved water treatment chemical, levels;
OR
Record of UV intensity testing;
AND
Record of flow rate testing.

For hot filling:

Records: Printout from digital time/temperature data logger;
OR
Recorder thermometer chart.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

At each processing step in which "introduction of pathogens after pasteurization" is identified as a significant hazard in the HACCP Plan Form (container sealing, water bath container cooling and hot filling), establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "introduction of pathogens after pasteurization"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control option discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - CONTROL OF RECONTAMINATION

For container sealing:

Verification: Obtain container seal guidelines from container or sealing machine manufacturer;
AND
Review monitoring and corrective action records within one week of preparation.

For container cooling:

Verification: Review monitoring and corrective action records within one week of preparation.

For hot filling:

Verification: Review monitoring and corrective action records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #18-1

Control Strategy Example 1 - Control of recontamination

This table is an example of a portion of a HACCP plan relating to the control of the introduction of pathogens after pasteurization for a processor of pasteurized blue crab meat, packed in 301 X 408 size steel cans, using Control Strategy Example 1 - Control of recontamination. It is provided for illustrative purposes only. Pathogen recontamination after pasteurization may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, pathogen growth and toxin formation during processing, pathogen survival through pasteurization, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Container sealing	Pathogen introduction	• No visible cutovers, seam sharpness, false seams, deadheading, droop, damage to the countersink wall indicating a broken chuck, cable cuts, product overlapping the flange, product leakage, or other obvious defects. • Cover hook: .070" minimum; body hook .072-.088"; width: .125" maximum; thickness .052-.058"; tightness 80%.	• Container integrity • Container integrity	• Visual seam examination • Double seam teardown examination, using micrometer at 3 points on seam, 120°F apart.	• One can per seaming head every 1/2 hr, at startup, after jams, adjustments, repairs, and prolonged shutdowns • One can per seaming head every 4 hrs, at startup, after jams, adjustments, repairs, and prolonged shutdowns	• Seamer operator • Seamer operator	• Identify and correct the source of the defect, and • Evaluate the seriousness of the defect, and hold for further evaluation if necessary • Same	• Visual seam examination record • Double seam teardown record	• Review monitoring and corrective action records within one week of preparation • Can seam guide-lines from can manufacturer • Same
Water bath container cooling	Pathogen introduction	Measurable residual chlorine	Residual chlorine in water bath	Rapid test	Every batch	Pasteurizer operator	Add chlorine and recheck for residual	Processing record	Review monitoring and corrective action records within one week of preparation

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

Notes:

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Certain food and color additives can cause an allergic-type reaction (food intolerance) in consumers. Examples of such food and color additives that are used on fish and fishery products include: sulfiting agents and FD&C Yellow #5. Sulfiting agents are mostly used during on-board handling of shrimp and lobster to prevent the formation of "black spot." They are sometimes used by cooked octopus processors as an antioxidant, to retain the red color of the octopus skin. FD&C Yellow #5 is used during in-plant processing. These food and color additives are permitted for use in foods, with certain restrictions, but their presence must be declared on the label. This label declaration is particularly important to sensitive individuals.

Certain other food and color additives are prohibited from use in food because of a determination by FDA that they present a potential risk to the public health. Examples of such food and color additives include: safrole and FD&C Red #4.

Additionally, a number of foods contain allergenic proteins that can pose a health risk to certain sensitive individuals. Appendix 6 contains a list of such foods that account for most of all food allergies. While the controls in this chapter are not directly applicable to the hazard of allergenic proteins, if these foods are part of or are directly added to your fishery product, you may use the principles contained in this chapter to ensure that the product is properly labeled. However, these controls are not designed to prevent the unintentional introduction of allergenic proteins from such foods into your fishery product because of cross-contact (e.g. use of common equipment, improper production scheduling, or improper use of rework material). Unintentional introduction of allergenic proteins must be controlled through a rigorous sanitation regime, either as part of a prerequisite program or as part of HACCP itself. The Seafood HACCP Regulation requires such a regime.

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT*

At each processing step, determine whether "allergens/additives" is a significant hazard. The criteria are:

1. Is it reasonably likely that a food or color additive that can cause an allergic-type reaction (e.g. sulfiting agents or FD&C yellow #5) or a prohibited substance (e.g. safrole and FD&C Red #4) will be introduced at a level that can cause an allergic-type reaction at this processing step (e.g. does it come in with the raw material or will the process introduce it)?

For example, under ordinary circumstances, it would be reasonably likely to expect that food or color additives that can cause an allergic-type reaction could enter the process under the following circumstances:

- Sulfiting agents may be used on shrimp and lobster between capture and delivery to the processor. However, in some regions even with these products (e.g. some aquacultured shrimp) this practice may not be reasonably likely.

- Sulfiting agents may also be used in the processing of cooked octopus.

Sulfiting agents added directly to a finished food must be declared on a product's labeling regardless of the concentration of the sulfiting agent. When not directly added to the finished food, sulfiting agents must be declared on a product's labeling when the level is at or above 10 ppm.

Continued

• FD&C Yellow #5 may be used in the processing of formulated fishery products or in the production of smoked fish.

2. Can the hazard be eliminated or reduced to an acceptable level here? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12)

"Allergens/additives" should also be considered a significant hazard at a processing step if a preventive measure is or can be used to prevent or eliminate the hazard or is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level, if it is reasonably likely to occur. Preventive measures for allergic-type reactions that can result from the presence of certain food and color additives (e.g. sulfiting agents and FD&C yellow #5) could include:

- Declaring the presence of food and color additives that can cause an allergic-type reaction on finished product labeling;
- Testing incoming shrimp or lobster for residues of sulfiting agents at or above 10 ppm;
- Receiving a supplier's certification of the lack of sulfiting agent use on incoming lots of shrimp or lobster (with appropriate verification – see Step #18);
- Reviewing the labeling (or accompanying documents, in the case of unlabeled product) on shipments of shrimp or lobster received from another processor for the presence of a sulfiting agent declaration

A preventive measure for the presence of prohibited food and color additives could include:

• Testing incoming lots of fish for the presence of prohibited food and color additives which there is reason to believe may be present.

• Receiving a supplier's certification that prohibited food and color additives were not used on the incoming lot of fish (with appropriate verification – see Step #18).

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. However, in the case of allergens/additives, it is not likely that the significance of the hazard will be affected by the intended use of the product.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "allergens/additives" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "allergens/additives":

1. In the case of shrimp or lobster for which you have identified sulfiting agents as a significant hazard, will the finished product label declare the presence of sulfiting agents?

a. If it will, you may identify the finished product labeling step as the CCP. Alternately, you may identify the receipt of product labels as the CCP (where you can check labels for the presence of a sulfiting agent declaration). The raw material receiving step would then not require control and would not need to be identified as a CCP for the hazard of improper use of allergens/additives.

In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the finished product labeling step or receipt of product labels step, and enter "No" for the raw material receiving step. In addition, for the raw material receiving step enter in Column 5 that the hazard is controlled by the finished product labeling step or the receipt of product labels step. (Note: if you have not previously identified "allergens/additives" as a significant hazard at the finished product labeling step or receipt of product labels step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) This control approach will be referred to as "Control Strategy Example 1" in Steps #14 through 18.

Example:

A frozen shrimp processor that labels all finished product with a sulfiting agent declaration could set the critical control point for sulfiting agents (allergens/additives) at the finished product labeling step. The processor would not need to have a critical control point for this hazard at the shrimp receiving step.

b. If the finished product labeling will not declare the presence of sulfiting agents, you may identify the raw material receiving step as the CCP.

In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the raw material receiving step. This control approach will be referred to as "Control Strategy Example 2" in Steps #14 through 18.

Example:

A frozen shrimp processor that receives shrimp directly from the harvest vessel and does not label finished product with a sulfiting agent declaration could set the critical control point for sulfiting agents (allegens/additives) at the raw material receiving step and test incoming lots of shrimp for the presence of sulfiting agents. The processor would not need to have a critical control point for this hazard at finished product labeling.

Example:

A frozen shrimp processor that receives shrimp from another processor and does not label finished product with a sulfiting agent declaration could set the critical control point for sulfiting agents (allegens/additives) at the raw material receiving step and reject incoming lots that are identified as having been treated with a sulfiting agent (e.g. identified on the labeling or, in the case of unlabeled product, on documents accompanying the shipment). The processor would not need to have a critical control point for this hazard at finished product labeling.

c. If the finished product labeling will only declare the presence of sulfiting agents when it is present in the raw material, you may identify the finished product labeling step or the receipt of product labels step (where you can check labels for the presence of a sulfiting agent declaration) as the CCP. Testing or certification at the raw material receiving step will be necessary to ensure control at the CCP. However, the raw material receiving step would not need to be identified as a CCP for the hazard of "allergens/additives."

In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the finished product labeling step or the receipt of product labels step, and enter "No" for the raw material receiving step. In addition, for the raw material receiving step enter in Column 5 that the hazard is controlled by the finished product labeling step or the receipt of product labels step. (Note: if you have not previously identified "allergens/additives" as a significant hazard at the finished

Continued

product labeling step or receipt of product labels step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) This control approach will be referred to as "Control Strategy Example 3" in Steps #14 through 18.

Example:

A frozen shrimp processor that receives shrimp directly from the harvest vessel and labels finished product with a sulfiting agent declaration only if testing at receipt identifies a residue of a sulfiting agent could set the critical control point for sulfiting agents (allergens/additives) at the finished product labeling step or the receipt of product labels step. The processor would not need to have a critical control point for this hazard at the raw material receiving step.

Example:

A frozen shrimp processor that receives shrimp from another processor and labels finished product with a sulfiting agent declaration only if the incoming lot was identified as having been treated with a sulfiting agent (e.g. identified on the labeling or, in the case of unlabeled product, on documents accompanying the shipment), could set the critical control point for sulfiting agents (allergens/additives) at the finished product labeling step or the receipt of product labels step. The processor would not need to have a critical control point for this hazard at the raw material receiving step.

2. In the case of cooked octopus for which you have identified sulfiting agents as a significant hazard, and in the case of products for which you have identified FD&C Yellow #5 as a significant hazard because you use one of these food and color additives in the product formulation, you should identify the finished product labeling step or receipt of product labels step (where you can check labels for the presence of a sulfiting agent or FD&C Yellow #5 declaration, as appropriate) as the CCP. The processing step at which you add a sulfiting agent or FD&C Yellow #5 would then not require control and would not need to be identified as a CCP for the hazard of "allergens/additives."

In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the finished product labeling step or receipt of product labels step, and enter "No" for the treatment step. In addition, for the treatment step enter in Column 5 that the hazard is controlled by the finished product labeling step or receipt of product labels step. (Note: if you have not previously identified "allergens/additives" as a significant hazard at the finished product labeling step or receipt of product labels step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) This control approach will also be referred to as "Control Strategy Example 1" in Steps #14 through 18.

Example:

A smoked sablefish processor that treats the fish with FD&C Yellow #5 before smoking could set the critical control point for FD&C Yellow #5 (allergens/additives) at the finished product labeling step or receipt of product labels step. The processor would not need to have a critical control point for this hazard at the treatment step.

Example:

A cooked octopus processor that treats the fish with a sulfiting agent could set the critical control point for sulfiting agents (allergens/additives) at the finished product labeling step or receipt of product labels step. The processor would not need to have a critical control point for this hazard at the treatment step.

3. In the case of products for which you have identified prohibited food and color additives (e.g. safrole and FD&C Red #4) as a significant hazard in incoming raw materials you should identify the raw material receiving step as the CCP.

In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the raw material receiving step. This control approach will be referred to as "Control Strategy Example 2" in Steps #14 through 18.

It is important to note that you may select a control strategy that is different from those which are suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "allergens/additives" is identified as a significant hazard on the HACCP Plan Form identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - LABELING CONTROLS

Critical Limit: All finished product labels must contain a sulfiting agent or FD&C Yellow #5 declaration, as appropriate.

- CONTROL STRATEGY EXAMPLE 2 - RAW MATERIAL SCREENING

Critical Limit: Incoming lots of shrimp or lobster must not contain a detectable level of sulfite;
OR
Incoming lots of shrimp or lobster must be accompanied by a supplier's lot-by-lot certificate that sulfiting agents were not used;
OR
The labeling or shipping documents for incoming lots of shrimp or lobster received from another processor must not contain a sulfiting agent declaration;
OR
Incoming lots of raw materials must not contain a detectable level of prohibited food and color additives;
OR
Incoming lots of raw materials must be accompanied by a supplier's lot-by-lot certificate that prohibited food and color additives were not used.

- CONTROL STRATEGY EXAMPLE 3 - LABELING CONTROLS WITH RAW MATERIAL SCREENING

Critical Limit: Finished product labels for product processed from raw materials that contain a detectable level of sulfite must contain a sulfiting agent declaration.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "allergens/additives" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

Continued

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy examples discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - LABELING CONTROLS

What: Finished product labels for presence of sulfiting agent or FD&C Yellow #5 declaration, as appropriate.

- CONTROL STRATEGY EXAMPLE 2 - RAW MATERIAL SCREENING

What: Representative sample of each lot at receipt for sulfiting agent residual analysis, or prohibited food and color additive residual analysis, as appropriate;
OR
Supplier's lot-by-lot certificate that no sulfiting agent, or prohibited food and color additive, as appropriate, was used on the lot (with appropriate verification – see Step #18);
OR
Labeling or accompanying documents for each lot received from another processor, for the presence of a sulfiting agent declaration.

- CONTROL STRATEGY EXAMPLE 3 - LABELING CONTROLS WITH RAW MATERIAL SCREENING

What: Finished product labels for presence of sulfiting agent declaration;
AND
One of the following:
- Representative sample of each lot for sulfiting agent residual analysis;

OR
- Supplier's lot-by-lot certificate that no sulfiting agent was used on the lot (with appropriate verification – see Step #18);

OR
Labeling or accompanying documents for each lot received from another processor, for the presence of a sulfiting agent declaration.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - LABELING CONTROLS

How: Visual examination.

- CONTROL STRATEGY EXAMPLE 2 - RAW MATERIAL SCREENING

How: Screening test for sulfiting agents or prohibited food and color additives, as appropriate;
OR
Visual examination of certificates;
OR
Visual examination of the labeling or accompanying documents, for lots received from another processor.

- CONTROL STRATEGY EXAMPLE 3 - LABELING CONTROLS WITH RAW MATERIAL SCREENING

How: Visual examination of labels;
AND
One of the following:
- Screening test for sulfiting agents;

OR
- Visual examination of certificates;

OR
Visual examination of the labeling or accompanying documents, for lots received from another processor.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - LABELING CONTROLS

Frequency: At least one label from every case of labels or one label from each pallet of pre-labeled packaging material delivered to the packaging area;
OR
At least one label from every case of labels or one label from each pallet of pre-labeled packaging material received at the firm.
OR
Once per day for on-site computer generated labels.

- CONTROL STRATEGY EXAMPLE 2 - RAW MATERIAL SCREENING

Frequency: Each incoming lot.

- CONTROL STRATEGY EXAMPLE 3 - LABELING CONTROLS WITH RAW MATERIAL SCREENING

Frequency: At least one label from every case of labels or one label from each pallet of pre-labeled packaging material delivered to the packaging area;
OR
At least one label from every case of labels or one label from each pallet of pre-labeled packaging material received at the firm.
OR
Once per day for on-site computer generated labels.
AND
Each lot of incoming shrimp or lobster.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - LABELING CONTROLS

Who: Monitoring may be performed by the labeling equipment operator, the receiving employee, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the proper content of the label.

- CONTROL STRATEGY EXAMPLE 2 - RAW MATERIAL SCREENING

Who: Monitoring may be performed by the receiving employee, a production supervisor, a member of the quality control staff, or any other person who that has an understanding of the proper screening procedure. Assignment of responsibility for testing procedures should be based, in part, on the degree of difficulty of the analysis.

- CONTROL STRATEGY EXAMPLE 3 - LABELING CONTROLS WITH RAW MATERIAL SCREENING

Who: Monitoring may be performed by the labeling equipment operator, the receiving employee, a production supervisor, a member of the quality control staff, or any other person that has an understanding of proper content of the label or the screening procedure, as appropriate. Assignment of responsibility for testing procedures should be based, in part, on the degree of difficulty of the analysis.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

Continued

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "allergens/additives" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - LABELING CONTROLS

Corrective Action: Segregate and relabel any improperly labeled product;
AND
Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper declaration.

- CONTROL STRATEGY EXAMPLE 2 - RAW MATERIAL SCREENING

Corrective Action: Reject any incoming lot in which sulfiting agent or prohibited food and color additive, as appropriate, is detected or declared or which is not accompanied by a supplier's certificate.

Note: If an incoming lot that fails to meet a receiving critical limit is mistakenly accepted, and the error is later detected, the following actions should be taken: 1) the lot and any products processed from that lot should be destroyed, diverted to a nonfood use or to a use in which the critical limit is not applicable, or placed on hold until a food safety evaluation can be completed; and 2) any products processed from that lot that have already been distributed should be recalled and subjected to the actions described above.

- CONTROL STRATEGY EXAMPLE 3 - LABELING CONTROLS WITH RAW MATERIAL SCREENING

Corrective Action: Segregate and relabel any improperly labeled product;
AND
Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper declaration.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "allergens/additives" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - LABELING CONTROLS

Records: Record of labeling checks.

- CONTROL STRATEGY EXAMPLE 2 - RAW MATERIAL SCREENING

Records: Test results for sulfiting agent or prohibited food and color additives, as appropriate;
OR
Supplier's lot-by-lot certificates;
OR
Record of raw material labeling or accompanying document checks.

- CONTROL STRATEGY EXAMPLE 3 - LABELING CONTROLS WITH RAW MATERIAL SCREENING

Records: Record of labeling checks;
AND
One of the following:
- Sulfiting agent test results;

OR
- Supplier's lot-by-lot certificates;

OR
Record of raw material labeling or accompanying document checks.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "allergens/additives" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of improper use of food and color additives; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - LABELING CONTROLS

Verification: Review monitoring and corrective action records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 2 - RAW MATERIAL SCREENING

Verification: Review monitoring, corrective action, and, where applicable, verification records within one week of preparation;
AND
When supplier's certificates are used for monitoring, collect at least one representative sample per quarter, randomly selected from among your suppliers, and analyze for sulfiting agents or prohibited food and color additives, as appropriate. Additionally, collect at least one representative sample for each new supplier, and analyze for sulfiting agents or prohibited food and color additives, as appropriate.

- CONTROL STRATEGY EXAMPLE 3 - LABELING CONTROLS WITH RAW MATERIAL SCREENING

Verification: Review monitoring, corrective action, and, where applicable, verification records within one week of preparation;
AND
When supplier's certificates are used for monitoring, collect at least one representative sample per quarter, randomly selected from among your suppliers, and analyze for sulfiting agents. Additionally, collect at least one representative sample for each new supplier, and analyze for sulfiting agents.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #19-1

Control Strategy Example 1 - Labeling controls

This table is an example of a portion of a HACCP plan relating to the control of sulfiting agents for a processor of wild-caught shrimp, using Control Strategy Example 1 – Labeling controls. It is provided for illustrative purposes only.
Allergens/additives may be only one of several significant hazards for this product.
Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Labeling receipt	Sulfiting agents	All finished product labels must contain sulfiting agent declaration	Finished product labels for presence of sulfiting agent declaration	Visual	One label from each case of labels at receipt	Receiving employee	Segregate and return any labels that do not contain the sulfiting agent declaration	Label receiving record	Review monitoring and correction action records within one week of preparation

TABLE #19-2

Control Strategy Example 2 - Raw material screening

This table is an example of a portion of a HACCP plan relating to the control of sulfiting agents for a processor of wild-caught frozen shrimp, using Control Strategy Example 2 – Raw material screening. It is provided for illustrative purposes only. Allergens/additives may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5) Monitoring	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Shrimp receiving	Sulfiting agents	Incoming lots of shrimp must be accompanied by a supplier's certificate that sulfiting agents were not used on the lot	Supplier's lot-by-lot certificate that no sulfiting agents were used on the lot	Visual	Every lot of incoming shrimp	Receiving employee	Reject any incoming lot of shrimp that is not accompanied by a supplier's certificate	Copies of supplier's guarantees	• Test one lot per quarter for sulfiting agent residue, and test one lot from each new supplier of shrimp for sulfiting agent residue • Review monitoring, correction action and verification records within one week of preparation

TABLE #19-3

Control Strategy Example 3 - Labeling controls with raw material screening

This table is an example of a portion of a HACCP plan relating to the control of sulfiting agents for a processor of wild-caught frozen shrimp, using Control Strategy Example 3 – Labeling controls with raw material screening. It is provided for illustrative purposes only. Allergens/additives may be only one of several significant hazards for this product.
Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Finished product labeling	Sulfiting agents	Finished product labels for product processed from sulfite-containing raw material shrimp must contain a sulfiting agent declaration	• Finished product labels for presence of sulfiting agent declaration • Three shrimp collected randomly from each lot of raw material shrimp for sulfiting agent residual analysis	• Visual • malachite green test	• One label from each case of labels delivered to packaging • Three shrimp from each lot of raw material shrimp	• Packaging machine operator • Quality control employee	• Segregate and relabel any improperly labeled product • Segregate and return any label stock that does not contain the proper declaration	Label check record	Review monitoring and corrective action records within one week of preparation

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Metal fragments can cause injury to the consumer.

Metal-to-metal contact, especially in mechanical cutting or blending operations, other equipment with metal parts that can break loose, such as moving wire mesh belts, injection needles, screens, portion control equipment, metal ties and can openers are likely sources of metal that may enter food during processing.

FDA's Health Hazard Evaluation Board has supported regulatory action against product with metal fragments of 0.3" (7 mm) to 1.0" (25mm) in length. See FDA Compliance Policy Guide #555.425.

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "metal inclusion" is a significant hazard. The criteria are:

1. Is it reasonably likely that metal fragments will be introduced at this processing step (e.g. does it come in with the raw material or will the process introduce it)?

For example, under ordinary circumstances, it would be reasonably likely to expect that metal fragments could enter the process from the following sources as a result of worn, damaged or broken equipment parts:

- Mechanical crabmeat pickers;
- Wire-mesh belts used to convey product in a batter/breading operation;
- Teeth from saw blades used to cut portions or steaks;
- Wire from mechanical mixer blades;
- Blades from mechanical chopping or blending equipment;
- Rings, washers, nuts, or bolts from sauce cooling, liquid dispensing, and portioning equipment;
- Blades from automatic filleting equipment;
- Injection needles;
- Metal ties used on raw material, in-process, or finished product containers or equipment.

Under ordinary circumstances it would not be reasonably likely to expect that metal fragments could enter the food from the following sources:

- Manual cutting, shucking, gutting, or boning knives;
- Metal processing tables or storage tanks;
- Wire mesh baskets or utensils.

2. Can metal fragments, which were introduced at an earlier step, be eliminated or reduced to an acceptable level at this processing step? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12.)

"Metal inclusion" should also be considered a significant hazard at any processing step where a preventive measure is or can be used to prevent or eliminate the inclusion of metal fragments, that have been introduced to the product at a previous step, or is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. Preventive measures for "metal inclusion" can include:

- Periodically checking cutting or blending equipment or wire-mesh belts for damage or missing parts;
- Passing the product through metal detection or separation equipment.

Visually inspecting equipment for damage or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire-mesh belts. Other, more complex, equipment may contain to many parts, some of which may not be readily visible, to make such visual inspection reliable in a reasonable time period.

Continued

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. In most cases you should assume that the product will be consumed in a way that would not eliminate any metal fragments that may be introduced during the process. In this case, you would need to identify the hazard as significant if the above criteria are met.

However, in some cases, if you have assurance that the product will be run through a metal detector, for detection of metal fragments, or through screens or a magnet, for separation of metal fragments, by a subsequent processor you may not need to identify metal fragment inclusion as a significant hazard.

Example:
A primary processor produces frozen fish blocks by mechanically heading, eviscerating, and filleting fish in-the-round. The primary processor sells exclusively to breaded fish stick processors and has been given assurance by these processors that the finished, breaded product will be subjected to a metal detector. The primary processor would not need to identify "metal inclusion" as a significant hazard.

In this case, you should enter "No" in Column 3 of the Hazard Analysis Worksheet for each of the processing steps. In addition, for each "No" entry briefly explain in column 4 that the hazard is controlled by a subsequent processor. In this case, you need not complete Steps #12 through 18 for this hazard.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "metal inclusion" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "metal inclusion":

Will the product be run through a metal detector, or through a screen, magnet, flotation tank, or other equipment for separation of metal fragments, on or after the last step where metal inclusion is identified as a significant hazard?

1. If it will be, you may identify final metal detection or separation as the CCP. Processing steps prior to metal detection will then not require control and will not need to be identified as CCPs for the hazard of metal fragments.

In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the metal detection or separation step, and enter "No" for the other processing steps where "metal inclusion" was identified as a significant hazard. In addition, for each "No" entry, note in Column 5 that the hazard is controlled by the final metal detection or separation step. (Note: if you have not previously identified "metal inclusion" as a significant hazard at the metal detection or separation step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) This control approach will be referred to as "Control Strategy Example 1" in Steps #14 through 18.

Example:
A breaded fish processor could set the critical control point for "metal inclusion" at the packaged product metal detection step, and would not need to have critical control points for this hazard at each of the steps at which there was a reasonably likelihood that metal fragments could be introduced.

You should recognize that by setting the critical control point at or near the end of the process, rather than at the point of potential metal fragment entry into the process, you are likely to have more labor and materials invested in the product before the problem is detected or prevented.

2. If the product will not be run through such a device, you should have procedures to periodically check the processing equipment for damage or lost parts at each processing step where "metal inclusion" is identified as a significant hazard. In this case you should identify those processing steps as CCPs. It would not ordinarily be necessary to identify these steps as CCPs in addition to identifying a final metal detection or separation step as a CCP.

Visually inspecting equipment for damage or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire-mesh belts. Other, more complex, equipment may contain to many parts, some of which may not be readily visible, to make such visual inspection reliable in a reasonable time period.

In this case, You should enter "Yes" in column 6 of the Hazard Analysis Worksheet for each of those processing steps. This control approach will be referred to as "Control Strategy Example 2" in Steps #14 through 18.

Example:
A processor that cuts tuna steaks from whole fish has identified the band saw cutting step as the only step that is reasonably likely to introduce metal fragments to the process. The processor does not have a final metal detection or separation step. The processor checks the condition of the band saw blade every four hours to ensure that it has not been damaged. The processor identifies the band saw cutting step as the CCP for this hazard.

It is important to note that you may select a control strategy that is different from those which are suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "metal inclusion" is identified as a significant hazard on the HACCP Plan Form identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

Critical Limit: No metal fragments in finished product. (Note: FDA's Health Hazard Evaluation Board has supported regulatory action against product with metal fragments of 0.3" [7 mm] to 1.0" [25mm] in length. See also FDA Compliance Policy Guide #555.425.)

Continued

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Critical Limit: No broken or missing metal parts from equipment at the CCPs for "metal inclusion"

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "metal inclusion" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy examples discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - EQUIPMENT CHECKS

What: The presence of metal fragments in product passing the CCP.

- CONTROL STRATEGY EXAMPLE 2 - METAL INCLUSION PREVENTION PROCEDURES

What: The presence of broken or missing metal parts from equipment at the CCPs.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

How: Use a metal detection device;
OR
Use a magnet for separating metal fragments from a product stream, where feasible (e.g. dry ingredients);
OR
Use screens for separating metal fragments from a product stream, where feasible (e.g. dry or liquid ingredients).

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

How: Visually check the equipment for broken or missing parts.

Examples:
- *Check saws for missing teeth;*
- *Check that all parts are secure on blending equipment;*
- *Check for missing links in metal belts.*

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

Frequency: Subject all product to the control.
Check that device is operating or is in place at start of each production day.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Frequency: Check before starting operations each day;
AND
Check every four hours during operation;
AND
Check at the end of operations each day;
AND
Check whenever there is an equipment malfunction that could increase the likelihood that metal could be introduced into the food.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

Who: Monitoring is performed by the equipment itself. A check should be made at least once per day to ensure that the device is operating or is in place. This may be performed by the equipment operator, a production supervisor, a member of the quality control staff, a member of the maintenance or engineering staff, or any other person who has an understanding of the operation of the equipment.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Who: Monitoring may be performed by the equipment operator, a production supervisor, a member of the quality control staff, a member of the maintenance or engineering staff, or any other person who has a thorough understanding of the proper condition of the equipment.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "metal inclusion" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

Corrective Action: Take the following corrective action to regain control over the operation after a CL deviation:
- Attempt to locate and correct the source of the fragments found in product by the metal detector or separated from the product stream by the magnets, screens, or other devices;

Continued

AND

Make adjustments to the materials, equipment, and/or process, as needed, to prevent future introduction of metal fragments;

AND

Take the following action to product involved in a CL deviation:

- Destroy;

OR

- Divert to non-food use;

OR

- Rework to eliminate metal fragments;

OR

- Hold and evaluate any product in which the metal detector has detected metal fragments;

AND

Take one of the following actions to the product when product is processed without a properly functioning metal detector or separation device:

- Destroy the product;

  OR
- Hold all product produced since controls were last confirmed as functioning properly until it can be run through a metal detector;

  OR
- Hold all product produced since controls were last confirmed as functioning properly until an inspection of the processing equipment that could contribute metal fragments can be completed to determine whether there are any broken or missing parts;

  OR
- Divert all product produced since controls were last confirmed as functioning properly to a use in which it will be run through a metal detector (e.g. divert fish fillets to a breading operation that is equipped with a metal detector);

  OR
- Divert all product produced since controls were last confirmed as functioning properly to a non-food use;

AND

- Repair or replace the metal detector or separation device

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Corrective Action: Take one of the following corrective actions to regain control over the operation after a CL deviation:

- Stop production;

AND

- If necessary, adjust or modify the equipment to reduce the risk of recurrence;

AND

Take one of the following actions to product involved in a CL deviation:

- Destroy all product produced since the previous satisfactory equipment check;

OR

- Run all product produced since the previous satisfactory equipment check through a metal detector;

OR

- Divert all product produced since the previous satisfactory equipment check to a use in which it will be run through a metal detector (e.g. divert fish fillets to a breading operation that is equipped with a metal detector);

OR

- Divert all product produced since the previous satisfactory equipment check to a non-food use.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "metal inclusion" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

Records: Record documenting that the metal detection or separation device is operating or is in place, as appropriate.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Records: Record of equipment inspections.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "metal inclusion" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of metal inclusion; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

Verification: Test the effectiveness of the metal detection device, or check the condition of the magnet, screen, or other metal separation device at least once per day, before start of operations;
AND
Review monitoring, corrective action and verification records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Verification: Review monitoring and corrective action records within one week of preparation.

Enter the verification procedures in column 10 of the HACCP Plan Form.

TABLE #20-1

Control Strategy Example 1 - Metal detection or separation

This table is an example of a portion of a HACCP plan relating to the control of metal fragment inclusion for a processor of frozen fish sticks, using Control Strategy Example 1 - Metal detection or separation. It is provided for illustrative purposes only. Metal inclusion may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants and *Staphylococcus aureus* toxin formation in the hydrated batter mix).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Metal detection	Metal inclusion	No detectable metal fragments in finished product	Presence of detectable metal fragments in finished product	Metal detector	Every finished product package, with operation check before start-up	Production employee	• Destroy any product rejected by metal detector • Identify source of metal found in product and fix damaged equipment • If product is processed without metal detection hold for metal detection	Metal detector operation log	• Test metal detector with three test units before production each day, and recalibrate if needed • Review monitoring, corrective action and verification records within one week of preparation

TABLE #20-2

Control Strategy Example 2 - Equipment Checks

This table is an example of a portion of a HACCP plan relating to the control of metal fragment inclusion for a processor of frozen tuna steaks, using Control Strategy Example 2 - Metal inclusion prevention procedures. It is provided for illustrative purposes only. Metal inclusion may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. histamine and parasites).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Band saw	Metal inclusion	No damage to saw blade	Check saw blade for damage	Visual	Before start-up, every four hours during operation, at end of day, and after equipment jam	Saw operator	• Stop production • Adjust equipment • Isolate product since last visual check • Hold product until it can be run through metal detector and destroy rejects	Equipment maintenance log	Review monitoring and corrective action records within one week of preparation

Notes:

This chapter is provided as draft guidance at this time. FDA requests that interested parties with information on the hazard of glass inclusion and its control provide comments on the content of the chapter.

Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Glass fragments can cause injury to the consumer. FDA's Health Hazard Evaluation Board has supported regulatory action against products with glass fragments of 0.3" (7 mm) to 1.0" (25 mm) in length. See FDA Compliance Policy Guide #555.425.

Glass inclusion can occur whenever processing involves the use of glass containers. Normal handling and packaging methods, especially mechanized methods, can result in breakage. Most products packed in glass containers are intended as a ready-to-eat commodity.

The purpose of this chapter is to address only the hazard of glass fragments that results from the use of glass containers. Glass fragments originating from other sources must be addressed where applicable in a prerequisite sanitation program. The Seafood HACCP Regulation requires such a program.

STEP #11: *DETERMINE IF THIS POTENTIAL HAZARD IS SIGNIFICANT.*

At each processing step, determine whether "glass inclusion" is a significant hazard. The criteria are:

1. Is it reasonably likely that glass fragments from glass containers will be introduced at this processing step (e.g. does it come in with the raw material or will the process introduce it)?

Under ordinary circumstances, it would be reasonably likely to expect that glass fragments could enter the process during processing of any product that is packed in a glass container. Likely areas of concern for glass container breakage are:

- Receiving;
- Storage, when cases are moved mechanically;
- Mechanized Cleaning;
- Conveyor Lines;
- Mechanized Filling;
- Hot-filling;
- Mechanized Capping;
- Pasteurizing.

2. Can glass fragments from glass containers, which were introduced at an earlier step, be eliminated or reduced to an acceptable level at this processing step? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step 12.)

"Glass inclusion" should also be considered a significant hazard at any processing step where a preventive measure is or can be used to prevent or eliminate the inclusion of glass fragments from glass containers, that have been introduced at a previous step, or is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. Preventive measures for "glass inclusion" can include:

- Visual examination of empty glass containers;
- Cleaning (water or compressed air) and inverting empty glass containers;
- Periodically monitoring processing lines for evidence of glass breakage;
- Proper adjustment of capping equipment (not a complete control);
- Visual examination of glass containers containing transparent liquid fishery products;
- Passing the product through x-ray equipment or other defect rejection system.

Continued

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps 12 through 18 for this hazard for those processing steps where you have recorded a "No."

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

• Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step 4. In most cases you should assume that the product will be consumed in a way that would not eliminate any glass fragments that may be introduced during the process. In this case, you would need to identify the hazard as significant if the above criteria are met.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "glass inclusion" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "glass inclusion":

Will the containers be run through x-ray equipment or other defect rejection system, undergo visual inspection for detection of glass fragments, or be cleaned (water or compressed air) and inverted on or after the last step where glass inclusion is identified as a significant hazard?

1. If it will be, you may identify final glass detection or separation as the CCP. Processing steps prior to glass detection or separation will then not require control and will not need to be identified as CCPs for the hazard of glass inclusion.

In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the glass detection or separation step, and enter "No" for the other processing steps where "glass inclusion" was identified as a significant hazard. In addition, for each "No" entry, note in Column 5 that the hazard is controlled by the glass detection or separation step. (Note: if you have not previously identified "glass inclusion" as a significant hazard at the glass detection or separation step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) This control approach will be referred to as "Control Strategy Example 1" in Steps 14 through 18.

Example:
A pickled herring processor that mechanically packs the product into glass jars could set the critical control point for "glass inclusion" at the packaged product x-ray examination step, and would not need to have critical control points for this hazard at each of the steps at which there was a reasonable likelihood that glass fragments could be introduced.

Example:
A processor that manually packs caviar into glass jars has identified the glass container receiving and storage steps as the only steps that are reasonably likely to introduce glass fragments into the process. The processor does not have finished product x-ray equipment. The processor manually inspects each container during the filling process. The processor identifies the container inspection step as the CCP for this hazard.

Example:
Another processor that manually packs caviar into glass jars has identified the glass container receiving and storage steps as the only steps that are reasonably likely to introduce glass fragments into the process. The processor does not have finished product x-ray equipment. Just before filling, the empty glass jars are inverted and cleaned, using filtered, compressed air. The processor identifies the container cleaning and inverting step as the CCP for this hazard.

You should recognize that by setting the critical control point at or near the end of the process, rather than at the point of potential glass fragment entry into the process, you are likely to have more labor and materials invested in the product before the problem is detected or prevented.

2. If the containers will not be run through detection equipment, visually inspected, or cleaned and inverted on or after the last step where "glass inclusion" is identified as a significant hazard, you should have procedures to periodically check the processing areas and equipment for glass breakage at each processing step where "glass inclusion" is identified as a significant hazard. In this case you should identify those processing steps as CCPs. It would not ordinarily be necessary to identify these steps as CCPs in addition to identifying a final glass detection or separation step as a CCP.

In this case, you should enter "Yes" in column 6 of the Hazard Analysis Worksheet for each of those processing steps. This control approach will be referred to as "Control Strategy Example 2" in Steps 14 through 18.

Example:
A processor bottles clam juice and has identified receiving, storage, mechanical conveying, mechanical filling, and mechanical capping, as processing steps reasonably likely to introduce glass fragments into the process. The processor does not have on-line x-ray equipment. The processor visually inspects all processing areas for broken glass at start-up and once every four hours. If broken glass is observed, the line is stopped, the glass is removed and the product that has moved through that area since the last inspection is placed on hold to be run through off-line x-ray equipment. The processor identifies receiving, storage, mechanical conveying, mechanical filling, and mechanical capping as the CCP's for this hazard.

It is important to note that you may select a control strategy that is different from those which are suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step 13 (Chapter 2) or to Step 10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "glass inclusion" is identified as a significant hazard on the HACCP Plan Form identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy examples discussed in Step 12.

Continued

- CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION

Critical Limit: No glass fragments in finished product. (Note: FDA's Health Hazard Evaluation Board has supported regulatory action against products with glass fragments of 0.3" [7 mm] to 1.0" [25 mm] in length. See also FDA Compliance Policy Guide #555.425.)

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Critical Limit: No broken glass at the CCPs for "glass inclusion".

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "glass inclusion" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL. You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy examples discussed in Step 12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION

What: The presence of glass fragments in glass containers passing the CCP.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

What: The presence of broken glass on or near equipment at the CCP's.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION

How: Use of x-ray equipment or other defect rejection system;
OR
Visual examination of empty glass containers;
OR
Visual examination of glass containers containing transparent liquid fishery products;
OR
Cleaning (water or compressed air) and inverting of empty glass containers.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

How: Visually check the glass handling areas for broken glass.

Examples:
- *Check pallets and cases of empty jars for damage, broken jars, and glass fragments;*
- *Check mechanical glass cleaning equipment and surrounding floors for broken glass;*
- *Check floors around conveyors for broken glass;*
- *Check filling and capping equipment and surrounding floors for broken glass;*
- *Check hot-filling and pasteurizing equipment and surrounding floors for broken glass.*

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION

Frequency: Continuous. Each container is subjected to detection or separation. For x-ray equipment, other defect rejection systems and glass separation equipment, check that the device is operating at least at the start of each production day. For visual inspection, check that appropriate personnel are assigned to the processing step at the start of each production day.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Frequency: Check before starting operations each day;
AND
Check at least every four hours during operation;
AND
Check at the end of operations each day;
AND
Check whenever there is an equipment or other malfunction that could increase the likelihood that glass containers could be damaged.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION

Who: For x-ray detection, other defect rejection systems, glass separation equipment and visual examination, monitoring is performed by the equipment itself or by properly trained and qualified inspection personnel. A check should be made at least once per day to ensure that the device is operating or that the appropriate personnel are on hand. This check may be performed by the equipment operator, a production supervisor, a member of the quality control staff, a member of the maintenance or engineering staff, or any other person who has an understanding of the operation of the equipment or the staffing needs.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Who: Monitoring may be performed by the equipment operator, a production supervisor, a member of the quality control staff, a member of the maintenance or engineering staff, production personnel, or any other person who has a thorough understanding of the proper condition of the equipment and surrounding area. In assigning responsibility for this monitoring function you should consider the complexity of the equipment and the level of understanding necessary to evaluate its condition.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "glass inclusion" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

Continued

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy examples discussed in Step 12.

- CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION

Corrective Action: Take the following corrective actions to regain control over the operation after a CL deviation:

- Stop operations and attempt to locate and correct the source of the glass fragments;

AND

- Make adjustments to the materials, equipment, and/or process, as needed, to prevent future introduction of glass fragments;

AND

Take one of the following corrective actions to product in which glass fragments were detected:

- Destroy the product;

OR

- Rework the product to eliminate the glass fragments;

OR

- Divert the product to non-food use;

OR

- Hold and evaluate the product;

AND

Take one of the following corrective actions when product is processed without properly functioning glass detection or separation equipment or without proper visual inspection:

- Destroy all product produced since controls were last confirmed as functioning properly;

OR

- Hold all product produced since controls were last confirmed as functioning properly until it can be examined by x-ray equipment or other defect rejection system, or visual inspection, where appropriate;

OR

- Divert all product produced since controls were last confirmed as functioning properly to a non-food use;

AND

- Repair or replace the glass detection or separation equipment.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Corrective Action: Take one of the following corrective actions to regain control over the operation after a CL deviation:

- Stop production;

AND

- If necessary, adjust or modify the materials, equipment and/or processes to reduce the risk of recurrence;

AND

- Remove all broken glass from the equipment and surrounding area;

AND

Take one of the following actions to the product involved in the critical limit deviation:

- Destroy all product produced since the previous satisfactory equipment check;

OR

- Hold all product produced since the previous satisfactory equipment check until it can be examined by x-ray equipment or other defect rejection system, or visual inspection if appropriate;

OR

- Divert all product produced since the previous satisfactory equipment check to a non-food use.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "glass inclusion" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step 15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a recordkeeping system for the control strategy examples discussed in Step 12.

- CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION

Records: Records documenting that the glass detection or separation device is operating, or that glass inspection personnel are assigned to the processing step, as appropriate.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Records: Records of equipment and processing area inspection results.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "glass inclusion" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of glass inclusion; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy examples discussed in Step 12.

- CONTROL STRATEGY EXAMPLE 1 - GLASS DETECTION OR SEPARATION

Verification: Test the effectiveness of the x-ray equipment, other defect reject system or glass separation equipment at least once per day, before start of operations;
AND
Review monitoring, corrective action and verification records within one week of preparation.

- CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

Verification: Review monitoring and corrective action records within one week of preparation.

Enter the verification procedures in column 10 of the HACCP Plan Form.

TABLE #21-1

Control Strategy Example 1 - Glass Detection or Separation

This table is an example of a portion of a HACCP plan relating to the control of glass inclusion for a processor of pickled herring in glass jars, using Control Strategy Example 1 - Glass Detection or Separation. It is provided for illustrative purposes only. Glass inclusion may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, 3-3 (Chapter 3) for other potential hazards (e.g., parasites, histamine, chemical contaminants, unapproved food & color additives, metal fragments, *Clostridium botulinum* toxin formation, and pathogen growth as a result of temperature abuse).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
X-ray equipment	Glass inclusion	No detectable glass fragments in finished product	Presence of detectable glass fragments in finished products	X-ray device	Every finished product package, with operation check before startup	Production employee	• Destroy any product rejected by x-ray equipment AND • Stop operations and identify source of glass found in product and fix damaged equipment AND • If product is processed without x-ray equipment, hold for detection by off-line x-ray equipment	X-ray operation log	• Test x- ray device before production each day, and recalibrate if needed • Review monitoring, corrective action and verification records within one week of preparation.

TABLE #21-2

Control Strategy Example 2 - Equipment Checks

This table is an example of a portion of a HACCP plan relating to the control of glass inclusion for a processor of clam juice in glass jars, using Control Strategy Example 2 – Equipment checks. It is provided for illustrative purposes only. Glass inclusion may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g., pathogens from the harvest area, chemical contaminants, natural toxins, unapproved food & color additives, and metal fragments)

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Receiving	Glass inclusion	No broken glass on pallets of empty jars	Presence of broken glass or physical damage to cases	Visual	Each pallet of jars	Receiving personnel	• Reject pallets with more than 3 damaged cases or with broken jars. • Isolate pallets with 1 to 3 damaged cases and open and inspect all cases. • Reject cases that contain broken glass.	Receiving report	Review monitoring and corrective action records within one week of preparation.
Mechanical filling and capping	Glass Inclusion	No broken glass at the filler/capper station	Broken glass on & around filler/ capper station	Visual	Before start-up, every 4 hours during operation, after breaks, and after equipment jams.	Capper operator	• Stop production AND • Adjust capping equipment AND • Isolate and hold product since last satisfactory check until it can be run through off-line x-ray and destroy rejects AND • Remove broken glass from area.	Equipment maintenance log	Review monitoring and corrective action records within one week of preparation

Note: Storage and conveying of empty jars are not identified as CCPs because cases of empty jars are handled manually, without forklifts or mechanized conveyors

Notes:

Appendix 1: **Forms**

This appendix contains a blank model HACCP Plan Form and a blank model Hazard Analysis Worksheet.

Continued

HACCP Plan Form

Firm Name: _____

Firm Address: _____

_____

_____

_____

Product Description: _____

_____

Method of Storage and Distribution: _____

_____

Intended Use and Consumer: _____

_____

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	**Significant Hazard(s)**	**Critical Limits for each Preventive Measure**	**Monitoring**				**Corrective Action(s)**	**Records**	**Verification**
			What	**How**	**Frequency**	**Who**			

Signature of Company Official: _____ Date: _____

HACCP Plan Form

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action(s)	Records	Verification
			What	How	Frequency	Who			

Hazard-Analysis Worksheet

Firm Name: _____ Product Description: _____

Firm Address: _____ Method of Storage and Distribution: _____

Intended Use and Consumer: _____

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/processing step	**Identify potential hazards introduced, controlled or enhanced at this step(1)**	**Are any potential food-safety hazards significant? (Yes/No)**	**Justify your decisions for column 3.**	**What preventative measures can be applied to prevent the significant hazards?**	**Is this step a critical control point? (Yes/No)**
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				

Hazard-Analysis Worksheet

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/processing step	**Identify potential hazards introduced, controlled or enhanced at this step(1)**	**Are any potential food-safety hazards significant? (Yes/No)**	**Justify your decisions for column 3.**	**What preventative measures can be applied to prevent the significant hazards?**	**Is this step a critical control point? (Yes/No)**
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				

Notes:

Appendix 2: **Sample Product Flow Diagram**

This appendix contains a sample product flow diagram that can be used as a model when you develop your own flow diagram.

Continued

FIGURE #A-1

Sample Product Flow Diagram (Salmon Fillets)

Appendix 3: CCP Decision Tree

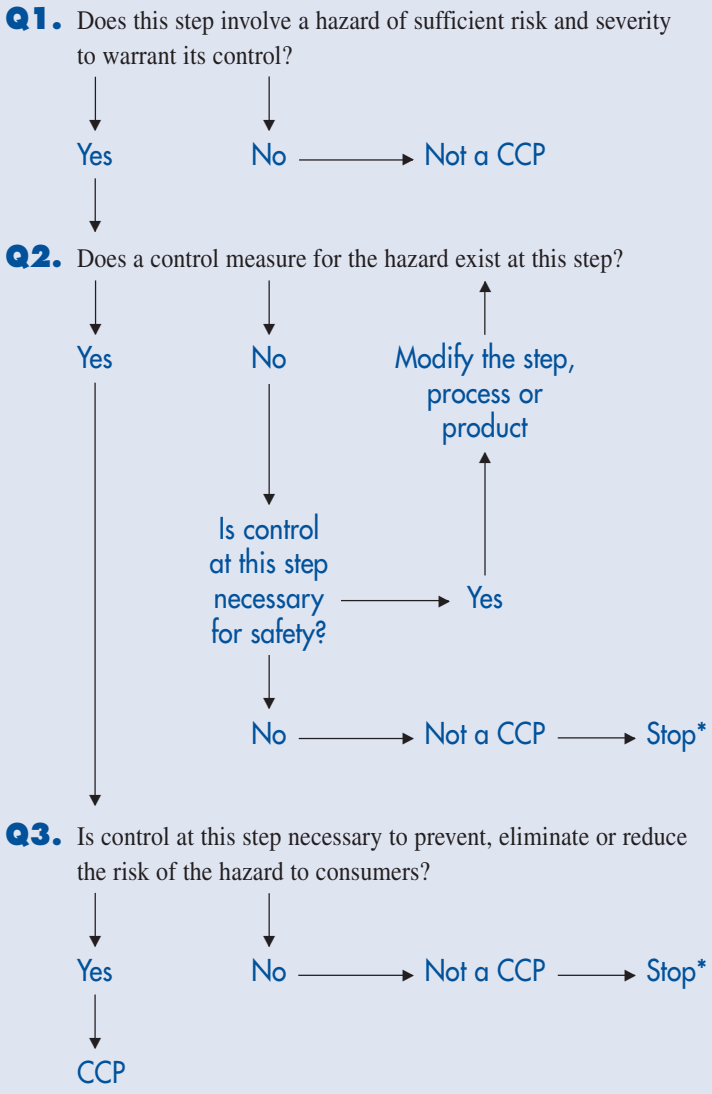
This appendix contains a decision tree that may be used to assist you in the identification of critical control points. You should not rely exclusively on the decision tree, as error may result.

The decision tree is derived from that developed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

Continued

FIGURE #A-2

CCP Decision Tree



** Proceed to the next step in process.*

Appendix 4: Bacterial Pathogen Growth and Inactivation

This appendix contains information on the growth and inactivation of bacterial pathogens.

Table #A-1 contains information on: the minimum water activity (a_W), acidity (pH), and temperature; the maximum, pH, water phase salt, and temperature; and oxygen requirements that will sustain growth for the bacterial pathogens that are of greatest concern in seafood processing. Data shown are the minimum or maximum values, the extreme limits reported among the references cited. These values may not apply to your processing conditions.

Table #A-2 contains information on maximum, cumulative time/internal temperature combinations for exposure of fish and fishery products that, under ordinary circumstances, will be safe for the bacterial pathogens that are of greatest concern in seafood processing. These maximum, cumulative exposure times are derived from published scientific information. Because the nature of bacterial growth is logarithmic, linear interpolation using the time/temperature guidance is not appropriate.

In summary, the table indicates that:

- If the product is held at internal temperatures above 70˚F (21˚C) during processing, exposure time should ordinarily be limited to two hours (three hours if *Staphylococcus aureus* is the only pathogen of concern);

- If the product is held at internal temperatures above 50˚F (10˚C), but not above 70˚F (21˚C), exposure time should ordinarily be limited to six hours (twelve hours if *Staphylococcus aureus* is the only pathogen of concern);

- If the product is held at internal temperatures both above and below 70˚F (21.1˚C), exposure times above 50˚F (10˚C) should ordinarily be limited to 4 hours, as long as no more than 2 of those hours are above 70˚F (21.1˚C).

It is not possible to furnish recommendations for each pathogen, process, type of seafood, and temperature or combination of temperatures. Programmable models to predict growth rates for certain pathogens associated with various foods under differing conditions have been developed by the U.S. Department of Agriculture ("Pathogen Modeling Program" [PMP]) and the United Kingdom ("Food MicroModel" [FMM]). These programs can provide growth curves for selected pathogens. You indicate the conditions, such as pH, temperature, and salt concentration that you are interested in and the models provide pathogen growth predictions (e.g., growth curve, time of doubling, time of lag phase, generation time). FDA does not endorse or require the use of such modelling programs, but recognizes that the predictive growth information they provide may be of assistance to some processors. However, you are cautioned that significant deviations between actual microbiological data in specific products and the predictions do occur, including those for the lag phase of growth. Therefore, you should validate the time-temperature limits derived from such predictive models.

Table #A-3 contains information on the destruction of *Listeria monocytogenes*. Lethal rate, as used in this table, is the relative lethality of one minute at the designated internal product temperature as compared to the lethality of one minute at the reference internal product temperature of 158˚F (70˚C) (i.e. z = 13.5˚F [7.5˚C]). For example, one minute at 145˚F (63˚C) is 0.117 times as lethal as one minute at 158˚F (70˚C). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *L. monocytogenes.* The length of time at a particular internal product temperature needed to accomplish a six logarithm reduction in the number of *L. monocytogenes* (6D) is, in part, dependent upon the food in which it is being heated. The values in the table are generally conservative and apply to all foods. You may be able to establish a shorter process time for your food by

Continued

conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in your food if supported by a scientific study of the normal innoculum in the food.

Table #A-4 contains information on the destruction of *Clostridium botulinum* type B (the most heat resistant form of nonproteolytic *Clostridium botulinum*). Lethal rate, as used in this table, is the relative lethality of one minute at the designated internal product temperature as compared to the lethality of one minute at the reference product internal temperature of 194˚F (90˚C) (i.e. for temperatures less than 194˚F [90˚C] z = 12.6˚F [7.0˚C]; for temperatures above 194˚F [90˚C] z = 18˚F [10˚C];). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *C. botulinum.* The values in the table are generally conservative. However, they may not be sufficient for the destruction of nonproteolytic *C. botulinum* in dungeness crabmeat, because of the potential protective effect of lysozyme. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in your food if supported by a scientific study of the normal innoculum in the food.

Table #A-1

Limiting Conditions for Pathogen Growth

Pathogen	*min. a_w (using salt)*	*min. pH*	*max. pH*	*max.% water phase salt*	*min. temp.*	*max. temp.*	*oxygen requirement*
Bacillus cereus	.92	4.3	9.3	10	39.2˚F 4˚C	131˚F**** 55˚C	aerobe
Campylobacter jejuni	.987	4.9	9.5	1.5	86˚F 30˚C	113˚F 45˚C	micro- aerophilic*
Clostridium botulinum, type A, and proteolytic B and F	.935	4.6	9	10	50˚F 10˚C	118.4˚F 48˚C	anaerobe**
Clostridium botulinum, type E, and nonproteolytic B and F	.97	5	9	5	37.9˚F 3.3˚C	113˚F 45˚C	anaerobe**
Clostridium perfringens	.93	5	9	7	50˚F 10˚C	125.6˚F 52˚C	anaerobe**
pathogenic strains of *Escherichia coli*	.95	4	9	6.5	43.7˚F 6.5˚C	120.9˚F 49.4˚C	facultative anaerobe***
Listeria monocytogenes	.92	4.4	9.4	10	31.3˚F -0.4˚C	113˚F 45˚C	facultative anaerobe***
Salmonella spp.	.94	3.7	9.5	8	41.4˚F 5.2˚C	115.2˚F 46.2˚C	facultative anaerobe***
Shigella spp.	.96	4.8	9.3	5.2	43˚F 6.1˚C	116.8˚F 47.1˚C	facultative anaerobe***
Staphylococcus aureus – growth	.83	4	10	20	44.6˚F 7˚C	122˚F 50˚C	facultative anaerobe***
Staphylococcus aureus – toxin	.85	4	9.8	10	50˚F 10˚C	118˚F 48˚C	
Vibrio cholerae	.97	5	10	6	50˚F 10˚C	109.4˚F 43˚C	facultative anaerobe***
Vibrio parahaemolyticus	.94	4.8	11	10	41˚F 5˚C	113.5˚F 45.3˚C	facultative anaerobe***
Vibrio vulnificus	.96	5	10	5	46.4˚F 8˚C	109.4˚F 43˚C	facultative anaerobe***
Yersinia enterocolitica	.945	4.2	10	7	29.7˚F -1.3˚C	107.6˚F 42˚C	facultative anaerobe***

* requires limited levels of oxygen ** requires the absence of oxygen *** grows either with or without oxygen **** growth significantly delayed (>24 hr.) at 131˚F (55˚C)

Table #A-2

Time/Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Seafoods

Potentially Hazardous Condition	*Product Temperature*	*Maximum Cumulative Exposure Time*
Growth and toxin formation by ***Bacillus cereus***	39.2-43˚F (4-6˚C) 44-50˚F (7-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	5 days 17 hours* 6 hours* 3 hours
Growth of ***Campylobacter jejuni***	86-93˚F (30-34˚C) Above 93˚F (above 34˚C)	48 hours 12 hours
Germination, growth, and toxin formation by ***Clostridium botulinum*** type A, and proteolytic B and F	50-70˚F (10-21˚C) Above 70˚F (above 21˚C)	11 hours 2 hours
Germination, growth, and toxin formation by ***Clostridium botulinum*** type E, and nonproteolytic B and F	37.9-41˚F (3.3-5˚C) 42-50˚F (6-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	7 days > 2 days 11 hours 6 hours
Growth of ***Clostridium perfringens***	50-54˚F (10-12˚C) 55-57˚F (13-14˚C) 58-70˚F (15-21˚C) Above 70˚F (above 21˚C)	21 days 1 day 6 hours* 2 hours*
Growth of pathogenic strains of ***Escherichia coli***	44.6-50˚F (7-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	14 days 6 hours 3 hours
Growth of ***Listeria monocytogenes***	31.3-41˚F (-0.4-5˚C) 42-50˚F (6-10˚C) 51-70˚F (11-2˚C) Above 70˚F (above 21˚C)	7 days 2 days 12 hours* 3 hours*
Growth of ***Salmonella*** species	41.4-50˚F (5.2-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	14 days 6 hours 3 hours
Growth of ***Shigella*** species	43-50˚˚F (6.1-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	14 days* 12 hours* 3 hours*
Growth and toxin formation by ***Staphylococcus aureus***	44.6-50˚F (7-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	14 days 12 hours* 3 hours
Growth of ***Vibrio cholerae***	50˚F (10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	21 days 6 hours* 2 hours*
Growth of ***Vibrio parahaemolyticus***	41-50˚F (5-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	21 days 6 hours* 2 hours*
Growth of ***Vibrio vulnificus***	46.4-50˚F (8-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	21 days 6 hours 2 hours
Growth of ***Yersinia enterocolitica***	29.7-50˚F (-1.3-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	1 days 6 hours 2.5 hours

* Additional data needed.

Table #A-3

Inactivation of *Listeria monocytogenes*

Internal Product Temperature (˚F)	*Internal Product Temperature (˚C)*	*Lethal Rate*	*Time for 6D Process (minutes)*
145	63	0.117	17.0
147	64	0.158	12.7
149	65	0.215	9.3
151	66	0.293	6.8
153	67	0.398	5.0
154	68	0.541	3.7
156	69	0.736	2.7
158	70	1.000	2.0
160	71	1.359	1.5
162	72	1.848	1.0
163	73	2.512	0.8
165	74	3.415	0.6
167	75	4.642	0.4
169	76	6.310	0.3
171	77	8.577	0.2
172	78	11.659	0.2
174	79	15.849	0.1
176	80	21.544	0.09
178	81	29.286	0.07
180	82	39.810	0.05
182	83	54.116	0.03
183	84	73.564	0.03
185	85	100.000	0.02

Note: z = 13.5˚F (7.5˚C)

Table #A-4

Inactivation of nonproteolytic *Clostridinum botulinum* type B

Internal Product Temperature (˚F)	*Internal Product Temperature (˚C)*	*Lethal Rate**	*Time for 6D Process (minutes)*
185	85	0.193	51.8
187	86	0.270	37.0
189	87	0.370	27.0
190	88	0.520	19.2
192	89	0.720	13.9
194	90	1.000	10.0
196	91	1.260	7.9
198	92	1.600	6.3
199	93	2.000	5.0
201	94	2.510	4.0
203	95	3.160	3.2
205	96	3.980	2.5
207	97	5.010	2.0
208	98	6.310	1.6
210	99	7.940	1.3
212	100	10.000	1.0

Note: for temperatures less than 194˚F [90˚C] z = 12.6˚F [7.0˚C]; for temperatures above 194˚F [90˚C] z = 18˚F [10˚C].

*Note: these lethal rates and process times may not be sufficient for the destruction of nonproteolytic *C. botulinum* in dungeness crabmeat, because of the potential that substances that may be naturally present, such as lysozyme, may enable the pathogen to more easily recover from heat damage.

Notes:

Appendix 5: **FDA & EPA Safety Levels in Regulations and Guidance**

This appendix contains a listing of FDA and EPA levels relating to safety attributes of fish and fishery products published in regulations and guidance. In many cases, these levels represent the point at or above which the agency will take legal action to remove products from the market. Consequently, the levels contained in this table may not always be suitable for critical limits.

Continued

Table #A-5

FDA & EPA Safety Levels in Regulations and Guidance

Product	*Level*	*Reference*
Ready to eat fishery products (minimal cooking by consumer)	Enterotoxigenic *Escherichia coli* (ETEC) - 1 x 10^3 ETEC/g, LT or ST positive.	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Listeria monocytogenes* - presence of organism.	Compliance Program 7303.842
All fish	*Salmonella* species- presence of organism.	Sec 555.300 Compliance Policy Guide
All fish	*Staphylococcus aureus* - 1. positive for staphylococcal enterotoxin, or 2. *Staphylococcus aureus* level is equal to or greater than 10^4/g (MPN).	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Vibrio cholerae* - presence of toxigenic 01 or non-01.	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Vibrio parahaemolyticus* - levels equal to or greater than 1 x 10^4/g (Kanagawa positive or negative).	Compliance Program 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Vibrio vulnificus* - presence of pathogenic organism.	Compliance Program 7303.842
All fish	*Clostridium botulinum* - 1. Presence of viable spores or vegetative cells in products that will support their growth; or 2. Presence of toxin.	Compliance Program 7303.842
Clams and oysters, and mussels fresh or frozen - imports	Microbiological - 1. *E. coli* - MPN of 230/100 grams (average of subs or 3 or more of 5 subs); or 2. APC - 500,000/gram (average of subs or 3 or more of 5 subs).	Sec 560.600 Compliance Policy Guide
Clams, oysters, and mussels, fresh or frozen - domestic	Microbiological - 1. *E. coli* or fecal coliform - 1 or more of 5 subs exceeding MPN of 330/100 grams or 2 or more exceeding 230/100 grams; or 2. APC - 1 or more of 5 subs exceeding 1,500,000/gram or 2 or more exceeding 500,000/gram.	Compliance Program 7303.842
Salt-cured, air-dried unеviscerated fish	Not permitted in commerce (Note: small fish exemption).	Sec 540.650 Compliance Policy Guide
Tuna, mahi mahi, and related fish	Histamine - 500 ppm based on toxicity. 50 ppm defect action level, because histamine is generally not uniformly distributed in a decomposed fish. Therefore, if 50 ppm is found in one section, there is the possibility that other units may exceed 500 ppm.	Sec 540.525 Compliance Policy Guide

Note: the term "fish" refers to fresh or saltwater fin fish, crustaceans, other forms of aquatic animal life other than birds or mammals, and all mollusks, as defined in 21 CFR 123.3(d).

Product	*Level*	*Reference*
All fish	Polychlorinated Biphenyls (PCBs) - 2.0 ppm (edible portion)*.	21 CFR 109.30
Fin fish and shellfish	Aldrin and dieldrin - 0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
Frog legs	Benzene Hexachloride - 0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Chlordane - 0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Chlordecone - 0.4 ppm in crabmeat and 0.3 ppm in other fish (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	DDT, TDE and DDE - 5.0 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Heptachlor and heptachlor epoxide - 0.3 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Mirex - 0.1 ppm (edible portion).	Sec 575.100 Compliance Policy Guide
All fish	Diquat - 0.1 ppm*.	40 CFR 180.226
Fin fish and crayfish	Fluridone - 0.5 ppm*.	40 CFR 180.420
Fin fish	Glyphosate - 0.25 ppm*.	40 CFR 180.364
Shellfish	Glyphosate - 3.0 ppm*.	40 CFR 180.364
Fin fish	Simazine - 12 ppm*.	40 CFR 180.213a
All fish	2,4-D - 1.0 ppm*.	40 CFR 180.142
Salmonids, catfish and lobster	Oxytetracycline - 2.0 ppm	21 CFR 556.500
All fish	Sulfamerazine - no residue permitted.	21 CFR 556.660
Salmonids and catfish	Sulfadimethoxine/ormetoprim combination - 0.1 ppm.	21 CFR 556.640
All fish	Unsanctioned drugs** – no residue permitted	Sec 615.200 Compliance Policy Guide
Crustacea	Toxic elements: 76 ppm arsenic; 3 ppm cadmium; 12 ppm chromium; 1.5 ppm lead; 70 ppm nickel.	FDA Guidance Document

* These values are tolerances.
** Sanctioned drugs are approved drugs and drugs used under an INAD. See Chapter 11 for additional information.
Note: the term "fish" refers to fresh or saltwater fin fish, crustaceans, other forms of aquatic animal life other than birds or mammals, and all mollusks, as defined in 21 CFR 123.3(d).

Product	*Level*	*Reference*
Clams, oysters, and mussels	Toxic elements: 86 ppm arsenic; 4 ppm cadmium; 13 ppm chromium; 1.7 ppm lead; 80 ppm nickel.	FDA Guidance Documents
All fish	Methyl mercury – 1.0 ppm***	Sec 540.600 Compliance Policy Guide
All fish	Paralytic shellfish poison - 0.8 ppm (80ug/100g) saxitoxin equivalent.	Sec 540.250 Compliance Policy Guide, and Compliance Program 7303.842
Clams, mussels and oysters, fresh, frozen or canned	Neurotoxic shellfish poison - 0.8 ppm (20 mouse units/ 100 gram) brevetoxin-2 equivalent.	National Shellfish Sanitation Program Manual of Operations
All fish	Amnesic shellfish poison - 20 ppm domoic acid, except in the viscera of dungeness crab, where 30 ppm is permitted.	Compliance Program 7303.842
All fish	Hard or sharp foreign object - generally 0.3 [7mm] to 1.0 [25mm] in length	Sec 555.425 Compliance Policy Guide

*** See Chapter 10 for additional information

Note: the term “fish” refers to fresh or saltwater fin fish, crustaceans, other forms of aquatic animal life other than birds or mammals, and all mollusks, as defined in 21 CFR 123.3(d).

Appendix 6: **Food Allergens**

Following is a listing, for which there is general scientific consensus, of the most common food allergens that can pose a health risk to certain sensitive individuals (Sec. 555.250 Compliance Policy Guide):

- Allergens
  Peanuts
  Soybeans
  Milk
  Eggs
  Fish
  Crustacea
  Tree nuts
  Wheat

Notes:

Appendix 7: **Bibliography**

The general reference section contains citations that are applicable to this guidance in general. Of particular interest is the reference for the *Federal Register* of December 18, 1995, which itself lists over 200 citations. References listed for each chapter specifically pertain to the information contained in that chapter.

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U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition

FISH AND FISHERIES PRODUCTS HAZARDS AND CONTROLS GUIDANCE:

Third Edition June 2001

APPENDIX 8

Seafood HACCP Regulation

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Title 21 of the Code of Federal Regulations Part 123 – Fish & Fishery Products

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Authority: Secs. 201, 402, 403, 406, 409, 701, 704, 721, 801, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393); secs. 301, 307, 361 of the Public Health Service Act (42 U.S.C. 241, 242l, 264).

- **Subpart A – General Provisions**
  - ***Sec. 123.3 Definition***

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

a. Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

b. Critical control point means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.

c. Critical limit means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

d. Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

e. Fishery product means any human food product in which fish is a characterizing ingredient.

f. Food safety hazard means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

g. Importer means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

h. Molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

i. Preventive measure means physical, chemical, or other factors that can be used to control an identified food safety hazard.

j. Process-monitoring instrument means an instrument or device used to indicate conditions during processing at a critical control point.

k. (1) Processing means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

(2) The regulations in this part do not apply to:

- (i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
- (ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.
- (iii) The operation of a retail establishment.

l. Processor means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processor includes any person engaged in the production of foods that are to be used in market or consumer tests.

m. Scombroid toxin-forming species means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

n. Shall is used to state mandatory requirements.

o. Shellfish control authority means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

p. Shellstock means raw, in-shell molluscan shellfish.

q. Should is used to state recommended or advisory procedures or to identify recommended equipment.

r. Shucked shellfish means molluscan shellfish that have one or both shells removed.

s. Smoked or smoke-flavored fishery products means the finished food prepared by:

(1) Treating fish with salt (sodium chloride), and

(2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

t. Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

- ***Sec. 123.5 Current good manufacturing practice***

a. Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

b. The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

- ***Sec. 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan***

a. Hazard analysis. Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

b. The HACCP Plan. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and per formed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

c. The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

- (i) Natural toxins;
- (ii) Microbiological contamination;

- (iii) Chemical contamination;
- (iv) Pesticides;
- (v) Drug residues;
- (vi) Decomposition in scombroid toxin- forming species or in any other species where a food safety hazard has been associated with decomposition;
- (vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;
- (viii) Unapproved use of direct or indirect food or color additives; and
- (ix) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

- (i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and
- (ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;

(3) List the critical limits that must be met at each of the critical control points:

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with Sec. 123.7(b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with Sec. 123.8(a);

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

d. Signing and dating the HACCP plan.

(1) The HACCP plan shall be signed and dated, either by the most responsible individual on-site at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:

- (i) Upon initial acceptance;

- (ii) Upon any modification; and
- (iii) Upon verification of the plan in accordance with Sec. 123.8(a)(1).

e. Products subject to other regulations. For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

f. Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Sec. 123.11(b) they need not be included in the HACCP plan, and vice versa.

g. Legal basis. Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processor's overall implementation of its HACCP plan, if one is required.

❍ *Sec. 123.7 Corrective actions*

a. Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

b. Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with Sec. 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

c. When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Sec. 123.10;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Sec. 123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

d. All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Sec. 123.8(a)(3)(ii) and the recordkeeping requirements of Sec. 123.9.

- ***Sec. 123.8 Verification***

a. Overall verification. Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1) *Reassessment of the HACCP plan.* A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Sec. 123.6(c).

(2) *Ongoing verification activities.* Ongoing verification activities including:

- (i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;
- (ii) The calibration of process-monitoring instruments; and,
- (iii) At the option of the processor, the performing of periodic end-product or in-process testing.

(3) *Records review.* A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, of the records that document:

- (i) *The monitoring of critical control points.* The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;
- (ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and
- (iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end- product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

b. Corrective actions. Processors shall immediately follow the procedures in Sec. 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

c. Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10.

d. Recordkeeping. The calibration of process- monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of Sec. 123.9.

❍ *Sec. 123.9 Records*

a. General requirements. All records required by this part shall include:

(1) The name and location of the processor or importer;

(2) The date and time of the activity that the record reflects;

(3) The signature or initials of the person performing the operation; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

b. Record retention.

(1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

c. Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

d. Public disclosure.

(1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in Sec. 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in Sec. 20.61 of this chapter.

(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

e. Tags. Tags as defined in Sec. 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of Sec. 123.28(c).

f. Records maintained on computers. The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

- ***Sec. 123.10 Training***

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

a. Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 123.6(b);

b. Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and

c. Performing the record review required by Sec. 123.8(a)(3);

The trained individual need not be an employee of the processor.

- ***Sec. 123.11 Sanitation control procedures***

a. Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

b. Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing

agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

The processor shall correct in a timely manner, those conditions and practices that are not met.

c. Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of Sec. 123.9.

d. Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by Sec. 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

- ***Sec. 123.12 Special requirements for imported products***

This section sets forth specific requirements for imported fish and fishery products.

a. Importer verification. Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

- (i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,
- (ii) Affirmative steps that may include any of the following:
  - A. Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

- B. Obtaining either a continuing or lot- by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;
- C. Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;
- D. Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part;
- E. Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,
- F. Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

b. Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

c. Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of Sec. 123.9.

d. Determination of compliance. There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

- **Subpart B – Smoked & Smoke-Flavored Fishery Products**
  - ***Sec. 123.15 General***

    This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

  - ***Sec. 123.16 Process controls***

    In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114

of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

- **Subpart C – Raw Molluscan Shellfish**
  - ***Sec. 123.20 General***

    This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

  - ***Sec. 123.28 Source controls***

    a. In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

    b. Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.

    c. To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in Sec. 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in Sec. 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

    (1) The date of harvest;

    (2) The location of harvest by State and site;

    (3) The quantity and type of shellfish;

    (4) The date of receipt by the processor; and

    (5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

d. To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with Sec. 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

(1) The date of receipt;

(2) The quantity and type of shellfish; and

(3) The name and certification number of the packer or repacker of the product.

Part 1240 – Control of Communicable Diseases

2. The authority citation for 21 CFR part 1240 continues to read as follows:

Authority: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

3. Section 1240.3 is amended by revising paragraph (r), and by adding new paragraphs (s), (t), and (u) to read as follows:

- ***Sec. 1240.3 General Definitions***

r. Molluscan shellfish. Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

s. Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

t. Shellfish control authority means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

u. Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

4. Section 1240.60 is amended by revising the section heading, by redesignating the existing text as paragraph (a) and adding the word "molluscan" before the word "shellfish" the two times that it appears, and by adding new paragraphs (b), (c), and (d) to read as follows:

- ***Sec. 1240.60 Molluscan Shellfish***

b. the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (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). In place of the tag, bulk shellstock shipments may be accompanied by a bill of

lading or similar shipping document that contains the same information.

c. All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.

d. Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

See also:

FDA Seafood List

Foodborne Pathogenic Microorganisms and Natural Toxins Handbook (Bad Bug Book)

Seafood Information and Resources

Seafood HACCP | Fish & Fisheries Products Hazards & Controls Guidance: *3rd Edition* (2001)

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