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Fish and Fishery Products Hazards and Controls Guidance

Fourth Edition – June 2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
OFFICE OF FOOD SAFETY

Fish and Fishery Products Hazards and Controls Guidance

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TABLE OF CONTENTS: **FISH AND FISHERY PRODUCTS HAZARDS AND CONTROLS GUIDANCE** - FOURTH EDITION - June 2021

GUIDANCE FOR THE INDUSTRY: **FISH AND FISHERY PRODUCTS HAZARDS AND CONTROLS GUIDANCE** FOURTH EDITION - JUNE 2021

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

I. INTRODUCTION

This guidance is intended to assist processors of fish and fishery products in the development of their Hazard Analysis Critical Control Point (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. The guidance will help consumers and the public generally to understand commercial seafood safety in terms of hazards and their controls. The 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.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

This guidance has been prepared by the Division of Seafood Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

II. DISCUSSION

A. Scope and Limitations

The control strategies and practices provided in this guidance are recommendations to the fish and fishery products industry unless they are required by regulation or statute. This guidance provides information that would likely result in a HACCP plan that is acceptable to FDA. Processors may choose to use other control strategies, as long as they comply with the requirements of the applicable food safety laws and regulations. However, processors that chose to use other control strategies (e.g., critical limits) should scientifically establish their adequacy.

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

The 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).

FDA announced its adoption of final regulations to ensure the safe and sanitary processing of fish and fishery products in the *Federal Register* of December 18, 1995 (60 FR 65096) (hereinafter referred to as the Seafood HACCP Regulation). This guidance, the Seafood HACCP Regulation (21 CFR 123), and the Control of Communicable Diseases regulation (21 CFR 1240) apply to all aquatic animal life, other than birds and mammals, used as food for human consumption. For example, in addition to fresh and saltwater finfish and crustaceans, this guidance applies to echinoderms such as sea cucumbers and sea urchins; reptiles such as alligators and turtles; amphibians such as frogs; and to all mollusks, including land snails (escargot). It also applies to extracts and derivatives of fish, such as eggs (roe), oil, cartilage, and fish protein concentrate. In addition, this guidance applies to products that are mixtures of fish and non-fish ingredients, such as tuna sandwiches and soups. Appendix 8, § 123.3, lists the definitions for "fish" and "fishery product" used in the Seafood HACCP Regulation.

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 (§ 123.6). Processors may use the principles included in this guidance for assistance in developing appropriate controls for these hazards.

This guidance does not cover the hazard associated with the formation of *Clostridium botulinum* (*C. botulinum*) toxin in low-acid canned foods (LACFs) or shelf-stable acidified foods. Mandatory controls for this hazard are contained in the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation (hereinafter referred to as the LACF Regulation, 21 CFR 113) and the Acidified Foods regulation (21 CFR 114). Such controls may be, but are not required to be, included in HACCP plans for these products.

This guidance does not cover all sanitation controls required by the Seafood HACCP Regulation. The maintenance of a sanitation monitoring program is an essential prerequisite to the development of a HACCP program. When sanitation controls are necessary for food safety, but are not included in a sanitation monitoring program, they must be included in the HACCP plan (21 CFR 123.6). However, this guidance document does contain recommendations only for allergen cleaning and sanitation, and allergen cross-contact through two new appendixes since normal cleaning and sanitation does not necessarily address allergen residues.

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, as required in § 123.7 and § 123.8. Additionally, this guidance does not restate the general requirements for records that are set out in § 123.9(a).

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

This 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 ("FDA and EPA Safety Levels in Regulations and Guidance"), should prove useful for this purpose.

B. Chapter Modifications

The following is a summary of the most significant changes made to this guidance. Moving forward, FDA will publish this guidance as a living document on the FDA Seafood website (www.fda.gov/seafood). Until all the chapters and/or appendixes have been updated this guidance will continue to be identified as the fourth edition with the date being modified to reflect the most recent changes. Each chapter or appendix will also reference the date (month and year) the most recent changes were made and published. Chapters and appendixes that have not been modified will reflect the original publication date of April 2011. Additionally, the "Guidance for Industry" section will identify the specific changes in the header with the date of publication. You should carefully review the chapters applicable to your product and process in addition to using this summarized list of significant changes.

The following changes have been made throughout this guidance document:

Chapter 1: "General Information" has been modified with the following recommendations as of April 2011:

Chapter 2: "Conducting a Hazard Analysis and Developing a HACCP plan" has been modified with the following recommendations as of April 2011:

Chapter 3: "Potential Species-Related and Process-Related Hazards" Introduction has been modified with the following recommendations as of June 2021:

- The following notes were added:
    - For endangered and threatened species: refer to NOAA and the U.S. Fish and Wildlife Services to identify endangered and threatened species with hyperlinks;
    - Identifying "The Seafood List" as the reference to consult for naming of seafood species;
    - Identifying that the tables in Chapter 3 should be used in conjunction with Chapters 4 – 21 in the development of a HACCP plan.

Chapter 3, Table 3-2: "Potential Vertebrate Species-Related Hazards" has been modified with the following recommendations as of June 2021:

- Crocodile – The following changes have been made:
    - Wild and aquacultured species have been identified;
    - Associated hazards have been added.
- Oreo Dory – *Allocyttus* spp., *Neocyuttus* spp., *Oreosoma* spp. and *Pseudocyttus* spp. have been added with the hazard of GFP.
- Roughy, Orange – *Hoplostethus atlanticus* has been added with the hazard of GFP.
- Scad (*Selar crumenophthalmus*) – The following change has been made:
    - Scombrotoxin (histamine) hazard has been added.

Chapter 3, Table 3-3: "Potential Invertebrate Species-Related Hazards" has been modified with the following recommendations as of June 2021:

- Barnacles, Gooseneck (*Pollicipes polymerus*) – Has been added with the hazards of natural toxins and environmental chemicals.
- Sea Cucumber – The following changes have been made:
    - Aquacultured species have been identified with the hazards of environmental chemicals and aquaculture drugs;
    - *Stichopus japonicus* is synonymous with *Apostichopus japonicus* and has been removed.
- Seabob (*Xiphopenaeus kroyeri*)– Shrimp has been added as a market name.
- Shrimp – The following changes have been made:
    - *Acetes japonicus* has been added with the hazard of environmental chemical.
- Snail or Escargot – The following changes have been made:
    - *Cornu aspersa*, *Elona quimperiana*, *Helix lucorum*, and *Pila polita* have been added with the hazards of parasites and environmental chemicals.
- Squid or Calamari – Nomenclature change from *Loligo opalescens* to *Doryteuthis opalescens*.

Chapter 3, Table 3-4: "Potential Process-Related Hazards" has been modified with the following recommendations as of August 2019:

- Footnote 2 has been removed.
- Footnotes 3, 4, 5, 6, and 7 have been renumbered as a result of footnote 2 being removed.
- Header – Allergens and Food Intolerance Substances – Chapter 19 – The following changes have been made:
    - Chapter title updated to remove "Prohibited Food and Color Additives;"
    - Footnote 5 has been added to the header.

- Smoked Fish (Other than ROP) – New listing for Chap 16 with Footnote 6 has been added.
- Dried Fish (All) - Footnote 7 for Chapter 13 has been added.
- Battered or Breaded Finished Product Food – The following changes have been made:
    - "Package Type" has been divided into two types;
    - New listing for Chapter 13 for the ROP Package Type has been added.
- Raw oysters, clams, and mussels (ROP) – The following changes have been made:
    - "Hot Fill" and "Steam Flush" has been removed from the Package Type description;
    - The hazard of undeclared allergen has been removed.
- Raw oysters, clams, and mussels (other than ROP) – The following changes have been made:
    - "Hot Fill" and "Steam Flush" has been removed from the Package Type description;
    - The hazard of undeclared allergen has been removed.
- Footnotes – Footnotes 5, and 6 have been added.

Chapter 4: "Pathogens from the Harvest Area" has been modified with the following recommendations as of April 2011:

- Hydrostatic pressure, individual quick freezing (IQF) with extended storage, and irradiation are now identified as processes that are designed to retain raw product characteristics and that can be used to reduce *Vibrio vulnificus* (*V. vulnificus*) and *Vibrio parahaemolyticus* (*V. parahaemolyticus*) to non-detectable levels;
- It is now recognized that a tag on a container of shellstock (in-shell molluscan shellfish) received from another dealer need not identify the harvester;
- Critical limits relating to control of pathogen growth prior to receipt of raw molluscan shellfish by the primary processor are now linked to monitoring the time that the shellfish are exposed to air (i.e., by harvest or receding tide) rather than to the time that the shellfish are harvested;
- Reference is now made to the role of the Federal, state, tribal, territorial and foreign government shellfish control authorities in determining whether the hazard of *V. parahaemolyticus* is reasonably likely to occur in raw molluscan shellfish and in the development of a *V. parahaemolyticus* control plan that will dictate, at least to some extent, the nature of the controls for this pathogen in HACCP plans;
- The control strategy examples are restructured for improved clarity: one for source controls (e.g., tagging, labeling, source waters, harvester licensure, and raw consumption advisory) and a second for time from harvest to refrigeration controls.

Chapter 5: "Parasites" has been modified with the following recommendations as of April 2011:

- It is now recognized that the parasite hazard may be reasonably likely to occur in fish raised in freshwater containing larvae of pathogenic liver, lung and intestinal flukes because these parasites enter the fish through the skin rather than in the food.

Chapter 6: "Natural Toxins" has been modified with the following recommendations as of August 2019:

- The information in the Chapter has been reorganized into two categories in each section.
    - "Fish other than molluscan shellfish" and
    - "Molluscan Shellfish."
- Natural Toxin Detection Section was removed. This information is utilized to confirm illnesses/ outbreaks, inform advisories for at risk harvest areas, and/or make a determination for harvest area closures. This information was never intended for a processor to include in the HACCP plan as a control measure. The information has been relocated to Appendix 5.
- Ciguatera Fish Poisoning (CFP) – The following changes have been made:

- Additional locations were included based on scientific discovery of the toxin;
- Areas included are Florida, Hawaii, and Puerto Rico;
- Addition of finfish to contain CFP – lionfish, mackerel and tang;
- Finfish previously listed in Chapter 3 are now included in Chapter 6.

- Tetrodotoxin – Symptomology development has been updated to align with the *Bad Bug Book*.
- Natural Toxins addition – The following changes have been made:
  - Clupeotoxin has been added as a natural toxin with associated information;
  - Ichthyohemotoxin has been added as a natural toxin with associated information;
  - Seafood-associated rhabdomyolysis (sometimes referred to as Haff disease) has been added as a natural toxin with associated information.
- A "Note" was added to the chapter regarding venomous fish. This was to correspond to the *Bad Bug Book's* new chapter to address the potential concern and FDA's thoughts.
- Amnesic shellfish poisoning (ASP) – Additional species of lobster, sardine, white mullet, menhaden, and predatory species, such as Florida pompano, Gulf Kingfish and spot, were included.
- Diarrhetic shellfish poisoning (DSP) – Addition locations for the toxin were included such as Puget Sound and the west coast of Canada, Texas, Washington State, Alabama, Maryland, Massachusetts, and New York.
- Paralytic shellfish poisoning (PSP) – The following additions were made:
  - Molluscan shellfish examples of clams, cockles, mussels, oysters, and scallops;
  - Information regarding retention of the toxin and depuration;
  - Expanded the information regarding gastropod accumulation of the toxin;
  - Addition of finfish species where the toxin has been found in the viscera such as mackerel, Dungeness crab, tanner crab and red rock crab.
- Natural Toxin Control Section – The following changes have been made: in the Natural Toxin Control Section:
  - ASP and PSP in fish other than molluscan shellfish – An example was added of the adductor muscle from the scallop to eliminate the toxin;
  - Molluscan Shellfish – The statement: "States must have a Biotoxin Contingency Plan" was added.
- Control Strategy Example 1 – Source control for fish other than molluscan shellfish – The following changes have been made:
  - Critical Limit – "ASP for consumption advisory" was added;
  - Establish Verification procedures – "Periodic verification of harvest locations" was added.
- Control Strategy Example 2 – Harvest Area for Molluscan Shellfish – The following changes have been made:
  - Critical Limit –
    - Update made to align with the NSSP and regulations for shellfish and HACCP, and
    - A note was added regarding dockside screening to align with NSSP;

- Monitoring Procedures –
  - Update made to include information that would be required for monitoring as identified through the regulation and NSSP;

- Bibliography was updated to reflect the additions throughout the chapter.

Chapter 7: "Scombrotoxin (Histamine) Formation" has been modified with the following recommendations as of April 2011:

- Information is now provided about the potential for scombrotoxin (histamine) formation in products like tuna salad that have been allowed to become recontaminated and then subjected to time and temperature abuse;

- The recommendations regarding on-board chilling of scombrotoxin-forming species of fish are now listed as follows:
  - Fish exposed to air or water temperatures above 83°F (28.3°C) should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible during harvest, but not more than 6 hours from the time of death, or
  - Fish exposed to air and water temperatures of 83°F (28.3°C) or less should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible during harvest, but not more than 9 hours from the time of death, or
  - Fish that are gilled and gutted before chilling should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible during harvest, but not more than 12 hours from the time of death, or
  - Fish that are harvested under conditions that expose dead fish to harvest waters of 65°F (18.3°C) or less for 24 hours or less should be placed in ice, refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than the time limits listed above, with the time period starting when the fish leave the 65°F (18.3°C) or less environment;

- Cautions are now provided that handling practices and processing controls that are recommended as suitable for preventing the formation of scombrotoxin may not be sufficient to prevent fish from suffering quality or shelf-life degradation (i.e., decomposition) in a way that may otherwise render it adulterated under the Federal Food, Drug, and Cosmetic Act;

- The lower anterior portion of the loin is now identified as the best place to collect a sample from large fish for histamine analysis;

- Fermenting, pickling, smoking, and drying are now identified as likely critical control points (CCPs) for this hazard;

- When fish are checked for internal temperature at off-loading, it is now recommended that:
  - For fish held iced or refrigerated (not frozen) onboard the vessel and off-loaded from the vessel by the processor 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) onboard the vessel and off-loaded from the vessel by the processor from 15 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) onboard the vessel and off-loaded from the vessel by the processor from 12 to less than 15 hours after death, the internal temperature should be 60°F (15.6°C) or below;

- The recommended level at which a lot should be rejected based on sensory examination when 118 fish are examined is now corrected to be no more than 2 fish to coincide with the goal of less than 2.5% decomposition in the lot;

- It is now recommended that the number of fish subjected to sensory examination be increased if there is likely to be greater than normal variability in the lot, and that only one species constitute a lot for sampling purposes;

- When histamine analysis is performed as a corrective action, it is now recommended that any fish found to exceed the internal temperature at receiving critical limit be included in the sample;

- When the sensory critical limit has not been met, it is now recommended that the processor perform histamine analysis of a minimum of 60 fish, collected representatively from throughout the lot, including all fish in the lot that show evidence of decomposition, and reject the lot if any fish are found with a histamine level greater than or equal to 50 ppm;

- Subdividing and retesting for histamine is no longer recommended after an initial failed histamine test;

- It is now recommended that employees who conduct sensory screening receive adequate training;

- It is now recommended that for shipments of scombrotoxin-forming species received under ice on open-bed trucks be checked for both sufficiency of ice and internal product temperature;

- It is now recommended that shipments of scombrotoxin-forming species received under gel packs be checked for both adequacy of gel packs and internal product temperature;

- It is now recommended that if only the internal temperature of fish is checked at receipt by a secondary processor because the transit time is no more than 4 hours, calculation of transit time should include all time outside a controlled temperature environment;

- It is now recommended that if only the internal temperature of fish is checked at receipt by a secondary processor because the transit time is no more than 4 hours, a temperature-indicating device (e.g., a thermometer) should be used to determine internal product temperatures in a minimum of 12 fish, unless there are fewer than 12 fish in a lot, in which case all of the fish should be measured;

- When checks of the sufficiency of ice or chemical cooling media, such as gel packs, or internal product temperatures are used at receipt of fish from another processor, it is now recommended that the number of containers examined and the number of containers in the lot be recorded;

- Control of scombrotoxin (histamine) formation during processing and storage are now provided as separate control strategy examples, and examples of HACCP plans are now provided for both strategies;

- The extended exposure times during processing (more than 12 hours, cumulatively, if any portion of that time is at temperatures above 70°F (21.1°C); or more than 24 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F (21.1°C)) previously recommended for fish that have been previously frozen are now also recommended for fish that have been previously heat treated sufficiently to destroy scombrotoxin-forming bacteria and are subsequently handled in a manner where there is an opportunity for recontamination with scombrotoxin-forming bacteria;

- It is now acknowledged that it may be possible to control scombrotoxin formation during unrefrigerated processing using a critical limit that is time of exposure only (i.e., no temperature component), if it is developed with an assumption that worst-case temperatures (e.g., in excess of 70°F (21.1°C)) may occur;

- Chemical coolants (e.g., gel packs) are no longer recommended for control of temperature during in-plant storage;

- For control of time and temperature during refrigerated storage, it is now noted that critical limits that specify a cumulative time and temperature of exposure to temperatures above 40°F (4.4°C) are not ordinarily suitable because of the difficulty in determining when specific products have entered and left the cooler and the time and temperature exposures to which they were subjected. However, there may be circumstances where this approach is suitable. It is also noted that minor variations in cooler temperature measurements can be avoided by submerging the sensor for the temperature-recording device in a liquid that mimics the characteristics of the product;

- High-temperature alarms are no longer recommended for monitoring temperatures in coolers or processing areas;

- When the adequacy of ice is established as the critical limit for refrigerated storage, it is now recommended that monitoring be performed with sufficient frequency to ensure control rather than at least twice per day.

Chapter 8: "Other Decomposition-Related Hazards" has been modified with the following recommendations as of April 2011:

- It is now noted that FDA has received consumer complaints concerning illnesses associated with the consumption of decomposed salmon, attributable to the production in the fish of toxins other than histamine (e.g., biogenic amines, such as putrescine and cadaverine);
- It is now noted that there are also some indications that chemicals formed when fats and oils in foods oxidize may contribute to long-term detrimental health effects.

Chapter 9: "Environmental Chemical Contaminants and Pesticides" has been modified with the following recommendations as of April 2011:

- Toxic element guidance levels for arsenic, cadmium, lead, and nickel are no longer listed;
- Tolerance levels for endothall and its monomethyl ester in fish and carbaryl in oysters are now listed;
- The collection of soil samples from aquaculture production sites is no longer listed as a preventive measure;
- An example of a HACCP plan is now provided for control of environmental chemical contaminants in molluscan shellfish;
- When testing for environmental chemical contaminants and pesticides is used as the control measure, it is now recommended that the adequacy of the testing methods and equipment be verified periodically (e.g., by comparing results with those obtained using an Association of Official Analytical Chemists (AOAC) or equivalent method, or by analyzing proficiency samples).

Chapter 10: "Methylmercury" has been modified with the following recommendations as of April 2011:

- Has been rewritten to acknowledge that FDA is receiving comments on a draft quantitative risk assessment for methylmercury, which may result in a reassessment of its risk management strategies

Chapter 11: "Aquaculture Drugs" has been modified with the following recommendations as of June 2021:

- The following have been added to the "Understand the Potential Hazard" section:
    - The explanation of residue and its metabolite(s);
    - A Note stating that aquaculture plants, seaweed and algae are not covered by the Seafood HACCP regulation;
    - The explanation of the FFD&C Act requirement for animal drug sell and use;
    - The reference to New Animal Drug Application Guidance;
    - Information regarding the use of medically important antimicrobials (Veterinary Feed Directive and prescriptions) and issue of antimicrobial resistance;
    - Reference to CVM website for more information regarding judicious use of therapeutic antimicrobials;
    - Hyperlink to the Drug Indexing;
    - Additional information regarding conditions of extra-label drug use (EDLU);
    - A Note to foreign farmers to consult with their country competent authority for information on prescription requirements and technical support as well as provided OIE definition of veterinarian;
    - Header "Unapproved Animal Drugs" with an explanation of unapproved drug; and
    - Information regarding FDA import tolerances and listed animal drugs with established import tolerances.

- The following have been added to the "Determine Whether the Potential Hazard is Significant" section:
    - Provided the overview of preventive measures for the hazard of aquaculture drugs used in aquaculture operations that can be employed by the processor;
    - Information regarding aquaculture drug testing strategy and its importance as the verification of control limits established for aquaculture drug hazards; and
    - Paragraph regarding common food processing activities and preparation techniques and their impact on the presence of animal drug residues in the product.
- The following have been added and/or modified in the "Identify Critical Control Points" section:
    - Description of on-farm visit conducted by the processor to review farming conditions and the farm's aquaculture drug use program;
    - The "letter of guarantee" term to the "Supplier's Certification" control strategy;
    - The example of control strategy that includes "Processor's Pre-Qualified Supplier Program" as example 3;
    - Control strategy "Farm's Records of Drug Use" example 3 changed to example 4;
    - Control strategy "Drug Residue testing by Processor" example 4 changed to example 5;
    - Control strategy "Quality Assurance Program" replaced with "Third-Party Farm Certification Program" and is listed as example 6; and
    - Control strategy "Control During Holding or Transport" example 6 changed to example 7.
- The following have been added and/or modified in the "Develop a Control Strategy" section:
    - Examples of factors to be considered when determining the appropriate preventative control and verification strategy by the processor;
    - Recommendation for a secondary processor; and
    - Examples of control strategy 1-7 have been re-numbered and formatted.
- The following have been modified in the "Bibliography" section:
    - Links have been updated.

Chapter 12: "Pathogenic Bacteria Growth and Toxin Formation (Other than *Clostridium botulinum*) as a Result of Time and Temperature Abuse" has been modified with the following recommendations as of April 2011:

- It is now recognized that *V. vulnificus*, *V. parahaemolyticus*, and *Vibrio cholarae* non-O1 and non-0139 are generally associated with marine and estuarine species of fish and may not be reasonably likely to occur in freshwater species or non-fishery ingredients, unless they have been cross-contaminated;
- It is now clarified that products that are partially cooked to set the batter or breading or stabilize the product shape (e.g., fish balls, shrimp egg rolls, and breaded fish portions) are not considered to be ready to eat;
- Information is now provided on the determination of CCPs for products that are a combination of raw, ready-to-eat and cooked, ready-to-eat fishery ingredients;
- Control of time and temperature abuse at receipt, during cooling after cooking, during unrefrigerated processing, and during refrigerated storage and processing are now provided as four separate control strategy examples. Examples of HACCP plans are now provided for all four strategies;
- For control of transit conditions at receipt of ready-to-eat fish or fishery products delivered refrigerated (not frozen), it is now recommended that all lots be accompanied by transportation records that show that the fish were held at or below an ambient or internal temperature of 40°F (4.4°C) throughout transit or, for transit times of 4 hours or less, that the internal temperature of the fish at time of receipt was at or below 40°F (4.4°C);
- For control of time and temperature during refrigerated storage and refrigerated processing,

it is now noted that critical limits that specify a cumulative time and temperature of exposure to temperatures above 40°F (4.4°C) are not ordinarily suitable because of the difficulty in determining when specific products have entered and left the cooler and the time and temperature exposures to which they were subjected. However, there may be circumstances where this approach is suitable. It is also noted that minor variations in cooler temperature measurements can be avoided by submerging the sensor for the temperature-recording device in a liquid that mimics the characteristics of the product;

- It is now recommended that if only the internal temperature of the fishery product is checked at receipt, because the transit time is no more than 4 hours, calculation of transit time should include all time outside a controlled temperature environment;

- It is now recommended that if only the internal temperature of product is checked at receipt by a secondary processor because the transit time is no more than 4 hours, a temperature-indicating device (e.g., a thermometer) should be used to determine internal product temperatures in a minimum of 12 containers (e.g., cartons and totes), unless there are fewer than 12 containers in a lot, in which case all of the containers should be measured;

- When checks of the sufficiency of ice or chemical cooling media, such as gel packs, or internal product temperatures are used at receipt of fish from another processor, it is now recommended that the number of containers examined and the number of containers in the lot be recorded;

- Chemical coolants (e.g., gel packs) are no longer recommended for control of temperature during in-plant storage;

- Recommended cumulative exposure times and temperatures (i.e., critical limits) are now listed as follows:

  For raw, ready-to-eat products:

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

    OR

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

  OR

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

  OR

  - The product is held at internal temperatures below 50°F (10°C),

    OR

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

  For cooked, ready-to-eat products:

  - If at any time the product is held at internal temperatures above 80°F (27.2°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 1 hour (3 hours if *S. aureus* is the only pathogen of concern),

    OR

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

  OR

  - If at any time the product is held at internal temperatures above 70°F (21.1°C), but

never above 80°F (26.7°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 2 hours (3 hours if *S. aureus* is the only pathogen of concern),

OR

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

OR

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

OR

- The product is held at internal temperatures below 50°F (10°C),

  OR

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

- High-temperature alarms are no longer recommended for monitoring temperatures in coolers or processing areas;
- When the adequacy of ice is established as the critical limit for refrigerated storage, it is now recommended that monitoring be performed with sufficient frequency to ensure control rather than at least twice per day;
- It is now recommended that monitoring shipments received under gel packs include both adequacy of gel packs and internal product temperature.

Chapter 13: "*Clostridium botulinum* Toxin Formation" has been modified with the following recommendations as of April 2011:

- Information is now provided on Time-Temperature Indicator (TTI) performance and suitability;
- A control strategy is now provided for application of TTIs on each of the smallest package units (i.e., the unit of packaging that will not be distributed any further, usually consumer or end-user package), where refrigeration is the sole barrier to prevent toxin formation;
- It is no longer recommended that consideration be given to whether the finished product will be stored and distributed frozen when determining whether the hazard is significant. A control strategy is now provided to ensure that frozen products are properly labeled when freezing is the sole barrier to prevent toxin formation;
- Processors are now advised to take particular care in determining the safety of a packaging material for a product in which (1) the spoilage organisms have been eliminated or significantly reduced by such processes as high-pressure processing and (2) refrigeration is the sole barrier to toxin formation. The generally recommended 10,000 cc/m^2/24 hours at 24ºC oxygen transmission rates may not be suitable in this case;
- High-temperature alarms are no longer recommended for monitoring temperatures in coolers or processing areas;
- Chemical coolants (e.g., gel packs) are no longer recommended for control of temperature during in-plant storage;
- When the adequacy of ice is established as the critical limit for refrigerated storage, it is now recommended that monitoring be performed with sufficient frequency to ensure control rather than at least twice per day;
- It is now recommended that a water phase salt level of 20% be achieved in shelf-stable, reduced oxygen packaged products in which salt is the only barrier to pathogenic bacteria growth and toxin formation;
- It is now recommended that monitoring shipments received under gel packs include both adequacy of gel packs and internal product temperature;
- It is now recommended that if only the internal temperature of the fishery product is checked at receipt, because the transit time is no more than 4 hours, calculation of transit time should

include all time outside a controlled temperature environment;

- It is now recommended that if only the internal temperature of product is checked at receipt by a secondary processor because the transit time is no more than 4 hours, a temperature-indicating device (e.g., a thermometer) should be used to determine internal product temperatures in a minimum of 12 containers (e.g., cartons and totes), unless there are fewer than 12 containers in a lot, in which case all of the containers should be measured;
- A control strategy example is now provided for receipt by a secondary processor of refrigerated reduced oxygen packaged products that may be stored and further distributed or used as an ingredient for further processing;
- It is now clarified that brining time should be monitored during the processing of smoked fish;
- It is now recommended that brine be treated to minimize microbial contamination or be periodically replaced as a good manufacturing practice control.

Chapter 14: "Pathogenic Bacteria Growth and Toxin Formation as a Result of Inadequate Drying" has been modified with the following recommendations as of April 2011:

- It is no longer recommended that consideration be given to whether the finished product will be stored and distributed frozen (in the case of reduced oxygen packaged products) or refrigerated (in the case of aerobically packaged products) when determining whether the hazard is significant. A control strategy to ensure that refrigerated dried products are properly labeled when refrigeration is the sole barrier to toxin formation is now provided. A control strategy to ensure that frozen products are properly labeled when freezing is the sole barrier to toxin formation is now provided in Chapter 13.

Chapter 15: "*Staphylococcus aureus* Toxin Formation in Hydrated Batter Mixes" has been modified with the following recommendations as of April 2011:

- The number of *S. aureus* organisms normally needed to produce toxin is now listed as 500,000 to 1,000,000 per gram;
- High-temperature alarms are no longer recommended for monitoring temperatures in processing areas.

Chapter 16: "Pathogenic Bacteria Survival Through Cooking or Pasteurization" has been modified with the following recommendations as of April 2011:

- The separate chapters that previously covered pathogen survival through cooking and pathogen survival through pasteurization are now combined;
- Pasteurization is now defined as a heat treatment applied to eliminate the most resistant pathogen of public health concern that is reasonably likely to be present in food;
- Information is now provided for an option to monitor End-Point Internal Product Temperature, instead of continuous time and temperature monitoring during cooking or pasteurization, when a scientific study has been conducted to validate that it will provide a 6D process for the target pathogen;
- For surimi-based products, soups, or sauces, the following pasteurization process is now recommended: a minimum cumulative, total lethality of $F_{194°F}$ ($F_{90°C}$) = 10 minutes, where z = 12.6°F (7°C) for temperatures less than 194°F (90°C), and z = 18°F (10°C) for temperatures above 194°F (90°C);
- For Dungeness crabmeat, the following pasteurization process is now recommended: a minimum cumulative total lethality of $F_{194°F}$ ($F_{90°C}$) = 57 minutes, where z = 15.5°F (8.6°C);
- Information concerning levels of *Listeria monocytogenes* (*L. monocytogenes*) in foods is now updated based on the final FDA/U.S. Department of Agriculture *L. monocytogenes* risk assessment.

Chapter 17: "Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics" has been modified with the following recommendations as of April 2011:

- A new chapter that contains guidance for the control of pathogen survival through processes designed to retain raw product characteristics, including high hydrostatic pressure processing,

mild heat processing, IQF with extended frozen storage, and irradiation. At present, the chapter applies exclusively to the processing of molluscan shellfish products for which there is a desire to retain raw product characteristics. However, these technologies may have other applications.

Chapter 18: "Introduction of Pathogenic Bacteria After Pasteurization and Specialized Cooking Processes" has been modified with the following recommendations as of April 2011:

- It is no longer recommended that consideration be given to whether the finished product will be stored and distributed frozen when determining whether the hazard is significant. A control strategy to ensure that frozen products are properly labeled when freezing is the sole barrier to prevent *C. botulinum* toxin formation is now provided in Chapter 13.

Chapter 19: "Undeclared Major Food Allergens and Certain Food Intolerances Causing Substances" has been modified with the following recommendations as of August 2019:

- The language regarding allergen cross-contact has been enhanced.
- The language regarding allergen sanitation and cleaning has been enhanced.
- The examples have been consolidated for relevance.
- Unnecessary examples have been removed.
- "Prohibited additives" has been removed from the title and chapter since they are prohibited.
- Label review for the appropriate identification of the allergen and being applied to the appropriate product has been added.
- CFR and other regulatory references have been removed.

Chapter 20: "Metal Inclusion" has been modified with the following recommendations as of April 2011:

- Foreign objects less than 0.3 inch (7 mm) are now identified as having a potential for causing trauma or serious injury to persons in special risk groups, such as infants, surgery patients, and the elderly;
- Additional information on calibration and validation of electronic metal detectors is now provided;
- Wire mesh baskets are no longer used as an example of an unlikely source of metal fragments;
- The recommended critical limit for the metal detection or separation control strategy has been expanded to read, "All product passes through an operating metal detection or separation device," and "No detectable metal fragments in a product passing through the metal detection or separation device." As a result, the recommended monitoring procedures are also expanded so that they now are designed to also ensure that the processes are in place and operating;
- It is now recommended that when metal fragments are found in a product by a metal detector or separated from the product stream by magnets, screens, or other devices, the source of the fragment is located and corrected.

Chapter 21: "Glass Inclusion" has been modified with the following recommendations as of April 2011:

- This chapter is no longer identified as a draft;
- The use of x-ray detection devices is no longer recommended as a reliable method for controlling glass inclusion;
- The recommended critical limit for the glass container cleaning and visual inspection control strategy has been expanded to read, "All container pass through an operating glass container inspection or cleaning process," and "No detectable glass fragments in glass containers passing the CCP." As a result, the recommended monitoring procedures are also expanded so that they now are designed to also ensure that the processes are in place and operating;
- The monitoring procedures for the glass container cleaning and visual inspection control strategy now include a recommendation that a representative sample of the cleaned or inspected containers be examined at the start of processing, every 4 hours during processing,

at the end of processing, and after any breakdowns;

- It is now recommended that monitoring for the presence of glass be performed at the start of each production day and after each shift change.
- It is now recommended that a representative sample of cleaned or inspected glass containers be examined daily, at the start of processing, every 4 hours during processing, at the end of processing, and after any breakdowns.

Appendix 1: "Forms" has been modified with the following recommendations as of June 2021:

- Updated for new page format and made 508 compliance.

Appendix 2: "Sample Product Flow Diagram" has been modified with the following recommendations as of June 2021:

- Updated for new page number format and made 508 compliance.

Appendix 3: "Critical Control Point Decision Tree" has been modified with the following recommendations as of June 2021:

- Updated for new page number format and made 508 compliance.

Appendix 4: "Bacterial Pathogen Growth and Inactivation," has been modified with the following recommendations as of April 2011:

- Recommended summary cumulative exposure times and temperatures are now listed as described above for Chapter 12;
- The maximum water phase salt level for growth of *Campylobacter jejuni* is now listed as 1.7%;
- The maximum level of acidity (pH) for growth of pathogenic strains of *Escherichia coli* (*E. coli*) is now listed as 10;
- The maximum recommended cumulative exposure times for *Bacillus cereus* are now listed as follows: 5 days at temperatures of 39.2 to 43°F (4 to 6°C); 1 day at temperatures of 44 to 59°F (7 to 15°C); 6 hours at temperatures of 60 to 70°F (16 to 21°C); and 3 hours at temperatures above 70°F (21°C);
- The maximum cumulative exposure times for *E. coli, Salmonella,* and *Shigella spp.* are now listed as follows: 2 days for temperatures from their minimum growth temperature 41.4 to 50°F (10°C); 5 hours for temperatures of 51 to 70°F (11 to 21°C); and 2 hours for temperatures above 70°F (21°C);
- The maximum cumulative exposure times for *Listeria monocytogenes* are now listed as follows: 7 days for temperatures of 31.3 to 41ºF (-0.4 to 5ºC); 1 day for temperatures of 42 to 50°F (6 to 10°C); 7 hours for temperatures of 51 to 70°F (11 to 21°C); 3 hours for temperatures of 71 to 86°F (22 to 30°C); and 1 hour for temperatures above 86°F (30°C);
- The maximum cumulative exposure times for *Vibrio cholerae*, *V. vulnificus*, and *V. parahaemolyticus* are now listed as follows: 21 days for temperatures from their minimum growth temperature to 50°F (10°C); 6 hours for temperatures of 51 to 70°F (11 to 21°C); 2 hours at temperatures of 71 to 80°F (22 to 26.7°C); and 1 hour at temperatures above 80°F (26.7°C), with the last temperature range applying only to cooked, ready-to-eat products.

Appendix 5: Table A-5, "FDA and EPA Safety Levels in Regulations and Guidance," has been modified with the following recommendations as of June 2021:

- Chemical Safety Levels – The following changes have been made:
  - Removal for lack of approved safety levels:
    - Fluzapyroxad for freshwater finfish, shellfish, crustacean, and molluscs;
  - Addition of the following:
    - Bensulfuron methyl for use in crayfish;
    - Chlorantraniliprole for use in crayfish;
    - Deltamethrin for use in freshwater finfish, farm raised finfish, saltwater finfish, tuna and other;
    - Imazethapyr for use in crayfish;

- Imidacloprid for use in fish, shellfish and molluscs;
- Pendimethalin for use in crayfish;
- Propanil for use in crayfish;
- Quizalofop ethyl for use in shellfish and crustacean;
- Triclopyr and its metabolites for use in fish and shellfish.

Appendix 6: "Japanese and Hawaiian Vernacular Names for Fish Eaten Raw" has been modified with the following recommendations as of April 2011:

- No longer lists food allergens.
- It now contains a table of Japanese and Hawaiian vernacular names and their corresponding U.S. market names.

Appendix 7: Bacterial and Viral Pathogens of Greatest Concern in Seafood Processing-Public Health Impacts" has been modified with the following recommendations as of April 2011:

- No longer lists the bibliography.
- It now contains information regarding the public health impacts of bacterial and viral pathogens of greatest concern in seafood processing

Appendix 8: "Procedures for Safe and Sanitary Processing and Importing of Fish and Fishery Products" has been modified with the following recommendations as of June 2021:

- Moved information to Addendum 1 to ensure the regulations are maintained in the last sections of the Guide.
- Statement referring to Addendum 1 added

Appendix 9: "Allergen Cross-Contact Prevention" has been modified with the following recommendations as of August 2019:

- New appendix with recommendations for establishing an allergen cleaning and sanitation program has been added.

Appendix 10: "Cleaning and Sanitation for the Control of Allergens" has been modified with the following recommendations as of August 2019:

- New appendix with recommendations for establishing controls to prevent cross-contact in a facility has been added.

Appendix 11: "Approved Aquaculture Drugs" has been modified with the following recommendations as of June 2021:

- New appendix with information on FDA approved animal drugs for aquaculture use.
- The approved drugs list has been formatted.

Appendix 12: "Unapproved Aquaculture Drugs" has been modified with the following recommendations as of June 2021:

- New appendix with information on unapproved drugs including examples of FDA's high enforcement priority drugs.

Addendum 1: "Regulations: Fish and Fishery Products (21 CFR 123) and Control of Communicable Diseases (21 CFR 1240.60)" has been modified with the following recommendations as of June 2021:

- New section
- Movement of regulation out of Appendix 8 to Addendum
- To ensure the regulations are maintained as the last sections of the Guide

Addendum 2: "Current Good Manufacturing Practices (cGMPs)" has been modified with the following recommendations as of June 2021:

- New section
- Addition of 21 CFR 117 subpart B current Good Manufacturing Practices for quick reference.
- To ensure the regulations are maintained as the last sections of the Guide.

NOTES:

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

THE GUIDANCE

This is the fourth edition of the Food and Drug Administration's (FDA's) "Fish and Fishery Products Hazards and Controls Guidance." This guidance relates to FDA's Fish and Fishery Products regulation (called the Seafood HACCP Regulation, 21 CFR 123, in this guidance document) and the Control of Communicable Diseases regulation, 21 CFR 1240, that require processors of fish and fishery products to develop and implement 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.

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 recommends that processors of fish and fishery products use the two documents together in the development of a HACCP system.

This guidance document will be maintained on the FDA.GOV website, which should be consulted for subsequent updates.

Copies of the training document may be purchased from:

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

Or

www.ifasbooks.com

Or you may download a copy from:

http://www.fda.gov/FoodGuidances

NOTES:

CHAPTER 2: **Conducting a Hazard Analysis and Developing a HACCP Plan**

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

THE HACCP PLAN FORM

This guidance document is designed to walk you through a series of 18 steps that will yield a completed Hazard Analysis Critical Control Point (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 Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products regulation, 21 CFR 123 (hereinafter, the Seafood HACCP Regulation), requires that you prepare a HACCP plan for fish and fishery products that you process if there are significant food safety hazards associated with the products. The regulation does not require that you use the form included in Appendix 1. However, using this standardized form may help you develop an acceptable plan and will expedite regulatory review. A separate HACCP plan should be developed for each location where fish and fishery products are processed and for each kind of fish and fishery product processed at that location. You may group products together in a single HACCP plan if the food safety hazards and controls are the same for all products in the group.

THE HAZARD ANALYSIS WORKSHEET

In order to complete the HACCP Plan Form, you will need to perform a process called hazard analysis. The Seafood HACCP Regulation requires that all seafood processors conduct, or have conducted for them, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur in their product and to the preventive measures that a processor can apply to control those hazards (21 CFR 123.6(a)). FDA has found that the use of a standardized Hazard Analysis Worksheet assists with 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. The Seafood HACCP Regulation does not require that the hazard analysis be kept in writing. However, FDA expects that a written hazard analysis will be 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 list of the steps that this guidance uses in HACCP plan development:

- **Preliminary Steps**
  - Provide 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 potential species-related hazards;
  - Identify potential process-related hazards;
  - Understand the potential hazard;
  - Determine whether the potential hazard is significant;
  - Identify critical control points.
- **HACCP Plan Form**
  - Set up the HACCP Plan Form;
  - Set critical limits;
  - Establish monitoring procedures:
    - What,
    - How,
    - Frequency,
    - Who;
  - Establish corrective action procedures;
  - Establish a recordkeeping system;
  - Establish verification procedures.

PRELIMINARY STEPS

STEP 1: Provide general information.

Record the name and address of your processing facility in the spaces provided on the first page of both 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 (Thunnus albacares);*
- *Shrimp (Pandals spp.);*
- *Jack mackerel (Trachurus spp.).*

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 clams;*
- *Fresh seafood salad, with shrimp and blue crabmeat;*
- *Frozen, breaded pollock sticks;*
- *Frozen crab 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 both 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.

Examples:

- *Stored and distributed frozen;*
- *Distributed on ice and then stored under refrigeration or on ice.*

Record this information in the space provided on the first page of both 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 also be another processor that 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 both 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 steps in the process that 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.

Biological, chemical, and physical hazards can affect the safety of fishery products. Some food safety hazards are associated with the product (e.g., the species of fish, the way in which the fish is raised or caught, and the region of the world from which the fish originates). These hazards are introduced outside the processing plant environment before, during, or after harvest. This guidance refers to these as "species-related hazards." Other food safety hazards are associated with the way in which the product is processed (e.g., the type of packaging, the manufacturing steps, and the kind of storage). These hazards are introduced within the processing plant environment. This guidance refers to these as "process-related hazards." They are covered in Step 8.

Find in Table 3-2 (Chapter 3) or Table 3-3 (Chapter 3) the market name (Column 1) or

Latin name (Column 2) of the product that you identified in Step 2. Use Table 3-2 for vertebrates (animals with backbones) such as finfish. Use Table 3-3 for invertebrates (animals without backbones) such as shrimp, oysters, crabs, and lobsters. Determine whether the species has a potential species-related hazard by looking for a "√" mark (or one- or three-letter codes for a natural toxin) in the right-hand columns of the table. If it does, record the potential species-related hazard(s) in Column 2 of the Hazard Analysis Worksheet, at every processing step.

Tables 3-2 and 3-3 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 occurring should be judged in the absence of controls. For example, the fact that scombrotoxin (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 time and temperature controls). In the first case, the hazard is not reasonably likely to occur. In the second case, the hazard is reasonably likely to occur, and the controls should be included in the HACCP plan.

STEP 8: Identify potential process-related hazards.

Find in Table 3-4 (Chapter 3) the finished product food (Column 1) and package type (Column 2) that most closely match the information that you developed in Steps 2 and 3. Record the potential hazard(s) listed in the table for that product in Column 2 of the Hazard Analysis Worksheet, at every processing step.

You may need to include potential hazards for more than one finished product food category from Table 3-4, which will happen when your product fits more than one description. For example, if you cook shrimp and use it to prepare a finished product salad, you should look at both the "cooked shrimp" and the "salads … prepared from ready-to-eat fishery products" categories in Table 3-4, Column 1. 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 3-4 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).

STEP 9: Understand the potential hazard.

Consult the hazards and controls chapters of this guidance document (Chapters 4 through 7, 9, and 11 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. Each chapter contains a section, "Understand the Potential Hazard," that provides information about the significance of the hazard, the conditions under which it may develop in a fishery product, and methods available to control the hazard.

STEP 10: Determine whether the potential hazard is significant.

Narrow the list of potential hazards that you entered in Column 2 of the Hazard Analysis Worksheet to those that are significant or, in other words, "reasonably likely to occur." The Seafood HACCP Regulation defines a food safety hazard that is reasonably likely to occur as "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."

The hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Determine Whether this Potential Hazard Is Significant," that provides information about how to assess the significance of potential hazards. You should evaluate the significance of a potential hazard independently at each processing step. It may be significant at one step but not at another. A potential hazard is significant at the processing or handling step if (1) it is reasonably likely that the hazard can be introduced at an unsafe level at that processing step; or (2) it is reasonably likely that the hazard can increase to an unsafe level at that processing step; or (3) it is significant at another processing or handling step and it can be prevented, eliminated, or reduced to an acceptable level at the current processing or handling step. When evaluating the significance of a hazard at a processing step, you should consider the method of distribution and storage and the intended use and consumer of the product, which you developed in Steps 3 and 4.

If you determine that a potential hazard is significant at a processing step, you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If you determine that a potential hazard is not significant at a processing step, you should answer "No" in that column. You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps 11 through 18 for a hazard for those processing steps where you have recorded a "No."

It is important to note that identifying a hazard as significant at a processing step does not mean that it must be controlled at that processing step. Step 11 will help you determine where in the process the critical control point is located.

STEP 11: Identify critical control points.

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

The hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Identify Critical Control Points (CCPs)," which provides information about where control should be exercised. Each chapter discusses one or more "control strategy example(s)" for how the hazard can be controlled, because there are often more ways than one to control a hazard. CCP(s) for one control strategy example often differ from those of another example for the same hazard. The control strategies contain preventive measure information. Record the preventive measure(s) in Column 5 of the Hazard Analysis Worksheet for each "Yes" answer in Column 3.

For every significant hazard, there must be at least one CCP where the hazard is controlled (21 CFR 123.6(c)(2)). In some cases, control may be necessary at more than one CCP for a single hazard. In other cases, a processing step may be a CCP for more than one hazard. CCPs are points in the process (i.e., processing steps) where the HACCP control activities will occur. Control activities at a CCP can effectively prevent, eliminate, or reduce the hazard to an acceptable level (21 CFR 123.3(b)).

If you determine that a processing step is a CCP for a significant hazard, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet. If you determine that a processing step is not a CCP for a significant hazard, you should enter "No" in that column. You need not complete Steps 12 through 18 for a hazard for those processing steps where you have recorded a "No."

HACCP PLAN FORM

STEP 12: Set up the HACCP Plan Form.

Find the processing steps that 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 Steps 13 through 18 for each of the significant hazards. These steps involve setting critical limits, establishing monitoring procedures, establishing corrective action procedures, establishing a recordkeeping system, and establishing verification procedures.

STEP 13: Set critical limits.

For each processing step where a significant hazard is identified on the HACCP Plan Form, identify the maximum or minimum value to which a parameter of the process must be controlled in order to control the hazard. Each control strategy example provided in the hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Set Critical Limits," that provides information about appropriate critical limits for each of the control strategy example(s) discussed.

You should set a critical limit at such a value that if it is 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 an unsafe product to reach the consumer.

As a practical matter, it may also 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 not met, but before a critical limit deviation 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.

Consider that the critical limit should directly relate to the parameter that you will be monitoring. For example, if you intend to monitor the temperature of the water in the cooker and the speed of the belt that carries the product through the cooker (because you have determined that these factors result in the desired internal product temperature for the desired time), you should specify water temperature and belt speed as critical limits, not the internal temperature of the product.

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

STEP 14: Establish monitoring procedures.

For each processing step where a significant hazard is identified on the HACCP Plan Form, describe monitoring procedures that will ensure that critical limits are consistently met (21 CFR 123.6(c)(4)). The hazards and controls chapters of this guidance document (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Establish Monitoring Procedures," that provides information about appropriate monitoring procedures for each of the control strategy example(s) discussed.

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

It is important for you to keep in mind that the monitoring process should directly measure the parameter for which you have established a critical limit. The necessary frequency of monitoring is dependent upon the circumstances. Continuous monitoring is always desirable, and in some cases necessary. In other cases, it may not be necessary or practical. You should monitor

often enough 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 products you are putting at risk should a measurement show a deviation from a critical limit has occurred, because you should assume that the critical limit had not been met since the last "good" value. Even with continuous monitoring, the paper or electronic record of the continuous monitoring should be periodically checked in order to determine whether deviations from the critical limit have occurred. The frequency of that check should be at least daily, and more frequent if required in order to implement an appropriate corrective action.

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

STEP 15: Establish corrective action procedures.

A corrective action must be taken whenever there is a deviation from a critical limit at a CCP (21 CFR 123.7((a)). For each processing step where a significant hazard is identified on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the critical limit has not been met. Note that the Seafood HACCP Regulation does not require that you predetermine your corrective actions. You may instead elect to follow the prescribed corrective action procedures listed at 21 CFR 123.7(c). However, a predetermined corrective action has the following advantages: (1) It provides detailed instructions to the processing employee that can be followed in the event of a critical limit deviation; (2) it can be prepared at a time when an emergency situation is not calling for an immediate decision; and (3) it removes the obligation to reassess the HACCP plan in response to a critical limit deviation.

The hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Establish Corrective Action Procedures," that provides information about appropriate corrective action procedures for each of the control strategy example(s) discussed. An appropriate corrective action procedure must accomplish two goals: (1) ensure that an unsafe product does not reach the consumer and (2) correct the problem that caused the critical limit deviation (21 CFR 123.7). If the corrective action involves testing the finished product, the limitations of the sampling plan should be understood. Because of these limitations, microbiological testing is often not a suitable corrective action. The Seafood HACCP Regulation requires that corrective actions be fully documented in records (21 CFR 123.7(d)). Note that if a critical limit deviation occurs repeatedly, the adequacy of that CCP for controlling the hazard should be reassessed. Remember that deviations from operating limits do not need to result in formal corrective actions.

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

STEP 16: Establish a recordkeeping system.

For each processing step where a significant hazard is identified on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step 14 (21 CFR 123.9(a)(2)).

The hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Establish a Recordkeeping System," that provides information about appropriate records for each of the control strategy example(s) discussed. Records must document monitoring of the CCP and shall contain the actual values and observations obtained during monitoring (21 CFR 123.6(b)(7)) The Seafood HACCP Regulation lists specific requirements about the content of the records (21 CFR 123.9(a)).

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

STEP 17: Establish verification procedures.

For each processing step where a significant hazard is identified on the HACCP Plan Form, describe the verification procedures that will ensure that the HACCP plan is (1) adequate to address the hazard and (2) consistently being followed (21 CFR 123.6(c)(6)).

The hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Establish Verification Procedures," that provides information about appropriate verification activities for each of the control strategy example(s) discussed. The information covers validation of the adequacy of critical limits (e.g., process establishment); calibration (including accuracy checks) of CCP monitoring equipment; performance of periodic end-product and in-process testing; and review of monitoring, corrective action, and verification records. Note that the Seafood HACCP Regulation does not require product testing (21 CFR 123.8(a)(2)(iii)). However, it can be a useful tool, especially when coupled with a relatively weak monitoring procedure, such as reliance upon suppliers' certificates.

When calibration or an accuracy check of a CCP monitoring instrument shows that the instrument is not accurate, you should evaluate the monitoring records since the last instrument calibration to determine whether the inaccuracy would have contributed to a critical limit deviation. For this reason, HACCP plans with infrequent calibration or accuracy checks can place more products at risk than those with more frequent checks should a problem with instrument accuracy occur.

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

STEP 18: Complete the HACCP Plan Form.

When you have finished these steps for all 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 (21 CFR 123.6(d)(1)). It signifies that the HACCP plan has been accepted for implementation by your firm.

CHAPTER 3: POTENTIAL SPECIES-RELATED AND PROCESS-RELATED HAZARDS

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

INTRODUCTION

- **Purpose**

The purpose of this chapter is to identify potential food safety hazards that are species related and process related.

To assist in identifying species-related and process-related hazards, this chapter contains three tables:

- Table 3-2, "Potential Vertebrate Species-Related Hazards," contains a list of potential hazards that are associated with specific species of vertebrates (species with backbones). These hazards are referred to as species-related hazards;
- Table 3-3, "Potential Invertebrate Species-Related Hazards," contains a list of potential hazards that are associated with specific species of invertebrates (species without backbones). These hazards are also referred to as species-related hazards; and
- Table 3-4, "Potential Process-Related Hazards," contains a list of potential hazards that are associated with specific finished fishery products, as a result of the finished product form, the package type, and the method of distribution and storage. These hazards are referred to as process-related hazards.

NOTES:

The following should be considered when identifying seafood:

- The tables provide lists of potential hazards. You should use the tables, together with the information provided in Chapters 4 through 21, and your own expertise or that of outside experts, to determine whether the hazard is significant for your particular product or process and, if so, how it should be controlled.
- Acceptable names should be used when labeling seafood products. Refer to "The Seafood List" to determine acceptable names for species subject to interstate commerce. This Guide is not the official resource for determination of acceptable names. The hyperlink to "The Seafood List" is: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=SeafoodList.
- Some species are endangered and/or have regulatory restrictions. For information concerning endangered species, please refer to National Oceanic and Atmospheric Administration (NOAA) "ESA Threatened & Endangered" list and/or the U.S. Fish & Wildlife Services "Endangered Species". The hyperlink to NOAA's EAS Threatened & Endangered list is Threatened and Endangered Species Directory Page | NOAA Fisheries. The hyperlink to the U.S. Fish and Wildlife Services "Endangered Species" is Endangered Species | Home Page (fws.gov).

- **Species substitution**

Illicit substitution of one species for another may constitute economic fraud and/or misbranding

violations of the Federal Food, Drug, and Cosmetic Act. Furthermore, species substitution may cause potential food safety hazards to be overlooked or misidentified by processors or end users, as shown in Table 3-1, "The Effect of Misbranding through Species Substitution on the Identification of Potential Species-Related Hazards." These examples are based on actual incidents of species substitution or misbranding.

TABLE 3-1.

THE EFFECT OF MISBRANDING THROUGH SPECIES SUBSTITUTION ON THE IDENTIFICATION OF POTENTIAL SPECIES-RELATED HAZARDS

Actual Market Name of Product:	Potential Species-Related Hazards Associated with the Actual Product: (Table 3-2)	Product Inappropriately Labeled as:	Potential Species-Related Hazards that would be Identified Based on Inappropriate Species Labeling: (Table 3-2)
Escolar	Gempylid Fish Poisoning: Scombrotoxin (Histamine)	Sea Bass	Parasites
Puffer Fish	Tetrodotoxin (Pufferfish Poisoning); Paralytic Shellfish Poisoning	Monkfish	Parasites
Spanish Mackerel	Parasites; Scombrotoxin (Histamine); Ciguatera Fish Poisoning	Kingfish	None
Basa	Environmental Chemicals; Aquaculture Drugs.	Grouper	Parasites; Ciguatera Fish Poisoning
Grouper	Parasites; Ciguatera Fish Poisoning	Cod	Parasites

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
AHOLEHOLE	*Kuhlia* spp.					
ALEWIFE or RIVER HERRING	*Alosa pseudoharengus*			✓	✓	
ALFONSINO	*Beryx* spp.					
	Centroberyx spp.					
ALLIGATOR	*Alligator mississipiensis*				✓	
	Alligator sinensis				✓	
ALLIGATOR, aquacultured	*Alligator mississipiensis*				✓	✓
	Alligator sinensis				✓	✓
AMBERJACK	*Seriola dumerili*		CFP	✓		
	S. rivoliana		CFP	✓		
	S. spp.			✓		
AMBERJACK or YELLOWTAIL	*Seriola lalandi*			✓		
AMBERJACK or YELLOWTAIL, aquacultured	*Seriola lalandi*	✓[4]		✓	✓	✓
AMBERJACK or BURI, aquacultured	*Seriola quinqueradiata*			✓	✓	✓
ANCHOVY [12]	*Anchoa* spp.	✓	ASP [5]	✓		
	Anchoviella spp.	✓	ASP [5]	✓		
	Cetengraulis mysticetus	✓	ASP [5]	✓		
	Engraulis spp.	✓	ASP [5]	✓		
	Stolephorus spp.	✓	ASP [5]	✓		
ANGELFISH	*Holacanthus* spp.					
	Pomacanthus spp.					
ARGENTINE QUEENFISH	*Argentina elongata*					

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ATKA MACKEREL	*Pleurogrammus monopterygius*	✓				
BARRACUDA	*Sphyraena barracuda*		CFP		✓	
	S. jello		CFP		✓	
	S. spp.				✓	
BARRAMUNDI	*Lates calcarifer*				✓	
BARRAMUNDI, aquacultured	*Lates calcarifer*				✓	✓
BASA or BOCOURTI	*Pangasius bocourti*				✓	
BASA or BOCOURTI, aquacultured	*Pangasius bocourti*				✓	✓
BASS	*Ambloplites* spp.				✓	
	Micropterus spp.				✓	
	Morone spp.				✓	
	Stereolepis gigas				✓	
	Synagrops bellus				✓	
BASS, aquacultured	*Centropristis* spp.				✓	✓
	Morone spp.				✓	✓
BASS, SEA	*Acanthistius brasilianus*	✓				
	Centropristis spp.	✓				
	Dicentrarchus labrax	✓				
	Lateolabrax japonicus	✓				

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BASS, SEA (cont.)	*Paralabrax* spp.	✓				
	Paranthias furcifer	✓				
	Polyprion americanus	✓				
	P. oxygeneios	✓				
	P. yanezi	✓				
BASS, SEA, aquacultured	*Dicentrarchus labrax*	✓			✓	✓
BATA	*Labeo bata*				✓	
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*					
	Acanthopagrus spp.					
	Argyrops spp.					
	Gymnocranius grandoculis					

TABLE 3-2
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MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
BREAM (cont.)	*Monotaxis* spp.					
	Sparus aurata					
	Wattsia spp.					
BREAM, aquacultured	*Abramis brama*				✓	✓
BREAM or BOGUE	*Boops boops*					
BREAM, THREADFIN	*Nemipterus japonicus*					
BUFFALOFISH	*Ictiobus* spp.				✓	
BULLHEAD	*Ameiurus* spp.				✓	
BURBOT	*Lota lota*				✓	
BUTTERFISH	*Odax pullus*				✓	
	Peprilus spp.				✓	
	Pampus cinereus				✓	
CAPARARI	*Pseudoplatystoma tigrinum*				✓	
CAPELIN and roe	*Mallotus villosus*	✓				
CARP	*Barbonymus* spp.				✓	
	Carassius carassius				✓	
	Cyprinus carpio				✓	
	Hypophthalmichthys molitrix				✓	
	H. nobilis				✓	
CARP, aquacultured	*Carassius carassius*				✓	✓
	Cyprinus carpio				✓	✓

TABLE 3-2
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MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
CARP, aquacultured (cont.)	*Hypophthalmichthys molitrix*				✓	✓
	H. nobilis.				✓	✓
CASCARUDO	*Callichthys callichthys*				✓	
CATFISH	*Ameiurus catus*				✓	
	Ictalurus spp.				✓	
	Pylodictis oliveris				✓	
CATFISH, aquacultured	*Ictalurus* spp.				✓	✓
CHAR	*Salvelinus alpinus*				✓	
CHAR, aquacultured	*Salvelinus alpinus*				✓	✓
CHARACIN	*Leporinus obtusidens*				✓	
CHARAL	*Chirostoma jordani*					
CHIMAERA	*Harriota raleighana*					
	Hydrolagus spp.					
CHIRING	*Apocryptes bato*					
CHUB	*Coregonus kiyi*				✓	
	Kyphosus spp.				✓	
	Semotilus atromaculatus				✓	
CISCO or CHUB	*Coregonus alpenae*				✓	
	C. reighardi				✓	
	C. zenithicus				✓	
CISCO or TULLIBEE	*Coregonus artedi*				✓	

TABLE 3-2
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CLARIAS FISH or WALKING CLARIAS FISH	*Clarias* spp.				✓	
CLARIAS FISH or WALKING CLARIAS FISH, or CLARESSE, aquacultured	*Clarias gariepinus x Clarias macrocephalus*				✓	✓
	C. spp.				✓	✓
	Heterobranchus longifilis x Clarias gariepinus				✓	✓
COBIA	*Rachycentron canadum*	✓				
COBIA, aquacultured	*Rachycentron canadum*	✓			✓	✓
COD	*Arctogadus* spp.	✓				
	Boreogadus saida	✓				
	Eleginus gracilis	✓				
	Gadus spp.	✓				
COD or ALASKA COD	*Gadus macrocephalus*	✓				
COD, MORID	*Lotella rhacina*	✓				
	Mora moro	✓				
	Pseudophycis barbata	✓				
	P. spp.	✓				
COD, aquacultured	*Gadus morhua*				✓	✓
COROATA	*Platynematichthys notatus*	✓			✓	

TABLE 3-2
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CORVINA	*Cilus gilberti*	✓				
	Micropogonias undulates	✓				
CRAPPIE	*Pomoxis* spp.				✓	
CROAKER	*Argyrosomus* spp.				✓	
	Bairdiella spp.				✓	
	Cheilotrema saturnum				✓	
	Genyonemus lineatus				✓	
	Micropogonias spp.				✓	
	Nebris microps				✓	
	Nibea spp.				✓	
	Odontoscion dentex				✓	
	Pachypops spp.				✓	
	Pachyurus spp.				✓	
	Paralonchurus spp.				✓	
	Plagioscion spp.				✓	
	Pseudotolithus spp.				✓	
	Pterotolithus spp.				✓	
	Roncador stearnsii				✓	
	Umbrina roncador				✓	

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CROAKER or CORVINA	*Cynoscion* spp.				✓	
CROAKER or SHADEFISH	*Argyrosomus regius*				✓	
CROAKER or YELLOWFISH	*Larimichthys polyactis*				✓	
CROCODILE	*Crocodylus johnsoni*	✓				
	Crocodylus moreletii	✓				
	Crocodylus novaequineae	✓				
	Crocodylus niloticus	✓				
	Crocodylus porosus	✓				
CROCODILE, aquacultured	*Crocodylus niloticus*	✓				✓
	Crocodylus porosus	✓				✓
CURIMBATA or GURAMATA	*Prochilodus lineatus*					
CUSK	*Brosme brosme*					
CUSK-EEL	*Brotula clarkae*					
	Lepophidium spp.					
CUTLASSFISH	*Aphanopus carbo*					
CUTLASSFISH	*Lepidopus caudatus*					
CUTLASSFISH	*Trichiurus* spp.					
DACE	*Rhinichthys* spp.				✓	
DACE, aquacultured	*Rhinichthys* spp.				✓	✓
DORAB	*Chirocentrus dorab*					
DORY	*Cyttus novaezealandiae*					
	Zenopsis spp.					
	Zeus spp.					
DRIFTFISH	*Hyperoglyphe* spp.					

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DRUM	*Collichthys* spp.				✓	
	Equetus punctatus					
	Larimus spp.				✓	
	Pogonias cromis				✓	
	Stellifer spp.				✓	
	Totoaba macdonaldi				✓	
	Umbrina coroides				✓	
DRUM or CUBBYU	*Pareques umbrosus*				✓	
DRUM, FRESHWATER	*Aplodinotus grunniens*				✓	
DRUM or MEAGRE	*Argyrosomus regius*				✓	
DRUM or QUEENFISH	*Seriphus politus*				✓	
DRUM or REDFISH	*Sciaenops ocellatus*				✓	
DRUM or REDFISH, aquacultured	*Sciaenops ocellatus*				✓	✓
EEL	*Anguilla anguilla*		IHT			
	A. spp.					
EEL, aquacultured	*Anguilla anguilla*		IHT		✓	✓
	A. australis				✓	✓
	A. dieffenbachii				✓	✓
	A. japonica				✓	✓
EEL, CONGER	*Ariosoma balearicum*				✓	
	Conger conger		IHT			

TABLE 3-2
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EEL, CONGER (cont.)	*Conger* spp.	✓			✓	
	Gnathophis cinctus				✓	
	Paraconger caudilimbatus				✓	
	Rhynchoconger spp.				✓	
EEL, FRESHWATER	*Anguilla rostrata*				✓	
EEL, FRESHWATER, aquacultured	*Anguilla rostrata*				✓	✓
EEL, MORAY	*Gymnothorax funebris*		CFP			
	Lycodontis javanicus		CFP			
	Muraena helena		IHT			
	Muraena retifera		CFP			
EEL, SPINY	*Notacanthus chemnitzii*					
EELPOUT	*Zoarces americanus*					
	Z. viviparus	✓				
ELEPHANT FISH	*Callorhynchus millii*					
EMPEROR	*Lethrinus* spp.		CFP			
ESCOLAR or OILFISH	*Lepidocybium flavobrunneum*		GFP	✓		
	Ruvettus pretiosus		GFP	✓		
FEATHERBACK	*Notopterus notopterus*					
FLATHEAD	*Platycephalus conatus*					
FLATWHISKERED FISH	*Pinirampus pirinampu*				✓	
FLOUNDER [15]	*Ancylopsetta dilecta*	✓			✓[1]	
	Arnoglossus scapha	✓			✓[1]	
	Bothus spp.	✓			✓[1]	

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
FLOUNDER [15] (cont.)	*Chascanopsetta crumenalis*	✓			✓[1]	
	Cleisthenes pinetorum	✓			✓[1]	
	Colistium spp.	✓			✓[1]	
	Cyclopsetta chittendeni	✓			✓[1]	
	Hippoglossina oblonga	✓			✓[1]	
	Hippoglossoides robustus	✓			✓[1]	
	Limanda ferruginea	✓			✓[1]	
	Liopsetta glacialis	✓			✓[1]	
	Microstomus achne	✓			✓[1]	
	Paralichthys albigutta	✓			✓[1]	
	P. olivaceus	✓			✓[1]	
	P. patagonicus	✓			✓[1]	
	P. squamilentus	✓			✓[1]	
	Pelotretis flavilatus	✓			✓[1]	
	Peltorhampus novaezeelandiae	✓			✓[1]	
	Platichthys spp.	✓			✓[1]	
	Pseudorhombus spp.	✓			✓[1]	
	Reinhardtius evermanni	✓			✓[1]	
	Rhombosolea spp.	✓			✓[1]	

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
FLOUNDER [15] (cont.)	*Samariscus triocellatus*	✓			✓[1]	
	Scophthalmus spp.	✓			✓[1]	
FLOUNDER [15], aquacultured	*Ancylopsetta dilecta*	✓[4]			✓	✓
	Arnoglossus scapha	✓[4]			✓	✓
	Bothus spp.	✓[4]			✓	✓
	Chascanopsetta crumenalis	✓[4]			✓	✓
	Cleisthenes pinetorum	✓[4]			✓	✓
	Colistium spp.	✓[4]			✓	✓
	Cyclopsetta chittendeni	✓[4]			✓	✓
	Hippoglossoides robustus	✓[4]			✓	✓
	Limanda ferruginea	✓[4]			✓	✓
	Liopsetta glacialis	✓[4]			✓	✓
	Microstomus achne	✓[4]			✓	✓
	Paralichthys spp.	✓[4]			✓	✓
	Pelotretis flavilatus	✓[4]			✓	✓
	Peltorhampus novaezeelandiae	✓[4]			✓	✓
	Pseudorhombus spp.	✓[4]			✓	✓
	Reinhardtius evermanni	✓[4]			✓	✓
	Rhombosolea spp.	✓[4]			✓	✓

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
FLOUNDER [15], aquacultured (cont.)	*Samariscus triocellatus*	✓[4]			✓	✓
	Scophthalmus spp.	✓[4]			✓	✓
FLOUNDER or DAB	*Limanda limanda*	✓			✓[1]	
	L. proboscidea	✓			✓[1]	
	L. punctatissima [7]	✓			✓[1]	
FLOUNDER or FLUKE	*Paralichthys dentatus*	✓			✓[1]	
	P. flesus	✓			✓[1]	
	P. lethostigma	✓			✓[1]	
	P. microps	✓			✓[1]	
FLOUNDER, ARROWTOOTH	*Atheresthes stomias* [7]	✓				
FLOUNDER OR CALIFORNIA FLOUNDER	*Paralichthys californicus*	✓				
FLYINGFISH and roe	*Cypselurus* spp.					
	Exocoetus spp.					
	Fodiator acutus					
	Hirundichthys spp.					
	Oxyporhamphus micropterus					
	Parexocoetus brachypterus					
	Prognichthys gibbifrons					
FROG	*Rana* spp.	✓			✓	
FROG, aquacultured	*Rana* spp.	✓			✓	✓
GAR	*Lepisosteus* spp.				✓	
GEMFISH	*Epinnula magistralis*					
GEMFISH	*Nesiarchus nasutus*					

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
GEMFISH or BARRACOUTA	*Rexea solandri*					
	Thyrsites atun					
GEMFISH or CABALLA	*Thyrsites lepidopoides*					
GILLIBACKER or GILLEYBAKA or WHISKERFISH [8]	*Sciades parkeri* [7]					
GOATFISH	*Mulloidichthys* spp.					
	M. vanicolenis					
	Mullus auratus					
	Parupeneus spp.					
	Pseudupeneus spp.					
	Upeneichthys lineatus					
	Upeneus spp.					
GOBY	*Neogobius melanostomus*				✓	
GRAYLING	*Thymallus arcticus*				✓	
GREENBONE	*Odax pullus*					
GREENLAND TURBOT	*Reinhardtius hippoglossoides*	✓				
GREENLING	*Hexagrammos* spp.					
GRENADIER	*Coryphaenoides* spp.					
	Lepidorhynchus denticulatus					
	Macruronus spp.					
	Nezumia bairdii					
	Trachyrhynchus spp.					
GROUPER	*Anyperodon* spp.	✓				
	Caprodon schlegelii	✓				
	Cephalopholis argus	✓	CFP			
	C. miniata	✓	CFP			
	C. spp.	✓	CFP			

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POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
GROUPER (cont.)	*Dermatolepis inermis*	✓	CFP			
	Diplectrum formosum	✓				
	Epinephelus fuscoguttatus	✓	CFP			
	E. lanceolatus	✓	CFP			
	E. morio	✓	CFP			
	E. spp.	✓	CFP			
	Mycteroperca bonaci	✓	CFP			
	M. spp.	✓	CFP			
	M. venenosa	✓	CFP			
	Variola louti	✓	CFP			
	V. spp.	✓	CFP			
GROUPER or CORAL GROUPER	*Plectropomus* spp.	✓	CFP			
GROUPER or GAG	*Mycteroperca microlepis*	✓	CFP			
GROUPER or HIND	*Epinephelus guttatus*	✓	CFP			
GROUPER or JEWFISH	*Epinephelus itajara*	✓	CFP			
GROUPER or SCAMP	*Mycteroperca phenax*	✓	CFP			
GROUPER, ORANGE -SPOTTED, aquacultured	*Epinephelus coioides*				✓	✓
GROUPER, MALABAR, aquacultured	*Epinephelus malabaricus*				✓	✓
GROUPER, aquacultured	*Epinephelus* spp.				✓	✓

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GRUNION	*Leuresthes tenuis*					
GRUNT	*Anisotremus interruptus*					
	Conodon nobilis					
	Haemulon spp.					
	Orthopristis chrysoptera					
	Pomadasys crocro					
GRUNT or CATALINA	*Anisotremus taeniatus*					
GRUNT or MARGATE	*Anisotremus surinamensis*					
	Haemulon album					
GRUNT or SWEETLIPS	*Plectorhinchus* spp.					
HADDOCK	*Melanogrammus aeglefinus*					
HAKE	*Urophycis* spp.					
HALIBUT	*Hippoglossus* spp.	✓				
HALIBUT, aquacultured	*Hippoglossus* spp.	✓[4]			✓	✓
HAMLET, MUTTON	*Alphestes afer*					
HERRING [12]	*Alosa* spp.	✓		✓	✓	
	Etrumeus teres	✓		✓	✓	
	Harengula thrissina	✓		✓	✓	
	Ilisha spp.	✓		✓	✓	
	Opisthopterus tardoore	✓		✓	✓	
	Pellona ditchela			✓	✓	
HERRING or SEA HERRING or SILD [12]	*Clupea* spp.	✓		✓		
HERRING or SEA HERRING or SILD [12] roe	*Clupea* spp.	✓				
HERRING, THREAD [12]	*Opisthonema* spp.				✓	

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POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
HIND	*Epinephelus adscensionis*	✓	CFP	✓		
	E. drummondhayi	✓				
	E. guttatus	✓	CFP			
HOGFISH	*Lachnolaimus maximus*	✓	CFP			
HORSE MACKEREL or SCAD	*Trachurus trachurus*	✓		✓		
JACK	*Carangoides bartholomaei*	✓	CFP	✓		
	Caranx ignobilis	✓	CFP	✓		
	C. latus	✓	CFP	✓		
	C. lugubris	✓	CFP	✓		
	C. melampygus	✓	CFP	✓		
	C. ruber	✓	CFP	✓		
	C. spp.	✓	CFP	✓		
	Oligoplites saurus	✓	CFP	✓		
	Selene spp.	✓		✓		
	Urapsis secunda	✓		✓		
JACK or BLUE RUNNER	*Caranx crysos*	✓	CFP	✓		
JACK or CREVALLE	*Alectis indicus*	✓		✓		
JACK or RAINBOW RUNNER	*Elagatis bipinnulata*	✓	CFP	✓		
JACK or ROOSTERFISH	*Nematistius pectoralis*	✓		✓		

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POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
JACKSMELT or SILVERSIDE	*Antherinopsis californiensis*		ASP			
JOBFISH or SNAPPER	*Aphareus* spp.	✓	CFP			
	Aprion spp.	✓	CFP			
	Pristipomoides spp.	✓	CFP			
KAHAWAI	*Arripis* spp.	✓		✓		
KINGFISH [6]	*Menticirrhus littoralis*		ASP			
	M. spp.					
KINGKLIP	*Genypterus* spp.					
LADYFISH	*Elops* spp.					
LING	*Molva* spp.					
LING, MEDITERRANEAN	*Molva macrophthalma*					
LINGCOD	*Ophiodon elongatus*					
LIZARDFISH	*Synodus* spp.					
LOACH	*Somileptus gongota*					
LIONFISH	*Pterois miles*		CFP [14]			
	P. volitans		CFP [14]			
LUMPFISH roe	*Cyclopterus lumpus*					
MACKEREL	*Gasterochisma melampus*	✓		✓		
	Grammatorcynus spp.	✓		✓		
	Rastrelliger kanagurta	✓		✓		
	Scomber scombrus	✓	PSP	✓		
MACKEREL, ATKA	*Pleurogrammus monopterygius*	✓				
MACKEREL, CHUB	*Scomber* spp.	✓		✓		
MACKEREL, JACK	*Trachurus* spp.	✓		✓		

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MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
MACKEREL, SPANISH	*Scomberomorus* spp.	✓		✓		
MACKEREL, SPANISH or CERO	*Scomberomorus regalis*	✓	CFP	✓		
MACKEREL, SPANISH or KING	*Scomberomorus cavalla*	✓	CFP	✓		
MACKEREL, SPANISH or NARROW-BARRED	*Scomberomorus commerson*		CFP	✓		
MAHI-MAHI	*Coryphaena* spp.			✓		
MAHI-MAHI, aquacultured	*Coryphaena* spp.			✓	✓	✓
MARLIN	*Makaira* spp.			✓		
	Tetrapturus spp.			✓		
MENHADEN	*Brevoortia partonus*		ASP	✓		
	B. spp.			✓[9]	✓[10]	
	Ethmidium maculatum			✓[9]	✓[10]	
MILKFISH	*Chanos chanos*			✓	✓	
MILKFISH, aquacultured	*Chanos chanos*			✓	✓	✓
MONKFISH	*Lophius* spp.	✓				
MORWONG	*Aplodactylus arctidens*					
	Cheilodactylus spp.					
	Goniistius spp.					
	Nemadactylus spp.					
MULLET	*Agonostomus monticola*	✓			✓	
	Aldrichetta forsteri	✓			✓	
	Crenimugil crenilabis	✓			✓	

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MULLET (cont.)	*Mugil cephalus*	✓			✓	
	M. curerna	✓	ASP			
	M. spp.	✓			✓	
	M. thoburni	✓			✓	
	Mullus spp.	✓			✓	
MUSKELLUNGE	*Esox masquinongy*				✓	
NILE PERCH	*Lates niloticus*				✓	
NILE PERCH, aquacultured	*Lates niloticus*				✓	✓
OPAH	*Lampris guttatus*					
OPALEYE	*Girella nigricans*					
OREO DORY[12]	*Allocyttus niger*					
	Allocyttus spp.		GFP			
	Neocyttus spp.		GFP			
	Oreosoma spp.		GFP			
	Pseudocyttus spp.		GFP			
OSCAR	*Astronotus ocellatus*				✓	
OSCAR, aquacultured	*Astronotus ocellatus*				✓	✓
PACU	*Myleus pacu*					
PADDLEFISH and roe	*Polyodon* spp.				✓	
PADDLEFISH and roe, aquacultured	*Polyodon* spp.				✓	✓
PANGASIUS, GIANT	*Pangasius gigas*				✓	
	P. sanitwongsei				✓	

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POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

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PANGASIUS SHORTBARBEL	*Pangasius micronemus*				✓	
PARROTFISH	*Bolbometopon* spp.					
	Chlorurus gibbus		CFP[2]			
	Scarus coeruleus		CFP			
	S. taeniopterus		CFP			
	Sparisoma chrysopterum		CFP			
	S. viride		CFP			
PATAGONIAN TOOTHFISH or CHILEAN SEABASS	*Dissostichus eleginoides*	✓				
PATAGONIAN TOOTHFISH or CHILEAN SEABASS, aquacultured	*Dissostichus eleginoides*				✓	✓
PERCH	*Hermosilla azurea*				✓	
	Perca fluviatilis				✓	
PERCH, LAKE or YELLOW	*Perca flavescens*				✓	
PERCH, NILE	*Lates niloticus*				✓	
PERCH, NILE, aquacultured	*Lates niloticus*				✓	✓
PERCH, OCEAN or ROCKFISH	*Sebastes* spp.	✓				
PERCH, PILE	*Rhacochilus vacca*				✓	
PERCH, SILVER	*Bairdiella chrysoura*				✓	
PERCH, WHITE	*Morone americana*				✓	
PICAREL	*Spicara maena*				✓	
PICKEREL	*Esox* spp.				✓	
PIKE	*Esox lucius*				✓	

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PILCHARD or SARDINE	*Sardina pilchardus*			✓		
	Sardinops spp.		ASP[5]	✓		
PIRAMUTABA or LAULAO FISH [8]	*Brachyplatystoma vaillantii*				✓	
PLAICE	*Hippoglossoides platessoides*	✓				
	Pleuronectes platessa	✓				
	P. quadrituberculatus	✓				
POLLOCK	*Pollachius pollachius*	✓				
	P. virens	✓				
POLLOCK or WALLEYE POLLOCK	*Gadus chalcogrammus* [7]	✓				
POMFRET	*Brama* spp.					
	Parastromateus spp.					
	Taractes rubescens					
POMPANO	*Alectis ciliaris*		CFP			
	Parastromateus niger					
	Trachinotus spp.					
POMPANO, aquacultured	*Trachinotus carolinus*				✓	✓
POMPANO or PERMIT	*Trachinotus kennedyi*					
	T. falcatus					
POMPANO or POMPANITO	*Trachinotus rhodopus*					
PORGY	*Calamus* spp.		CFP			
	Chrysophrys auratus					
	Dentex spp.					
	Diplodus spp.					
	Lagodon rhomboides					
	Pagrus spp.					

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PORGY (cont.)	*Pterogymnus laniarus*					
PORGY	*Stenotomus caprinus*					
PORGY or SCUP	*Stenotomus chrysops*					
PUFFER FISH [8, 16]	*Sphoeroides maculatus* [11b]					
	S. nephelus [11a]		PFP			
	Takifugu rubripes [11c]		PFP			
PUFFER FISH [8, 16,] aquacultured	*Takifugu rubripes* [11c]		PFP		✓	✓
RACEHORSE	*Congiopodus leucopaecilus*					
RITA	*Rita rita*					
ROCKFISH	*Scorpaena cardinalis*	✓				
	S. papillosus	✓				
	Sebastes spp.	✓				
ROCKLING	*Ciliata* spp.					
ROHU	*Labeo rohita*				✓	
ROSEFISH	*Helicolenus dactylopterus*					
ROUGHY	*Paratrachichthys trailli*					
ROUGHY, ORANGE [12]	*Hoplostethus atlanticus*		GFP			
ROUGHY, SILVER	*Hoplostethus mediterraneus*					
SABLEFISH	*Anoplopoma fimbria*	✓				
SABLEFISH, aquaculture	*Anoplopoma fimbria*				✓	✓
SAILFISH	*Istiophorus platypterus*			✓		
SALMON and roe, aquacultured	*Oncorhynchus* spp.	✓[4]			✓	✓
	Salmo salar	✓[4]			✓	✓

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SALMON and roe (WILD, FRESHWATER)	*Oncorhynchus* spp.	✓			✓	
	Salmo salar	✓			✓	
SALMON and roe, (WILD, OCEAN)	*Oncorhynchus* spp.	✓				
	Salmo salar	✓				
SANDDAB	*Citharichthys sordidus*				✓	
SANDPERCH	*Mugiloides chilensis*					
	Parapercis spp.					
SARDINE [12]	*Harengula clupeola*		ASP	✓		
	H. jaguana		ASP	✓		
	H. spp.			✓		
	Sardinella spp.			✓		
	Sardinops sagax		ASP	✓		
SAUGER	*Sander canadensis*					
SAURY	*Cololabis saira*			✓		
	Scomberesox saurus			✓		
SCAD	*Atule mate*	✓				
	Decapterus spp.	✓				
	Selar crumenophthalmus	✓		✓		
	Trachurus spp.	✓		✓		
SCAD or HORSE MACKEREL	*Trachurus trachurus*	✓		✓		

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SCULPIN	*Hemitripterus americanus*					
	Myoxocephalus polyacanthocephalus					
	Scorpaenichthys marmoratus					
SEA BREAM	*Archosargus rhomboidalis*					
	Chrysophrys auratus					
	Pagellus spp.					
SEA BREAM, aquacultured	*Sparus aurata*				✓	✓
SEAROBIN	*Chelidonichthys* spp.					
	Peristedion miniatum					
	Prionotus carolinus					
	Pterygotrigla picta					
SEATROUT	*Cynoscion* spp.	✓				
SHAD	*Alosa* spp.		ASP[5]	✓	✓	
SHAD roe	*Alosa* spp.				✓	
SHAD, GIZZARD	*Dorosoma* spp.			✓	✓	
	Nematoalosa vlaminghi			✓	✓	
SHAD, HILSA	*Tenualosa ilisha*			✓		
SHARK	*Carcharhinus* spp.					
	Cetorhinus maximus					
	Galeocerdo cuvier					
	Galeorhinus spp.					
	Hexanchus griseus					
	Lamna ditropis					
	Negaprion brevirostris					
	Notorynchus cepedianus					
	Prionace glauca					

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SHARK (cont.)	*Sphyrna* spp.					
	Triaenodon obesus					
	Triakis semifasciata					
SHARK, ANGEL	*Squatina* spp.					
SHARK, DOGFISH or CAPE SHARK	*Centrophorus* spp.					
	Mustelus spp.					
	Scyliorhinus spp.					
	Squalus spp.					
SHARK, MAKO	*Isurus* spp.					
SHARK or PORBEAGLE	*Lamna nasus*					
SHARK or SMOOTHHOUND	*Mustelus* spp.					
SHARK, THRESHER	*Alopias* spp.					
SHEEPHEAD	*Archosargus probatocephalus*				✓	
	Semicossyphus pulcher				✓	
SHINER	*Notropis* spp.				✓	
SILVERSIDE	*Atherinopsis californiensis*		ASP		✓	
	A. spp.					
	Basilichthys australis				✓	
	Membras marinica		ASP			
	Menidia menidia				✓	
SKATE	*Amblyraja* spp.				✓	
	Bathyraja spp.				✓	
	Leucoraja spp.				✓	

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
SKATE (cont.)	*Malacoraja* spp.				✓	
	Raja spp.				✓	
SKILLFISH	*Erilepis zonifer*					
SMELT	*Allosmerus elongatus*				✓	
	Argentina spp.				✓	
	Hypomesus spp.				✓	
	Osmerus spp.				✓	
	Plecoglossus altivelis altivelis				✓	
	Retropinna retropinna				✓	
	Spirinchus spp.				✓	
	Thaleichthys pacificus				✓	
SNAKEHEAD	*Channa striata*					
	Parachanna obscura					
SNAPPER	*Apsilus dentatus*					
	Etelis spp.					
	Lutjanus bohar		CFP			
	L. buccanella		CFP			
	L. cyanopterus		CFP			
	L. gibbus		CFP			
	L. griseus		CFP			
	L. jocu		CFP			
	L. sebae		CFP			
	Macolor spp.					
	Ocyurus chrysurus		CFP [14]			
	Pristipomoides spp.	✓	CFP			

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
SNAPPER (cont.)	*Rhomboplites aurorubens*					
	Symphorichthys spilurus					
	Symphorus nematophorus		CFP			
SNAPPER or SCHOOLMASTER	*Lutjanus apodus*		CFP			
SNAPPER, aquacultured	*Lutjanus* spp.				✓	✓
SNOOK	*Centropomus* spp.				✓	
SOLE or FLOUNDER	*Aseraggodes* spp.	✓				
	Austroglossus spp.	✓				
	Brachirus orientalis	✓				
	Buglossidium luteum	✓				
	Clidoderma asperrimum	✓				
	Embassichthys bathybius	✓				
	Eopsetta jordani	✓				
	Glyptocephalus spp.	✓				
	G. zachirus	✓				
	Gymnachirus melas	✓				
	Hippoglossina spp.	✓				
	Lepidopsetta bilineata	✓				
	Lyopsetta exilis	✓				
	Microchirus spp.	✓				

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
SOLE or FLOUNDER (cont.)	*Microstomus kitt*	✓				
	M. pacificus	✓				
	Parophrys vetulus	✓				
	Psettichthys melanostictus	✓				
	Pseudopleuronectes americanus	✓				
	Solea solea	✓				
	Trinectes spp.	✓				
	Xystreurys liolepis	✓				
SOLE or FLOUNDER, aquacultured	*Aseraggodes* spp.	✓[4]			✓	✓
	Austroglossus spp.	✓[4]			✓	✓
	Brachirus orientalis	✓[4]			✓	✓
	Buglossidium luteum	✓[4]			✓	✓
	Clidoderma asperrimum	✓[4]			✓	✓
	Embassichthys bathybius	✓[4]			✓	✓
	Eopsetta jordani	✓[4]			✓	✓
	Glyptocephalus spp.	✓[4]			✓	✓
	G. zachirus	✓[4]			✓	✓
	Gymnachirus melas	✓[4]			✓	✓
	Hippoglossina spp.	✓[4]			✓	✓

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
SOLE or FLOUNDER, aquacultured (cont.)	*Lepidopsetta bilineata*	✓[4]			✓	✓
	Lyopsetta exilis	✓[4]			✓	✓
	Microchirus spp.	✓[4]			✓	✓
	Parophrys vetulus	✓[4]			✓	✓
	Psettichthys melanostictus	✓[4]			✓	✓
	Pseudopleuronectes americanus	✓[4]			✓	✓
	Solea solea	✓[4]			✓	✓
	Trinectes spp.	✓[4]			✓	✓
	Xystreurys liolepis	✓[4]			✓	✓
SORUBIM or SURUBI	*Pseudoplatystoma corruscans*				✓	
SPADEFISH	*Chaetodipterus* spp.					
SPEARFISH	*Tetrapturus* spp.			✓		
SPOT	*Leiostomus xanthurus*		ASP		✓	
SPRAT or BRISTLING	*Sprattus* spp.	✓		✓		
SQUIRRELFISH	*Holocentrus* spp.					
	Myripristis spp.					
	Sargocentron spp.					
STURGEON and roe (CAVIAR) [8]	*Acipenser* spp.				✓	
	Huso huso				✓	
	Pseudoscaphirhynchus spp.				✓	
	Scaphirhynchus spp.				✓	

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
STURGEON and roe (CAVIAR) [8], aquacultured	*Acipenser* spp.				✓	✓
	Huso huso				✓	✓
	Pseudoscaphirhynchus spp.				✓	✓
	Scaphirhynchus spp.				✓	✓
SUCKER	*Carpiodes* spp.				✓	
	Catostomus commersonii				✓	
	Cycleptus elongatus				✓	
SUCKER or REDHORSE	*Moxostoma macrolepidotum*				✓	
SUNFISH	*Archoplites interruptus*				✓	
	Lepomis spp.				✓	
SURFPERCH	*Amphistichus* spp.				✓	
	Cymatogaster aggregata				✓	
	Embiotoca spp.				✓	
	Hyperprosopon argenteum				✓	
	Rhacochilus toxotes				✓	
SUTCHI or SWAI	*Pangasianodon hypophthalmus*				✓	
SUTCHI or SWAI, aquacultured	*Pangasianodon hypophthalmus*				✓	✓
SWORDFISH	*Xiphias gladius*			✓		
TANG	*Acanthurus* spp.		CFP [2]			
	Ctenochaetus striatus		CFP [2]			

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
TANG (cont.)	*C. strigosus*		CFP [2]			
	Naso spp.		CFP [2]			
	Zebrasoma spp.					
TARPON	*Megalops atlanticus*				✓	
TAUTOG	*Tautoga onitis*				✓	
THORNYHEAD	*Sebastolobus* spp.	✓			✓	
THREADFIN	*Eleutheronema tetradactylum*					
	Galeoides decadactylus					
	Polydactylus spp.					
	Polynemus spp.					
TIGERFISH	*Datnioides microlepis*				✓	
	D. polota				✓	
TILAPIA	*Oreochromis* spp.	✓			✓	
	Sarotherodon spp.	✓			✓	
	Tilapia spp.	✓			✓	
TILAPIA, aquacultured	*Oreochromis* spp.	✓[4]			✓	✓
	Sarotherodon spp.	✓[4]			✓	✓
	Tilapia spp.	✓[4]			✓	✓
TILEFISH	*Caulolatilus* spp.					
	Lopholatilus chamaeleonticeps					
	Malacanthus plumieri					
	Prolatilus jugularis					
TINFOIL	*Barbonymus altus*					

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
TOMCOD	*Microgadus* spp.	✓				
TONGUESOLE	*Cynoglossus* spp.	✓				
TRAHIRA	*Hoplias malabaricus*					
TREVALLY	*Caranx ignobilis*	✓	CFP	✓		
	C. melampygus	✓	CFP	✓		
	C. spp.	✓		✓		
	Gnathanodon speciosus					
TRIGGERFISH	*Balistes vetula*		CFP			
	Canthidermis sufflamen					
	Melichthys niger					
	Navodon spp.					
TRIPLETAIL	*Datnioides quadrifasciatus*					
	Lobotes spp.					
TROUT, aquacultured	*Oncorhynchus aguabonita*				✓	✓
	O. clarkii				✓	✓
	O. gilae				✓	✓
	O. mykiss				✓	✓
	Salmo trutta				✓	✓
	Salvelinus fontinalis				✓	✓
	S. malma				✓	✓
	S. namaycush				✓	✓
	Stenodus leucichthys				✓	✓

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
TROUT, RAINBOW or STEELHEAD	*Oncorhynchus mykiss*	✓				
TRUMPETER	*Latridopis* spp.				✓	
	Latris lineata				✓	
TUNA	*Allothunnus fallai*	✓		✓		
	Auxis spp.	✓		✓		
	Euthynnus spp.	✓		✓		
	Katsuwonus pelamis	✓		✓		
	Thunnus alalunga		ASP	✓		
	T. albacares			✓		
	T. atlanticus			✓		
	T. maccoyii			✓		
	T. obesus			✓		
	T. thynnus			✓		
	T. tonggol	✓		✓		
TUNA, aquacultured	*Thunnus* spp.	✓[4]		✓	✓	✓
TURBOT	*Pleuronichthys guttulatus*	✓				
	P. spp.	✓				
	Psetta maxima	✓				

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
TURBOT (cont.)	*Psettodes* spp.	✓				
	Reinhardtius hippoglossoides	✓				
TURBOT, aquacultured	*Psetta maxima*	✓[4]			✓	✓
TURTLE	*Apalone* spp.				✓	
	Chelydra spp.				✓	
	Malaclemys spp.				✓	
	Trachemys spp.				✓	
TURTLE, aquacultured	*Apalone* spp.				✓	✓
	Chelydra spp.				✓	✓
	Malaclemys spp.				✓	✓
	Trachemys spp.				✓	✓
UNICORNFISH	*Naso unicornis*		CFP			
WAHOO	*Acanthocybium solandri*			✓		
WALLEYE	*Sander vitreus*				✓	
WAREHOU	*Seriolella* spp.					
WEAKFISH	*Cynoscion* spp.	✓			✓	
WEAKFISH or BANGAMARY	*Macrodon ancylodon*					
WHISKERED FISH	*Arius* spp.				✓	
WHISKERED FISH or GAFFTOPSAIL FISH	*Bagre marinus*				✓	
WHISKERED FISH or HARDHEAD WHISKERED FISH	*Ariopsis felis*				✓	

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

MARKET NAMES	LATIN NAMES	Parasite[3] Hazards CHP 5	Natural Toxin[13] Hazards CHP 6	Scombrotoxin (Histamine) Hazards CHP 7	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
WHITEFISH	*Coregonus* spp.				✓	
	Prosopium cylindraceum				✓	
WHITING	*Merluccius gayi*	✓				
	M. hubbsi	✓				
	M. merluccius	✓				
WHITING, BLUE	*Micromesistius* spp.	✓				
WHITING, NEW ZEALAND	*Macruronus novaezelandiae*					
WHITING or PACIFIC WHITING	*Merluccius productus*	✓				
WRASSE	*Cheilinus undulatus*		CFP			
WOLFFISH	*Anarhichas* spp.	✓				
YELLOWTAIL or AMBERJACK	*Seriola lalandi*			✓		
YELLOWTAIL or AMBERJACK, aquacultured	*Seriola lalandi*	✓[4]		✓	✓	✓
ZANDER	*Sander lucioperca*				✓	
ZANDER, aquacultured	*Sander lucioperca*				✓	✓

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS [17]

ACRONYMS: ASP = Amnesic Shellfish Poisoning; **CFP** = Ciguatera Fish Poisoning; **GFP** = Gempylid Fish Poisoning; **IHT** = Ichthyohemotoxic fish; **PSP** = Paralytic Shellfish Poisoning; and **PFP** = Pufferfish Poisoning

FOOTNOTES:

1. This hazard does not apply to offshore catch (e.g., areas not subject to shoreside contaminant discharges).
2. Indicates that the ciguatera hazard is associated with this species only in the tropical Pacific Ocean.
3. This hazard applies 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.
4. Species that normally have a parasite hazard as a result of consuming infected prey apparently do not have the same parasite hazard when raised only on pelleted feed in an aquaculture operation. See Chapter 5 for further information.
5. This hazard only applies if the product is marketed uneviscerated.
6. Amberjack, yellowtail, Spanish mackerel, king mackerel, and other scombrotoxin-forming fish are sometimes marketed incorrectly as kingfish.
7. The scientific name for this species has changed since the previous edition of this guidance.
8. The market name for this species has been changed since the previous edition of this guidance.
9. This hazard does not apply to products intended for animal feed or fish oil products but does apply to products intended for direct human consumption of the muscle and to aqueous components, such as fish protein concentrates that are to be used as food additives.
10. This hazard only applies to food products for human consumption, such as oil extracts used as dietary ingredients.
11. Puffer Fish:
    a. PFP has been associated with fish from the east coast of Florida specifically in the following counties: Volusia, Brevard, Indian River, St. Lucie, and Martin.
    b. There have been no reported tetrodotoxin or PFP illnesses associated with this species as of May 2018.
    c. *Takifugu rubripies* is the only species to be offered for importation from Japan based on the agreement between US FDA and the government of Japan.
12. Other Natural Marine Toxins may be applicable to this species. Refer to Chapter 6 for clarification.
13. Many of the fish and families of fish listed in this table have been identified with specific natural marine toxins as a result of illnesses/ outbreaks which have occurred or have been identified through research. For further information regarding each toxin refer to Chapter 6 and its references.
14. The toxin has been identified through an FDA research project; however, the toxin levels found do not exceed the established guidance levels and/or have not been associated with illnesses.
15. Other flounder are also known as sole and can be found under “Sole or Flounder.”
16. FDA recommends consuming these species of fish only as appropriate.
17. You should identify pathogens from the harvest area as a potential species-related hazard id you know, or have reason to know, that the fish will be consumer without a process sufficient to kill pathogens or if you represent, label, or intend for the product to be so consumed. (See Chapter 4 for guidance on controlling pathogens from the harvest area.)

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
ABALONE	*Haliotis laevigata*			✓	✓	
	H. ruber				✓	
	H. spp.				✓	
	Marinauris roei				✓	
ARKSHELL	*Anadara* spp.	✓		✓	✓	
	Arca spp.	✓		✓	✓	
BARNACLES, GOOSENECK	*Pollicipes polymerus*			✓	✓	
CLAM, BENTNOSE	*Macoma nasuta*	✓		✓	✓	
CLAM BUTTER	*Saxidomus* spp.	✓		✓	✓	
CLAM, CALICO	*Macrocallista maculata*	✓		✓	✓	
CLAM, GEODUCK	*Panopea bitruncata*	✓		✓	✓	
	P. spp.	✓		✓	✓	
CLAM, HARD	*Arctica islandica*	✓		✓	✓	
	Meretrix spp.	✓		✓	✓	
	Venus mortoni	✓		✓	✓	
CLAM, HARDSHELL or QUAHOG	*Mercenaria* spp.	✓		✓	✓	
	Protothaca thaca	✓		✓	✓	
CLAM, LITTLENECK	*Protothaca staminea*	✓		✓	✓	
	P. tenerrima	✓		✓	✓	

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
CLAM, LITTLENECK (cont.)	*Tapes variegata*	✓		✓	✓	
	T. virginea	✓		✓	✓	
	Venerupis aurea	✓		✓	✓	
	V. decussata [4]	✓		✓	✓	
	V. philippinarum	✓		✓	✓	
CLAM, MARSH	*Corbicula japonica*	✓		✓	✓	
CLAM, PISMO	*Tivela stultorum*	✓		✓	✓	
CLAM, RAZOR	*Ensis* spp.	✓		✓	✓	
	Siliqua spp.	✓		✓	✓	
	Solen spp.	✓		✓	✓	
	Tagelus spp.	✓		✓	✓	
CLAM, SANGUIN	*Sanguinolaria* spp.	✓		✓	✓	
CLAM, SOFTSHELL	*Mya arenaria*	✓		✓	✓	
CLAM, SURF or SURFCLAM	*Mactra* spp.	✓		✓	✓	
	Mactrellona alata	✓		✓	✓	
	Mactromeris spp.	✓		✓	✓	
	Mactrotoma spp.	✓		✓	✓	
	Simomactra spp.	✓		✓	✓	

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
CLAM, SURF or SURFCLAM (cont.)	*Spisula* spp.	✓		✓	✓	
	Tresus spp.	✓		✓	✓	
CLAM, SURF or SURFCLAM, aquacultured	*Mactra schalinensis*	✓		✓	✓	
CLAM, VENUS	*Chione* spp.	✓		✓	✓	
	Chionista spp.	✓		✓	✓	
	Macrocallista nimbosa	✓		✓	✓	
CLAM, WEDGE	*Paphies* spp.	✓		✓	✓	
COCKLE	*Cardium* spp.	✓		✓	✓	
	Clinocardium spp.	✓		✓	✓	
	Dinocardium robustum	✓		✓	✓	
	Serripes groenlandicus	✓		✓	✓	
CONCH	*Lambis lambis*	✓		✓		
	Strombus spp.	✓		✓		
COQUINA	*Donax* spp.	✓		✓	✓	
COQUINA, FALSE	*Iphigenia brasiliana*	✓		✓	✓	
CRAB, BENI-ZUWAI	*Chionocetes japonicus*				✓	
CRAB, BLUE	*Callinectes sapidus*				✓	
CRAB, BLUE, aquacultured	*Callinectes sapidus*				✓	✓
CRAB, BROWN	*Chaceon fenneri*				✓	

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
CRAB, GOLDEN KING	*Lithodes aequispinus*				✓	
CRAB, CENTOLLA	*Lithodes antarcticus*				✓	
	L. murrayi				✓	
CRAB, CHINESE MITTEN	*Eriocheir sinensis*				✓	
CRAB, CHINESE MITTEN, aquacultured	*Eriocheir sinensis*				✓	✓
CRAB, DEEPSEA	*Paralomis granulosa*				✓	
CRAB, DUNGENESS	*Metacarcinus* magister [4]			✓[2]	✓	
CRAB, JAPANESE FRESHWATER	*Geothelphusa dehaani*		✓[1]		✓	
CRAB, JONAH	*Cancer borealis*			✓[2]	✓	
CRAB, KING	*Paralithodes camtschaticus*				✓	
	P. platypus				✓	
CRAB, KING or HANASAKI	*Paralithodes brevipes*				✓	
CRAB, KOREAN or KEGANI	*Erimacrus isenbeckii*				✓	
CRAB, LITHODES	*Neolithodes brodiei*				✓	
CRAB, RED	*Chaceon quinquedens*				✓	
CRAB, RED ROCK	*Cancer productus*			✓[2]	✓	
CRAB, ROCK	*Cancer irroratus*				✓	
	C. pagurus				✓	
CRAB, SANTOLLA, NOVA, or SOUTHERN RED	*Lithodes santolla*				✓	

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
CRAB, SHEEP	*Loxorhynchus grandis*				✓	
CRAB, SNOW	*Chionoecetes angulatus*				✓	
	C. bairdi				✓	
	C. opilio				✓	
	C. tanneri				✓	
CRAB, SPIDER	*Jacquinotia edwardsii*				✓	
	Maja squinado				✓	
CRAB, STONE	*Menippe* spp.				✓	
CRAB, SWAMP	*Scylla serrata*				✓	
CRAB, SWAMP, aquacultured	*Scylla serrata*				✓	✓
CRAB, SWIMMING	*Callinectes arcuatus*				✓	
	C. toxotes				✓	
	Ovalipes punctatus				✓	
	Portunus spp.				✓	
CRAB, SWIMMING, aquacultured	*Portunus pelagicus*				✓	✓
CRAWFISH or CRAYFISH	*Astacus* spp.				✓	
	Cambarus spp.				✓	
	Cherax spp.				✓	
	Euastacus armatus				✓	

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
CRAWFISH or CRAYFISH (cont.)	*Pacifastacus* spp.				✓	
	Paranephrops spp.				✓	
	Procambarus spp.				✓	
CRAWFISH or CRAYFISH, aquacultured	*Astacus* spp.				✓	✓
	Cambarus spp.				✓	✓
	Cherax spp.				✓	✓
	Euastacus armatus				✓	✓
	Pacifastacus spp.				✓	✓
	Paranephrops spp.				✓	✓
	Procambarus spp.				✓	✓
CUTTLEFISH	*Sepia* spp.			✓[2]		
JELLYFISH	*Rhopilema* spp.					
KRILL	*Euphausia* spp.					
KRILL	*Meganyctiphanes norvegica*					
KRILL	*Thysandoessa inermis*					
LANGOSTINO	*Cervimunida johni*					
	Munida gregaria					
	Pleuroncodes spp.					
LIMPET	*Cellana denticulata*					
	Diodora aspera					
	Fissurella maxima					
	Lottia gigantea					
	Patella caerulea					
	Tectura testudinalis					

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
LOBSTER	*Homarus* spp.			✓[2]		✓[3]
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					
MUREX or MEREX	*Murex brandaris*					
MUSSEL	*Modiolus* spp.	✓		✓	✓	
	Mytilus spp.	✓		✓	✓	
	Perna canaliculus	✓		✓	✓	
OCTOPUS	*Eledone* spp.		✓[1]	✓[2]		
	Octopus spp.		✓[1]	✓[2]		
OCTOPUS, BLUE-RINGED	*Hapalochlaena spp.*			✓		
OYSTER	*Crassostrea* spp.	✓		✓	✓	
	Ostrea spp.	✓		✓	✓	
	Spondylus spp.	✓		✓	✓	
	Tiostrea spp.	✓		✓	✓	
PEN SHELL	*Atrina pectinata*	✓		✓	✓	
PERIWINKLE	*Littorina littorea*	✓[2]		✓[2]	✓	

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
SCALLOP	*Aequipecten* spp.	✓[2]		✓[2]	✓	
	Amusium spp.	✓[2]		✓[2]	✓	
	Argopecten nucleus	✓[2]		✓[2]	✓	
	Chlamys spp.	✓[2]		✓[2]	✓	
	Euvola 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]	✓	
	Euvola 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]	✓	

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
SEA CUCUMBER	*Apostichopus* spp.					
	Cucumaria spp.				✓	
	Holothuria spp.				✓	
	Parastichopus spp.				✓	
	Stichopus spp.				✓	
SEA CUCUMBER, aquacultured	*Apostichopus japonicus*				✓	✓
	Holothuria scabras				✓	✓
SEA URCHIN roe	*Echinus esculentus*				✓	
	Evechinus chloroticus				✓	
	Heliocidaris spp.				✓	
	Loxechimus spp.				✓	
	Paracentrotus spp.				✓	
	Pseudocentrotus spp.				✓	
	Strongylocentrotus spp.				✓	
SEABOB or SHRIMP	*Xiphopenaeus kroyeri*					
SEA SQUIRT	*Styela* spp.			✓		
SHIRMP	*Acetes japonicus*				✓	
	Crangon spp.					
	Farfantepenaeus spp.					
	Fenneropenaeus spp.					
	Litopenaeus spp.					

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
SHRIMP (cont.)	*Marsupenaeus* spp.					
	Melicertus spp.					
	Metapenaeus affinis					
	Palaemon serratus					
	Palaemonetes vulgaris					
	Pandalopsis dispar					
	Pandalus spp.					
	Penaeus spp.					
	Pleoticus muelleri					
	Plesionika martia					
SHRIMP, aquacultured	*Crangon* spp.				✓	✓
	Exopalaemon styliferus				✓	✓
	Farfantepenaeus spp.				✓	✓
	Fenneropenaeus spp.				✓	✓
	Litopenaeus spp.				✓	✓
	Marsupenaeus spp.				✓	✓
	Macrobrachium spp.				✓	✓
	Melicertus spp.				✓	✓
	Metapenaeus spp.				✓	✓
	Palaemon serratus				✓	✓
	Palaemonetes vulgaris				✓	✓
	Pandalopsis dispar				✓	✓
	Pandalus spp.				✓	✓

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
SHRIMP, aquacultured (cont.)	*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*					
	P. jordani					
SHRIMP or PRAWN	*Haliporoides sibogae* [4]					
SNAIL or ESCARGOT	*Achatina fulica*				✓	
	Cornu aspersa		✓[1]		✓	
	Elona quimperiana		✓[1]		✓	
	Helix lucorum		✓[1]		✓	
	Helix pomatia				✓	
	Otala spp.		✓[1]			
	Pila polita		✓[1]		✓	
SNAIL, MOON	*Polinices* spp.			✓		
SQUID or CALAMARI	*Berryteuthis magister*		✓[1]			
	Doryteuthis opalescens			✓		
	Dosidicus gigas		✓[1]	✓[2]		
	Illex spp.		✓[1]			

TABLE 3-3

POTENTIAL INVERTEBRATE SPECIES-RELATED HAZARDS [5]

MARKET NAMES	LATIN NAMES	Pathogen Hazards CHP 4	Parasite Hazards CHP 5	Natural Toxin Hazards CHP 6	Environmental Chemical Hazards CHP 9	Aquaculture Drug Hazards CHP 11
SQUID or CALAMARI (cont.)	*Loligo media*		✓[1]			
	L. 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	*Monodonta* turbinate [4]					
	Turbo cornutus					
WHELK or SEA SNAIL	*Buccinum* spp.					
	Busycon spp.			✓		
	Neptunea spp.			✓[2]		
	Zidona dufresnei					

FOOTNOTES:

1. This hazard applies 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.
2. This hazard only applies if the product is marketed uneviscerated.
3. This hazard only applies if the lobsters are held in pounds.
4. The scientific name for this species has changed since the last edition of this guidance.
5. You should identify pathogens from the harvest area as a potential species-related hazard if you know, or have reason to know, that the fish will be consumed without a process sufficient to kill pathogens or if you represent, label, or intend for the product to be consumed. (See Chapter 4 for guidance on controlling pathogens from the harvest area.)

TABLE 3-4

POTENTIAL PROCESS-RELATED HAZARDS

Finished Product Food [1]	Package Type	CHP 12: Pathogenic Bacteria Growth - Temperature Abuse	CHP 13: *C. botulinum* Toxin	CHP 14: *S. aureus* Toxin – Drying	CHP 15: *S. aureus* Toxin – Batter	CHP 16: Pathogenic Bacteria Survival Through Cooking or Pasteurization	CHP 17: Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics	CHP 18: Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes	CHP 19: Allergens and Food Intolerance Substances [4]	CHP 20: Metal Inclusion	CHP 21: Glass Inclusion
Battered or breaded (including surface-browned) raw shrimp, finfish, oysters, clams, squid, and other fish.	Reduced oxygen packaged (e.g., mechanical vacuum, MAP, CAP, hermetically sealed).		✓		✓				✓	✓	
Battered or breaded (including surface-browned) raw shrimp, finfish, oysters, clams, squid, and other fish.	Other than reduced oxygen packaged.				✓				✓	✓	
Cooked shrimp, crab, lobster, and other fish, including cooked meat, sections, and whole fish, and surimi-based analog products.	Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed, or packed in oil).	✓	✓			✓			✓	✓	
Cooked shrimp, crab, lobster, and other fish, including cooked meat, sections, and whole fish, and surimi-based analog products.	Other than reduced oxygen packaged.	✓				✓			✓	✓	
Dried fish.	All.	✓	✓[6]	✓					✓	✓	
Fermented, acidified, pickled, salted, and LACFs.	All.	✓	✓[2]						✓	✓	✓
Fish oil.	All.								✓[3]		

TABLE 3-4

POTENTIAL PROCESS-RELATED HAZARDS

Finished Product Food [1]	Package Type	CHP 12: Pathogenic Bacteria Growth - Temperature Abuse	CHP 13: *C. botulinum* Toxin	CHP 14: *S. aureus* Toxin – Drying	CHP 15: *S. aureus* Toxin – Batter	CHP 16: Pathogenic Bacteria Survival Through Cooking or Pasteurization	CHP 17: Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics	CHP 18: Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes	CHP 19: Allergens and Food Intolerance Substances [4]	CHP 20: Metal Inclusion	CHP 21: Glass Inclusion
Fully cooked prepared foods.	Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed, or packed in oil).	✓	✓			✓			✓	✓	✓
Fully cooked prepared foods.	Other than reduced oxygen packaged.	✓				✓			✓	✓	✓
Pasteurized crab, lobster, and other fish, including pasteurized surimi-based analog products.	Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP hermetically sealed, or packed in oil).	✓	✓			✓		✓	✓	✓	
Pasteurized crab, lobster, and other fish, including pasteurized surimi-based analog products.	Other than reduced oxygen packaged.	✓				✓		✓	✓	✓	
Raw fish other than oysters, clams, and mussels (finfish and non-finfish).	Reduced oxygen packaged (e.g. mechanical vacuum, MAP, CAP, hermetically sealed, or packed in oil).	✓	✓						✓	✓	
Raw fish other than oysters, clams, and mussels (finfish and non-finfish).	Other than reduced oxygen packaged.	✓							✓	✓	

TABLE 3-4

POTENTIAL PROCESS-RELATED HAZARDS

Finished Product Food [1]	Package Type	CHP 12: Pathogenic Bacteria Growth - Temperature Abuse	CHP 13: *C. botulinum* Toxin	CHP 14: *S. aureus* Toxin – Drying	CHP 15: *S. aureus* Toxin – Batter	CHP 16: Pathogenic Bacteria Survival Through Cooking or Pasteurization	CHP 17: Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics	CHP 18: Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes	CHP 19: Allergens and Food Intolerance Substances [4]	CHP 20: Metal Inclusion	CHP 21: Glass Inclusion
Raw oysters, clams, and mussels.	Reduced oxygen packaged (e.g., mechanical vacuum, MAP, CAP, hermetically sealed, or packed in oil).	✓	✓				✓			✓	✓
Raw oysters, clams, and mussels.	Other than reduced oxygen packaged.	✓					✓			✓	✓
Salads, sandwiches, dips, cocktails, and similar seafood products prepared from ready-to-eat fishery products.	Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed, or packed in oil).	✓	✓						✓	✓	✓
Salads, sandwiches, dips, cocktails, and similar seafood products prepared from ready-to-eat fishery products.	Other than reduced oxygen packaged.	✓							✓	✓	✓
Smoked fish.	Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed, or packed in oil).	✓	✓			✓[5]			✓	✓	
Smoked fish.	Other than reduced oxygen packaged.	✓				✓[5]			✓	✓	

TABLE 3-4

POTENTIAL PROCESS-RELATED HAZARDS

Finished Product Food [1]	Package Type	CHP 12: Pathogenic Bacteria Growth - Temperature Abuse	CHP 13: *C. botulinum* Toxin	CHP 14: *S. aureus* Toxin – Drying	CHP 15: *S. aureus* Toxin – Batter	CHP 16: Pathogenic Bacteria Survival Through Cooking or Pasteurization	CHP 17: Pathogenic Bacteria Survival Through Processes Designed to Retain Raw Product Characteristics	CHP 18: Pathogenic Bacteria Contamination After Pasteurization and Specialized Cooking Processes	CHP 19: Allergens and Food Intolerance Substances [4]	CHP 20: Metal Inclusion	CHP 21: Glass Inclusion
Stuffed crab, shrimp, finfish, and other fish.	Reduced oxygen packaged (e.g., mechanical vacuum, MAP, CAP, or hermetically sealed).	✓	✓						✓	✓	
Stuffed crab, shrimp, finfish, and other fish.	Other than reduced oxygen packaged.	✓							✓	✓	
Uncooked prepared food.	Reduced oxygen packaged (e.g., mechanical vacuum, steam flush, hot fill, MAP, CAP, hermetically sealed, or packed in oil).	✓	✓						✓	✓	✓
Uncooked prepared food.	Other than reduced oxygen packaged.	✓							✓	✓	✓

ACRONYMS: ***C. botulinum*** = *Clostridium botulinum*; ***S. aureus*** = *Staphylococcus aureus*; **MAP** = modified atmosphere packaging; **CAP** = controlled atmosphere packaging; and **LACF** = low-acid canned food

FOOTNOTES:

1. You should include potential hazards from more than one finished product food category if your product fits more than one description.
2. Controls for this hazard need not be included in HACCP plans for shelf-stable acidified and LACFs. See Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation (21 CFR 113), called the LACF Regulation in this guidance document, and Acidified Foods regulation (21 CFR 114) for mandatory controls.
3. This hazard does not apply to highly refined fish oil.
4. Applies to finfish and crustacean only in accordance with the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004. Molluscan shellfish are not subject to FALCPA.
5. This hazard applies to hot smoked fish.
6. This hazard applies to dried uneviscerated fish in any type of packaging and to other dried fish and fishery products in reduced oxygen packaging used to prevent rehydration. Fish and fishery products are defined in 21 CFR 123.3.

NOTES:

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

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

UNDERSTAND THE POTENTIAL HAZARD

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

- **Strategies for control of pathogens**

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

- Controlling the source (i.e., harvest waters) of molluscan shellfish and the time from exposure to air (i.e., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the amount of moisture that is available for pathogenic bacterial growth (water activity) in the product by formulation (covered in Chapter 13);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the level of acidity (pH) in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by Chapter 13, for refrigerated acidified products);
- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *Clostridium botulinum*, in Chapter 13; and for *Staphylococcus aureus* in hydrated batter mixes, in Chapter 15);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16) or retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation (hereinafter, the Low-Acid Canned Foods (LACF) Regulation), 21 CFR 113);
- Killing pathogenic bacteria by processes that retain raw product characteristics (covered in Chapter 17).

- **Molluscan shellfish**

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

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

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

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

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

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

Control of pathogens of human or animal origin

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

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

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

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

Control of naturally occurring pathogens

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

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

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

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

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

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

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

- **Fish other than molluscan shellfish**

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

Control of pathogens

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

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

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

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

DETERMINE WHETHER THIS POTENTIAL HAZARD IS SIGNIFICANT.

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

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

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

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

   In addition:

   - Under ordinary circumstances, it would be reasonably likely that an unsafe level of *V. vulnificus* (a naturally occurring pathogen) could enter the process from oysters harvested from areas that have been confirmed as the original source of oysters associated with two or more *V. vulnificus* illnesses (e.g., states bordering the Gulf of Mexico);
   - Under ordinary circumstances, it would be reasonably likely that an unsafe level of *V. parahaemolyticus* could enter the process from oysters harvested from an area that meets any one of the following conditions:
     - The shellfish control authority has conducted a risk evaluation and determined that the risk of *V. parahaemolyticus* illness from the consumption of oysters harvested

from that growing area is reasonably likely to occur. Specific guidance for determining risk can be found in the "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision";

- The shellfish control authority has determined that harvesting occurs in the growing area at a time when average monthly daytime water temperatures exceed 60°F for waters bordering the Pacific Ocean and 81°F for waters bordering the Gulf of Mexico and the Atlantic Ocean (New Jersey and south), except where a more rigorous risk evaluation has led the shellfish control authority to conclude that the risk of *V. parahaemolyticus* illness from the consumption of oysters harvested from that growing area is not reasonably likely to occur;
- The growing area has been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past 3 years.

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

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

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

- **Intended use**

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

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

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

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

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for pathogens from the harvest area:

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

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

    Example:

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

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

    Example:

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

Example:

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

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

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

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

      Example:

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

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

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

      Example:

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

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

3. If the finished product is raw oyster shellstock intended for raw consumption and is harvested from an area where: (1) The shellfish control authority has conducted a risk evaluation and determined that the risk of V. parahaemolyticus illness from the consumption of oysters harvested from that growing area is reasonably likely to occur; (2) the shellfish control authority has determined that harvesting occurs in the growing area at a time when average monthly daytime water temperatures exceed 60°F for waters bordering the Pacific Ocean and 81°F for waters bordering the Gulf of Mexico and the Atlantic Ocean (New Jersey and south); or (3) the waters of the state have been confirmed as the original source of oysters associated with two or more V. parahaemolyticus illnesses in the past 3 years, will it be subjected in your facility to a process that is designed to retain raw product characteristics (e.g., mild heat processing, IQF with extended storage, high hydrostatic pressure processing, or irradiation) and is sufficient to kill V. parahaemolyticus (i.e., reduced to a non-detectable level of less than 30 MPN/gram, as defined in the "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision")?

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

      Example:

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

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

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

      Example:

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

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

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

DEVELOP A CONTROL STRATEGY.

The following guidance provides three examples of control strategies for pathogens from the harvest area. You may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations, except that some parts of "Control Strategy Example 1 - Source Control" are specifically required by the Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products regulation, 21 CFR 123 (called the Seafood HACCP Regulation in this guidance document).

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

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

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

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

Set Critical Limits.

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

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

OR

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

OR

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

AND

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

AND

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

AND

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

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

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

AND

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

  OR

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

AND

- The harvester's license, where applicable;

AND

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

» **How Will Monitoring Be Done?**

- Perform visual checks;

  AND

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

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

- For checking incoming tags:
  - Every container;

  OR

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

  OR

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

  AND

- For checking licenses:
  - Every delivery;

  AND

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

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Reject the lot;

  OR

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

  OR

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

AND

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

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

  OR
- Modify labeling practices.

Establish a Recordkeeping System.

For shellstock:

- Receiving record that documents:
  - Date of harvest;

    AND
  - Location of harvest by state and site;

    AND
  - Quantity and type of shellfish;

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

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

    AND
  - Certification number of the shipper, where applicable;

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

For shucked molluscan shellfish:

- Receiving record that documents:
  - Date of receipt;

    AND
  - Quantity and type of shellfish;

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

    AND
  - Presence of the raw consumption advisory.

Establish Verification Procedures.

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

TABLE 4-1

CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

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

Pathogens from the harvest area may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., natural toxins, environmental chemical contaminants and pesticides, and pathogens during processing).

Example Only
See Text for Full Recommendations

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

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

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

Set Critical Limits.

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

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

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

Note: AMMAT is determined by the shellfish control authority.

OR

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

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

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

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

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

OR

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

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

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

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

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

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

  AND
- The time shellstock was placed under refrigeration;

» **How Will Monitoring Be Done?**

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

    OR
  - Check the harvester's log or tags;

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

    OR
  - Ask the harvester.

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

- Every delivery.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Reject lots that do not meet the critical limit;

  OR

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

  OR

- Destroy the product;

  OR

- Divert the product to a non-food use.

AND

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

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

Establish a Recordkeeping System.

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

    AND

  - Time shellstock was placed under refrigeration;

    AND

  - AMMWT.

Establish Verification Procedures.

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

TABLE 4-2

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

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

Pathogens from the harvest area may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., natural toxins, environmental chemical contaminants and pesticides, and pathogens during processing).

Example Only
See Text for Full Recommendations

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

AMMWT = Average Monthly Maximum Water Temperature

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UNDERSTAND THE POTENTIAL HAZARD

Parasites (in the larval stage) consumed in uncooked or undercooked 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* (*C. sinensis*), *Opisthorchis spp., Heterophyes spp., Metagonimus spp., Nanophyetes salmincola,* and *Paragonimus spp.*) are of most concern in seafood. Most of these parasites cause mild-to-moderate illness, but severe symptoms can occur. Roundworms may embed in the intestinal wall and cause nausea, vomiting, diarrhea, and severe abdominal pain and sometimes may penetrate the intestine. Tapeworms can cause abdominal swelling and abdominal cramps and may lead to weight loss and anemia. Intestinal flukes (*Heterophyes spp., Metagonimus spp.,* and *Nanophyetes salmincola*) may cause abdominal discomfort and diarrhea. Some intestinal flukes may also migrate to and damage the heart and central nervous system. Liver flukes (*C. sinensis* and *Opisthorchis spp.*) and lung flukes (*Paragonimus spp.*) may migrate to the liver and lung and sometimes cause serious problems in other vital organs.

Some products that have been implicated in human parasite infection are the following: 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 survey of U.S. gastroenterologists confirmed that seafood-borne parasitic infections occur in the United States with sufficient frequency to recommend preventive controls 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 bacterial pathogens is provided in Chapters 13 (hot smoking) and 16 (cooking and pasteurization). Regulatory requirements for retorting (i.e., thermal processing of low acid canned foods) are contained in the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (hereinafter, the Low-Acid Canned Foods (LACF) Regulation). This guidance does not provide further information 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 species and source 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 to freezing than roundworms.

Freezing and storing at an ambient temperature of -4°F (-20°C) or below for 7 days (total time), or freezing at an ambient temperature of -31°F (-35°C) or below until solid and storing at an ambient temperature of -31°F (-35°C) or below for 15 hours, or freezing at an ambient temperature of -31°F (-35°C) or below until solid and storing at an ambient temperature of -4°F (-20°C) or below for 24 hours are sufficient to kill parasites. Note that these conditions may not be suitable for freezing particularly large fish (e.g., thicker than 6 inches).

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 sacs (skeins), but generally not within the eggs themselves. For this reason, eggs that have been removed from the sac 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.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether parasites are a significant hazard at a 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 3-2 and 3-3 (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 know or have reason to know that the fish will be consumed without thorough cooking by the end user or if you represent, label, or intend for the product to be consumed in that manner.

   Species of fish not listed with a parasite hazard in Tables 3-2 and 3-3 may have a parasite hazard that has not been identified if these fish are not customarily consumed raw or undercooked, or if the hazard occurs in certain localized harvest areas that are not known commercial sources of fresh fish for the U.S. You should consider this possibility in your hazard analysis.

   Species that normally have a parasite hazard as a result of consuming infected prey apparently do not have the same parasite hazard when raised only on pelleted feed 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, fresh fish, or plankton may have a parasite hazard, even when wild-caught fish of that species do not normally have a parasite hazard. Pellet fed fish that sometimes depend on wild-caught prey to supplement their diet may have a parasite hazard. In addition, fish raised in freshwater may have a parasite hazard from trematodes because these parasites enter the fish through the skin rather than in the food. You should verify the culture methods used by your aquaculture producers before eliminating parasites as a significant hazard.

   If the finished product is fish eggs that have been removed from the sac (skein) and rinsed, the fish eggs are not reasonably likely to contain parasites and you need not consider such product as having a parasite hazard. However, unrinsed fish eggs or fish eggs that remain in the sac ordinarily will have a parasite hazard if the species is identified in Table 3-2 or 3-3 as having a parasite hazard.

   If you receive the fish frozen and have documented assurance from your supplier that the fish are frozen in a way that will

kill the parasites (e.g., consistent with the guidance in this chapter), you do not need to identify the hazard of parasites as reasonably likely to occur in your product.

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

2. Can the parasite hazard that was introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?

   Parasites should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard that was introduced at an earlier step or to reduce to an acceptable level the likelihood of occurrence of the hazard. Preventive measures for parasites can include:

   - Retorting (covered in 21 CFR 113, the LACF Regulation);
   - Hot smoking (covered in Chapter 13);
   - Cooking and pasteurization (covered in Chapter 16);
   - Freezing (covered in this chapter).

- **Intended use**

If the consumer intends to cook the fish thoroughly before consumption, then you do not need to consider the hazard significant, even if Table 3-2 or 3-3 lists the species as having a potential parasite hazard. In order to eliminate parasites as a significant hazard when you are unsure of the product's intended use, you should obtain documented assurance from the subsequent processor, restaurateur, or institutional user (e.g., prison or nursing home) that the fish will be processed in a way that will kill the parasites.

Example:

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

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for parasites:

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

   a. If the process contains a heating step, you should identify the heating step as the CCP and would not need to identify receiving as a CCP for this hazard.

      See Chapters 13 (*Clostridium botulinum* toxin formation) and 16 (Pathogen bacteria survival through cooking or pasteurization), and the LACF Regulation (21 CFR 113) for further information on this control strategy.

      Example:

      A hot-smoked salmon processor should set the CCP for parasites at the hot-smoking step and would not need to identify the receiving step as a CCP for this hazard.

   b. If the process does not contain a heating step, you should identify a freezing step as the CCP, and would not need to identify receiving as a CCP for this hazard.

      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 CCP for this hazard.

      This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Freezing."

DEVELOP A CONTROL STRATEGY.

The following guidance provides an example of a control strategy for parasites. It is important to note that you may select a control strategy that is different from that which is suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

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

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Freezing	✓	✓

- **CONTROL STRATEGY EXAMPLE - FREEZING**

Set the Critical Limits.

- Freezing and storing at an ambient temperature of -4°F (-20°C) or below for 7 days (total time);

  OR

- Freezing at an ambient temperature of -31°F (-35°C) or below until solid and storing at an ambient temperature of -31°F (-35°C) or below for 15 hours;

  OR

- Freezing at an ambient temperature of -31°F (-35°C) or below until solid and storing at an ambient temperature of -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 6 inches). It may be necessary for you to conduct a study to determine effective control parameters specific to your freezing method, fish thickness, fish species, method of preparation, and target parasites.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Freezer temperature;

  AND

- Length of time fish is held at freezer temperature or held solid frozen, as appropriate:
  - For 7-day freezing critical limit:
    - Starting time of freezing and ending time of the frozen storage period;

    OR
  - For 15-hour and 24-hour freezing critical limits:
    - Time when all fish are solid frozen and ending time of the frozen storage period.

» **How Will Monitoring Be Done?**

- Use a continuous temperature-recording device (e.g., a recording thermometer);

  AND

- Perform a visual check of time and physical check of solid frozen condition, as appropriate.

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

- For temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once during each freezing or storage period, but no less than once per day;

  AND

- For time:
  - Each batch, at the beginning and end of the freezing or storage period, as appropriate.

» **Who Will Do the Monitoring?**

- The device itself performs the monitoring. Any person who has an understanding of the nature of the controls may perform the visual check of the data generated by this device to ensure that the critical limits have been met consistently.

Establish Corrective Action Procedures.

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

- Refreeze and store the product at an ambient temperature of -4°F (-20°C) or below for 7 days (total time), or refreeze it at an ambient temperature of -31°F (-35°C) or below until solid

and store at an ambient temperature of -31°F (-35°C) or below for 15 hours, or refreeze it at an ambient temperature of -31°F (-35°C) or below until solid and store at an ambient temperature of -4°F (-20°C) or below for 24 hours. Note that these conditions may not be suitable for freezing particularly large fish (e.g., thicker than 6 inches);

OR

- Destroy or divert the product to a non-raw or non-food use.

AND

Take the following corrective action 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.

Establish a Recordkeeping System.

- Record of continuous temperature monitoring;

  AND

- Record of visual checks of recorded data.

  AND

- Record of notation of the start time and end time of the freezing periods;

  AND

- Record of notation of the time the fish is solid frozen (if appropriate).

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to the National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

  AND

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

  AND

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

  AND

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

TABLE 5-1

CONTROL STRATEGY EXAMPLE - FREEZING

This table is an example of a portion of a Hazard Analysis Critical Control Point plan using "Control Strategy Example 1 - Freezing." This example illustrates how a processor can control parasites in frozen salmon fillets with pin bones removed, where the finished product will be distributed to other processors for the production of refrigerated lox. It is provided for illustrative purposes only.

Parasites may be only one of several significant hazards for this product. Refer to Tables 3-2, and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides, aquaculture drugs, food and color additives, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			MONITORING						
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	WHAT	HOW	FREQUENCY	WHO	CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
Freezing	Parasites	Blast 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 thermometers	Continuous, with visual check of recorded data at end of each freezing process	Freezer operator	Adjust or repair freezer Refreeze product	Recorder chart with notations for visual temperature check, time solid frozen, and time at end of storage period	Check the recorder thermometer for accuracy and damage and to ensure that it is operational before putting into service; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
			Time when all fish are visually solid frozen and time at end of storage period	Visual and physical checks	Each batch, at beginning and end of storage period				

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CHAPTER 6: **NATURAL TOXINS**

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UNDERSTAND THE POTENTIAL HAZARD

Fish and molluscan shellfish contaminated with natural toxins from the water in which they lived can cause consumer illness. Most of these toxins are produced by naturally occurring marine algae (phytoplankton). Fish or molluscan shellfish consume the algae, or animals that have consumed the algae, which causes the toxins to accumulate in the fish's or molluscan shellfish's flesh. The toxin continues to accumulate in the feeding animal's body at each point of consumption and results in higher levels further up the food chain. Typically, contamination occurs following blooms of the toxic algal species; however, toxin contamination is possible even when algal concentrations are low in certain instances. In addition, there are a few natural toxins and harmful compounds, not produced by algae, that are specific to certain fish species.

There are numerous natural toxins identified worldwide; however, there are currently six recognized natural toxin poisoning syndromes that can occur from consuming contaminated fish and fishery products which are:

- amnesic shellfish poisoning (ASP),
- azaspiracid shellfish poisoning (AZP),
- ciguatera fish poisoning (CFP),
- diarrhetic shellfish poisoning (DSP),
- neurotoxic shellfish poisoning (NSP), and
- paralytic shellfish poisoning (PSP).

All safety levels identified through guidance and regulations for natural toxins may be found in "Appendix 5: FDA and EPA Safety Levels in Regulations and Guidance" of this Guide; however, these levels should not be identified in the HACCP plan as they are utilized for confirming illnesses (i.e. CFP), inform advisories for at risk harvest areas (i.e., CFP) and/or make a determination for harvest area closures (i.e., ASP, AZP, DSP, NSP, and PSP.)

Scombrotoxin fish poisoning, resulting from consumption of certain species of fish that have been time/temperature abused, is caused by spoilage bacteria that form biogenic amines, such as histamine, that are not considered natural toxins. Refer to Chapter 7 for information related to scombrotoxin formation and associated controls.

This chapter has been organized to identify specific information regarding the natural toxins and controls that are specifically associated with "fish other than molluscan shellfish" and "molluscan shellfish." Refer to specific sections appropriately.

- **Specific Information Associated with Recognized Natural Toxins in Fish Other Than Molluscan Shellfish**

This section provides information regarding the implicated finfish, geographic regions, and illness characteristics associated with natural toxins in fish other than molluscan shellfish. It is important to note that additional geographic locations may occur because the distribution of the source algae can vary over time. Processors should always be alert to the potential for emerging hazards in harvest waters and fish sources.

While CFP is the prominent syndrome associated with fish as presented in this section, there are other natural toxins that may occur in fish such as ASP and PSP toxins. Refer to specific toxins in the molluscan shellfish section for information regarding other natural toxins that may occur in fish other than molluscan shellfish.

Ciguatera fish poisoning (from ciguatoxin) is commonly related to the consumption of subtropical and tropical reef fish which have accumulated naturally occurring ciguatoxins through their diet. The highest incidences of ciguatoxins occur between latitudes 35° north and 35° south, and include areas of the Caribbean Sea, Gulf of Mexico, and Atlantic, Pacific, and Indian Oceans. Unsafe ciguatoxin levels have also been detected from fish populations in areas such as the Flower Garden Banks of the Gulf of Mexico, and specific areas of Florida, Hawaii, Puerto Rico, and the U.S. Virgin Islands.

Ciguatoxins originate from marine algae, are transferred through the food web, and accumulate in the flesh of reef dwelling fish with the highest levels of the toxin being observed in long-lived fish-eating predators. These fish may then be harvested by commercial or recreational fishermen for human consumption. Due to differences in life history and diet, not all fish within a given region are equally contaminated. Thus, fish caught side by side may contain widely differing toxin levels. Because ciguatoxic endemic areas are localized, the primary seafood processors should recognize and avoid purchasing fish from known and/or emerging areas of concern.

Many fish species have been associated with CFP including but not limited to: barracuda (Family: Sphyraenidae), grouper (Family: Serranidae), snapper (Family: Lutjanidae), jacks and trevally (Family: Carangidae), wrasse (Family: Labridae), mackerel (Family: Scombridae), tang (Family: Acanthuridae), moray eels (Family: Muraenidae), and parrotfish (*Scarus* spp.). Ciguatoxins have also been found in lionfish (*Pterois volitans* and *Pterois miles*) collected in waters surrounding the U.S. Virgin Islands.

CFP is characterized by gastrointestinal symptoms including: nausea, vomiting, and diarrhea. Neurological symptoms include: numbness and tingling of the lips and extremities; itching of hands and feet; joint pain; muscle pain; muscle weakness; reversal and sensitivity to temperature; dizziness; and vertigo. Cardiovascular symptoms may occur and include irregular heartbeat and low blood pressure. The onset of symptoms typically occurs within 6 hours after consuming toxic fish and may persist from several days to weeks. In severe cases, some neurological symptoms may persist for months and can recur for years. Fatalities do not usually occur from CFP; however, isolated fatalities have been reported.

- **Additional Toxins Found in Fish Other Than Molluscan Shellfish**

There are naturally occurring toxins in some fish species that are either not a result or have not yet been proven conclusively to be a result, of marine algae such as: clupeotoxin, ichthyohemotoxin, gempylotoxin, tetramine, tetrodotoxin, and a possible unidentified toxin that causes seafood-associated rhabdomyolysis (sometimes referred to as Haff disease).

Clupeotoxin poisoning is a rare but severe type of seafood poisoning resulting from the consumption of certain filter-feeding fish such as sardines, herring, and anchovies. The exact cause of clupeotoxin poisoning is unknown but it has been suggested that the marine toxin palytoxin, produced by certain marine algae, contributes to this illness. All illnesses as of August 2019 have been linked to fish harvested from African, Caribbean, and Indo-Pacific waters. No suspected cases of clupeotoxin poisoning have been linked to fish harvested from U.S. waters and no cases of clupeotoxin poisoning have occurred in the U.S. Clupeotoxin poisoning is associated with a high mortality rate.

Gempylotoxin(s) are wax esters naturally found in high concentrations in the meat of escolar (*Lepidocybium flavobrunneum*) and oilfish (*Ruvettus pretiosus*). These particular wax esters are indigestible and may cause diarrhea, abdominal cramps, nausea, headache, and vomiting when consumed in sufficient quantities or consumed in lower quantities by sensitive individuals. The exact quantity required to cause these purgative effects is not known and appears to vary based on individual sensitivities. FDA advises against the importation and interstate marketing of these fish. Additionally, deep sea fish species, such as orange roughy (*Hoplostethus atlanticus*), and oreo dory (*Allocyttus* spp*., Pseudocyttus* spp*., Oreosoma* spp*.,* and *Neocyttus* spp*.*) are known to contain lesser amounts of the same indigestible wax esters as escolar and oilfish. Sensitive individuals may also experience symptoms from the consumption of these fish. Improperly handled escolar and oilfish also have been associated with scombrotoxin (histamine) poisoning (Refer to Chapter 7).

Ichthyohemotoxin is found in the blood of a variety of different species of eels and considered a rare form of food poisoning. Known implicated species of eels include *Anguilla anguilla*, *Conger conger*, and *Muraena helena*. Very little is known

about the nature of the toxin. Ichthyohemotoxin manifests in two different forms: 1. Systemic (caused by the consumption of fresh, uncooked blood); and 2. Topical. Symptoms of the systemic form include: diarrhea, bloody stools, nausea, vomiting, hypersalivation, skin eruptions, cyanosis, apathy, irregular pulse, weakness, paresthesia, paralysis, respiratory distress, and possibly death. Symptoms from the topical form includes a severe inflammatory response when raw eel serum comes in contact with eyes or the mouth. Oral symptoms consist of burning, redness of mucosa and hypersalivation. Ocular contact invokes a severe burning sensation and redness of the conjunctivae, lacrimination, and swelling of the eyelids. Eye irritation may persist for a several days. Recovery is usually spontaneous. Care should be taken when handling eels. Cooking has been known to denature the toxic properties.

Tetramine is a toxin that is found in the salivary glands of whelks (*Neptunia* spp.). This hazard can be controlled through the removal of the glands. Symptoms of tetramine poisoning include: double vision, temporary blindness, difficulty in focusing, tingling of the fingers, prostration, nausea, vomiting, diarrhea, and loss of muscle control. Symptoms usually develop within 1 hour of consumption.

Tetrodotoxin poisoning is usually 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 northern puffer fish (*Sphoeroides maculatus*) as of August 2019, which was once harvested and marketed as "sea squab" on the U.S. east coast.

Puffer fish are also known as fugu, swellfish, bok, blowfish, globefish, toadfish, blaasop, or balloonfish, depending on the country of origin. Other fish species such as xanthid crabs, marine gastropods, and goby fish may contain this toxin and have been implicated in tetrodotoxin illnesses outside of the U.S. Reports of these illnesses have mainly been limited to Asia, and involve species unlikely to be imported into the U.S. Although strictly regulated, it should be noted that there have been several cases of tetrodotoxin illness in the U.S. from the consumption of illegally imported and commercially sold puffer fish products in multiple forms (i.e., frozen and dried).

A restriction exists on the importation of all species of puffer fish and fishery products containing puffer fish. See "The Exchange of Letters between Japan and the U.S. Food and Drug Administration Regarding Puffer Fish" (at website: https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm107601.htm), Import Alert #16-20 (at website: https://www.accessdata.fda.gov/cms_ia/importalert_37.html), and the Regulatory Food Code for Retail Foods (at website: https://www.fda.gov/food/retail-food-protection/fda-food-code) for further details regarding importation and control of tetrodotoxin. In addition to tetrodotoxin, some puffer fish have also been found to be contaminated with PSP toxins, which are covered elsewhere in this chapter.

Tetrodotoxin poisoning is characterized by symptoms including: numbness of the lips and tongue; tingling sensation in the face and extremities; headache; abdominal pain; nausea; diarrhea; vomiting; difficulty in walking; paralysis; respiratory distress; difficulty in speech; shortness of breath; blue or purplish discoloration of the lips and skin; lowering of blood pressure; convulsions; mental impairment; irregular heartbeat; and death in extreme cases. Symptoms usually develop within 3 hours after consumption of contaminated fish and may last from 24 to 48 hours. Death from this toxin commonly occurs due to muscle paralysis resulting in respiratory failure when ventilatory support is not accessible.

Seafood-associated rhabdomyolysis (sometimes referred to as Haff disease) was first documented in Russia in 1924 with 1,000 cases being reported over a 15-year period at that time from consuming burbot, eel, and pike. Several cases have been reported in the U.S. from the consumption of commercially available domestic buffalo fish. Other isolated cases have been documented from the consumption of crayfish, salmon and imported canned mackerel. Internationally, similar cases have been reported after the consumption of crayfish in China and recently from amberjack and yellow jack from Brazil. The cause(s) of seafood-associated rhabdomyolysis is unknown. Seafood-associated rhabdomyolysis results in the breakdown of skeletal muscle (rhabdomyolysis), with a risk of acute kidney failure that develops within 24 hours after consuming certain fish. FDA is currently collecting meal remnants from patients diagnosed with seafood-associated rhabdomyolysis to confirm the causative species and research the causative

agent(s).

FDA makes no recommendations in this guidance document and has no specific expectations with regard to specific controls for clupeotoxin, gempylotoxin, ichthyohemotoxin, tetramine, and seafood-associated rhabdomyolysis for use in a processor's HACCP plan(s).

Note: **Venomous Fish**: Care should be taken when handling venomous fish such as lionfish, scorpion fish and certain species of catfish. The potential for harm from consuming the venom of any venom-producing fish has not been adequately investigated. Currently, FDA makes no recommendations in this guidance and has no specific guidance for food processors with regard to controlling the hazard associated with fish venom. Additional information regarding venomous fish may be found in the "Venomous fish" chapter of the FDA's *Bad Bug Book*, which can be found at the following website: https://www.fda.gov/food/foodborne-pathogens/bad-bug-book-second-edition.

- **Specific Information Associated with Recognized Natural Toxins in Molluscan Shellfish**

This section provides information regarding the implicated molluscan shellfish, geographic regions, and illness characteristics that have been historically associated with natural toxin poisoning syndromes. However, it is important to note that historical precedent may not be an adequate guide for future occurrences regarding geographic locations because the distribution of the source algae may vary over time. Processors should always be alert to the potential for emerging hazards in harvest waters.

ASP, AZP, DSP, NSP, and PSP are not considered a likely food safety hazard for 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.

Amnesic shellfish poisoning (from domoic acid) has been associated with molluscan shellfish, crabs, and finfish species. It is most often associated with the consumption of bivalve molluscan shellfish (e.g., mussels, scallops, and razor clams) from the northeast and northwest coasts of North America. Domoic acid has also been identified in the viscera of lobster, Dungeness crab (*Cancer magister*), Tanner crab (*Chionoecetes bairdi*), and Red Rock crab (*Cancer productus*) in these regions. In recent years, levels of domoic acid in Dungeness crab on the west coast have exceeded guidance levels for this toxin and required harvesting closures. Along the west coast of the U.S., domoic acid has also been detected in other fish species including the sardine (*Sardinops sagax*), anchovy (*Engraulis mordax*), Pacific sanddab (*Citharichthys sordidus*), chub mackerel (*Scomber japonicas*), albacore tuna (*Thunnus alalunga*), jack smelt (*Atherinopsis californiensis*), and market squid (*Loligo opalescens*). Domoic acid has also been detected in several finfish species from the U.S. Gulf of Mexico, including plankton-eating fish [e.g., white mullet (*Mugil curema*), menhaden (*Brevoortia partonus*), and predatory species, such as the Florida pompano (*Trachinotus carolinus*), Gulf kingfish (*Menticirrhus littoralis*), and spot (*Leiostomus xanthurus*).]

ASP is characterized by gastrointestinal symptoms including: nausea, vomiting, abdominal cramps, and diarrhea. These symptoms develop within 24 hours of consumption. In severe cases, neurological symptoms may also occur within 48 hours of consumption including: dizziness, headache, seizures, disorientation, short-term memory loss, respiratory difficulty, and coma. In severe cases, ASP should be considered a potentially life-threatening illness. There have been no confirmed cases of ASP in the U.S. since 1987, following the implementation of effective seafood toxin-monitoring programs.

Azaspiracid shellfish poisoning (from azaspiracids) is associated with consumption of bivalve molluscan shellfish. AZP was first recognized following a 1995 outbreak of severe gastroenteritis in the Netherlands which was linked to the consumption of mussels harvested in Ireland. Since then, several outbreaks of AZP have been reported in Europe. In 2008, two cases of AZP were reported in the U.S., and traced to azaspiracid contaminated mussels imported from Ireland. AZP toxins have recently been reported for the first time in Washington State but toxins in excess of guidance levels have not been reported in any commercially harvested shellfish in the U.S. as of August 2019.

AZP is characterized by severe gastrointestinal disorders including: abdominal pain, nausea, vomiting, and diarrhea. Symptoms develop within a few hours following the consumption of contaminated shellfish and can persist for several days. AZP illness is self-limiting and non-fatal.

Diarrhetic shellfish poisoning (from okadaic acid and dinophysistoxins) is generally associated with the consumption of bivalve molluscan shellfish with outbreaks being reported worldwide. In 2008, DSP toxin levels were documented in excess of the guidance level for the first time in several locations along the Texas Gulf Coast during a large algal bloom which led to the first closure of shellfish harvest areas in the U.S.

DSP and DSP-like illnesses have also been associated with shellfish harvested in the Pacific northwest of North America, including Puget Sound and the west coast of Canada. In addition to Texas and Washington State, harvesting closures due to DSP toxins have recently occurred in Maine and Massachusetts. DSP toxins have now been found in shellfish from Alabama, California, Delaware, Maryland, and New York; however, not above guidance levels in commercial growing areas as of August 2019.

DSP is characterized by gastrointestinal symptoms including: nausea, abdominal pain, vomiting, and diarrhea. In addition, headaches and fever may also occur and are usually associated with dehydration. Symptoms typically develop within 3 hours after consuming contaminated shellfish and may persist for several days. DSP is normally considered self-limiting and non-life threatening. However, complications could occur as a result of severe dehydration in compromised individuals. Due to the similarity of symptoms, DSP can be misidentified as a bacterial or viral illness.

Neurotoxic shellfish poisoning (from brevetoxins) in the U.S. is generally associated with the consumption of bivalve molluscs (clams and oysters) from coastal waters of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. Gastropods (whelk) harvested from the Florida Gulf Coast have also caused NSP. In addition, there have been occurrences of the toxins in New Zealand shellfish and reports of brevetoxin-producing algae in other regions of the world. The largest recorded NSP outbreak occurred in New Zealand from 1992 – 1993; cockles, green shell mussels, and oysters were implicated in the outbreak.

NSP is characterized by gastrointestinal symptoms including diarrhea and vomiting. Neurological symptoms include: tingling and numbness of the lips, tongue, and throat; muscular aches; and dizziness. Symptoms develop within a few hours of consuming contaminated seafood. Treatment consists mainly of supportive care.

Paralytic shellfish poisoning (from saxitoxins) in the U.S. is most often associated with the consumption of bivalve molluscan shellfish (e.g., clams, cockles, mussels, oysters, and scallops) from the northeast and northwest coastal regions. PSP in other parts of the world has been associated with molluscan shellfish from tropical to temperate waters.

Bivalve molluscan shellfish can retain the toxin for different lengths of time. Some species depurate toxins rapidly, whereas others are much slower to depurate the toxins. This lengthens the period of time they pose a human health risk from consumption. For example, most species of bivalves can eliminate the toxin within weeks; however, others such as Washington butter clams, sea scallops, and Atlantic surfclams have been known to retain high levels of toxins for months to more than five years.

Certain predatory gastropods (e.g., conch, snails, and whelk) are also known to accumulate PSP toxins by feeding on toxic bivalve molluscs. In particular, moon snails and whelk from the northeast U.S. are commonly found to contain PSP toxins. Gastropods can accumulate high concentrations of toxin through their predation on toxic bivalves and those concentrations can exceed the levels found in the bivalves. Since gastropods accumulate high concentrations of the toxins, they are a significant risk to humans if consumed when harvested from closed waters or waters where PSP has been found. Gastropods may also retain the toxin for longer periods of time than bivalve molluscan shellfish since they are slow to depurate the toxin.

Abalone from South Africa and Spain have been reported to contain PSP toxins, although there have been no reports of the toxin in abalone from U.S. waters. Similarly, PSP toxins have been reported in echinoderms (e.g., sea cucumbers) and cephalopods (e.g., octopi and squid) harvested for human consumption from Australia and Portugal; however, there have been no reports of PSP toxins in echinoderms or cephalopods from U.S. waters. In the U.S., moon snails and whelks from the northeast U.S. are commonly found to contain PSP toxins. PSP toxins have also been reported in the viscera of mackerel (*Scomber scombrus*), lobster (*Homarus* spp.), Dungeness crab (*Metacarcinus magister*), Tanner crab (*Chionoecetes bairdi*), and Red Rock crab (*Cancer productus*). While the viscera of mackerel are not usually consumed, the viscera of lobsters and crabs may pose a health hazard

if harvested from contaminated waters. In 2008, FDA advised against the consumption of American lobster tomalley from New England waters due to unusually high levels of PSP toxins.

In 2002, the first reported case of PSP in the U.S. from the consumption of puffer fish harvested from the central east coast of Florida was identified. PSP toxins were detected in southern (*Sphoeroides nephelus*), checkered (*Sphoeroides testudineus*), and bandtail (*Sphoeroides spengleri*) puffer fish. As a result, Florida Department of State has prohibited the taking of puffer fish (genus Sphoeroides) from the central east coast of Florida per rule 68B-3.007.

PSP symptoms can include: vomiting; abdominal pain; numbness, burning, or tingling of the face and extremities; incoherent speech; loss of coordination and muscle paralysis; shortness of breath; and in severe cases respiratory paralysis. Respiratory paralysis can result in death if ventilator support is not provided in a timely manner. The onset of symptoms can develop within 2 hours post consumption of the PSP toxin contaminated seafood. PSP is an extremely potent toxin with a high mortality rate in cases where medical support is not available.

- **Additional Toxins Found in Molluscan Shellfish**

A number of toxins identified in molluscan shellfish have shown toxicity in mouse studies but have not been linked to human illnesses. These toxins are as follows:

- Cyclic imines have been found in phytoplankton and/or molluscan shellfish in Canada, Denmark, New Zealand, Norway, Scotland, Tunisia, and the U.S.
- Pectenotoxins (PTX) have been detected in phytoplankton and/or molluscan shellfish in Australia, Italy, Japan, New Zealand, Norway, Portugal, Spain, and the U.S.
- Yessotoxins (YTX) have been detected in phytoplankton and/or molluscan shellfish in Australia, Canada, Italy, Japan, New Zealand, Norway, the United Kingdom, and the U.S.

Note: PTX and YTX have been found to co-occur with DSP toxins (okadaic acid and dinophysistoxins) in shellfish.

At this time, FDA makes no recommendations in this guidance document and has no specific expectations with regard to controls for PTX, YTX, and cyclic imines for processors' Hazard Analysis Critical Control Point (HACCP) plans.

- **Natural Toxin Controls**

Natural toxins are odorless, tasteless, colorless, and temperature stable; therefore, they cannot be reliably eliminated through cooking or freezing.

Amnesic shellfish poisoning and paralytic shellfish poisoning in fish other than molluscan shellfish: Where ASP or PSP is a potential hazard in finfish or crustaceans, states have generally closed or restricted fishing areas. Harvesters and processors must rely on public announcements, postings, and advisories by state authorities to avoid harvesting or receiving finfish or crustacean from potential unsafe waters. In addition, removal and destruction of the viscera may eliminate the hazard, and at times is required by state public health authorities. For example, eviscerating fish or harvesting the adductor muscle from the scallop can eliminate the food safety hazards of ASP and/or PSP.

Ciguatera Fish Poisoning: Due to the nature of CFP, a harvest water management system similar to the molluscan shellfish system is not an appropriate control measure. Some states issue advisories identifying endemic areas. For areas without an advisory system, fishermen and processors must rely on their knowledge to avoid harvesting and receiving fish from areas where illnesses have been associated. The state or local department of health and/or associated departments of fisheries would be able to further assist in determining whether harvest areas are free of ciguatoxins.

Guidance levels have been established for Caribbean and Pacific CFP toxins (see Appendix 5) but at this time, these guidance levels are only used to confirm CFP as the cause of illnesses/outbreaks, to establish CFP endemic regions, and to determine potential CFP-causing species based on the analysis of meal remnants involved in cases of CFP.

Molluscan Shellfish: To minimize the risk of molluscan shellfish containing natural toxins from the harvest area, state and foreign government agencies, called shellfish control authorities, manage harvesting activities, based in part on the presence of natural toxins in water and shellfish meats. Shellfish control authorities may also use cell counts of the toxin-forming algae in the harvest waters to manage shellfish harvest areas, and in areas with no previous history of illnesses.

States must have a Biotoxin Contingency Plan that will provide information regarding actions to be taken if toxin-forming algae or natural toxins are likely or have been detected. Shellfish control authorities exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where shellfish are determined to be safe. In this context, molluscan shellfish include oysters, clams, mussels, and scallops, except where the scallop product contains only the shucked adductor muscle.

Other significant elements of shellfish control authorities' efforts to manage the harvesting of molluscan shellfish include requirements that:

- Molluscan shellfish harvesters be licensed (note that licensing may not be required in all jurisdictions);
- Processors that ship, reship, shuck, or repack molluscan shellfish be certified;
- Containers of molluscan shellfish (shellstock) bear a tag with the harvester's identification number, type and quantity of shellfish, date of harvest, and harvest location;

AND

- Containers of shucked molluscan shellfish bear a label with the processor's name, address, and certification number.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT

The following guidance will assist you in determining whether natural toxins are considered a significant hazard at a processing step:

1. Is it reasonably likely that unsafe levels of natural toxins will be introduced at this processing step (e.g., is the natural toxin present in the raw material at an unsafe level)?

Tables 3-2 and 3-3 in Chapter 3 identify the species of vertebrate and non-vertebrate species of fish and molluscan shellfish for which natural toxins are 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 for those species. There may be other circumstances in a geographic area to conclude that a particular natural toxin is reasonably likely to occur at unsafe levels in those fish or molluscan shellfish. The information provided in this *Guide* and the historical occurrence of a toxin in the fish or molluscan shellfish, where toxin levels exceed established guidance, should be utilized to make a determination whether these fish and molluscan shellfish are harvested and received at the processor. Awareness of emerging geographic areas and additional species of fish should be monitored and acted upon appropriately. Examples of fish species recently identified with the hazard of natural toxins are lobster, specifically the tomalley, containing PSP, anchovies containing ASP, and lionfish have been found with levels of CFP that can cause illness.

The following preventive measures for natural toxins can be applied as appropriate:

- Fish other than molluscan shellfish:
    - Ensuring that incoming fish have not been caught in an area from which harvesting is prohibited, restricted due to the presence of a natural toxin, or where an advisory exists such as for the presence of CFP.
- Molluscan shellfish:
    - Ensuring that incoming molluscan shellfish (shellstock) are from an Approved or Conditionally Approved area in the open status;
    - Ensuring that incoming molluscan shellfish are properly tagged or labeled; and
    - Ensuring that incoming molluscan shellfish are supplied by a licensed harvester (where licensing is required by law) or by a certified dealer.

FDA requires both primary and secondary processors of raw molluscan shellfish to implement steps at receiving to assure that their shellfish originate from safe sources.

2. Can natural toxins that were introduced at unsafe levels at an earlier step be eliminated or reduced to an acceptable level here?

Even though natural toxins should be considered a significant hazard at any processing step, they are usually controlled at receiving by the primary processor who has the ability to directly communicate with the harvester

to identify the harvest locations. FDA also requires subsequent processors who receive raw molluscan shellfish to consider natural toxins as a significant hazard. Similarly, the hazard usually may be controlled at receiving where the processor has the ability to assure that the shellfish has originated from certified facilities.

Since, natural toxins are not eliminated through cooking or freezing, subsequent processing steps after receiving the potentially contaminated fish are unlikely to eliminate the hazard. Therefore, if the fish or molluscan shellfish has been identified as potentially containing the hazard of natural toxins, and no measures were taken to prevent its harvest from endemic areas, the processor should not accept the fish or molluscan shellfish.

If a processor chooses to implement controls other than at the receiving step, those controls must provide an equivalent assurance of safety and should be supported by sound scientific evidence. There are limited instances where processing may in fact be able to remove the toxin from the consumed part of the fish or molluscan shellfish. These exceptions are dependent on the type of fish or molluscan shellfish, toxin, and process. Examples include but are not limited to eviscerating the fish, such as lobsters, crabs, and anchovies, or only receiving the adductor muscle of scallops.

- **Intended Use**

In most cases, it is unlikely that the intended use of the product would determine whether the hazard of natural toxin is significant. An exception is with certain products where only the muscle tissue will be consumed. For example, where the finished product is **only** the shucked adductor muscle of the scallop, it is reasonable to assume that the product will not contain natural toxins. In this case, you may not need to identify natural toxins as a significant hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for natural toxins.

Where preventive measures during processing, such as those described above, are not feasible, the hazard of natural toxins should be controlled at the receiving step. Two strategies have been identified as controls and are referred to in this chapter as:

- "Control Strategy Example 1 – Source Control for Fish Other Than Molluscan Shellfish" and
- "Control Strategy Example 2 – Harvest Area Control for Molluscan Shellfish."

DEVELOP A CONTROL STRATEGY.

The following guidance provides two control strategy examples for natural toxins. A control strategy different from those suggested is acceptable, provided it complies with requirements of all applicable food safety laws and regulations.

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

Control Strategy	May apply to primary processor	May apply to secondary processor
Source control for fish other than molluscan shellfish	✓	
Harvest area control for molluscan shellfish	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 – SOURCE COUNTROL FOR FISH OTHER THAN MOLLUSCAN SHELLFISH**

This strategy only applies to primary processors (processors that receive or off-load the fish from the harvest vessel).

Set Critical Limits.

Suspect fish may not be received by the primary processor when harvest locations are:

- Closed to fishing by foreign, federal, state, tribal, territorial, or local authorities (e.g., certain counties in Florida for puffer fish);

  OR

- The subject of a consumption advisory for ASP, AZP, CFP, DSP, NSP, PSP, or other naturally occurring toxins;

  OR

- Known to be contaminated with ciguatoxin.

Establish Monitoring Procedures.

➢ **What Will Be Monitored?**

- The status of the harvest location identified on the harvest vessel records are not restricted, subject of an advisory, or prohibited from harvest based on governmental or other known resources, or through declaration stating that the harvest area are free from natural toxins.

➢ **How Will Monitoring Be Done?**

- Obtain assurances through visual examination of the harvest records for the harvest area location, or declaration identifying the harvest area location is not under a restriction, advisory or prohibition from fishing.

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

- Every lot of raw fish received from the harvest vessel.

➢ **Who Will Do the Monitoring?**

- Any person with an understanding of the nature of the controls and areas of restricted fishing due to natural toxin hazard.

Establish Corrective Action Procedures.

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

- Reject the lot.

AND

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

- Discontinue use of the supplier until evidence is obtained that harvesting practices have changed through record review of harvest locations.

Establish a Recordkeeping System.

- Receiving record(s) that documents the location and status (e.g., prohibited, restricted, or unrestricted) of the harvest area.

Establish Verification Procedures.

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

- Periodically monitor governmental and other resources for the most current information regarding harvest restrictions, advisories, and fishing prohibitions due to natural toxins.

TABLE 6-1

Control Strategy Example 1 – SOURCE CONTROL FOR FISH OTHER THAN MOLLUSCAN SHELLFISH

This example table illustrates a hypothetical application of the control strategy just presented in "Control Strategy Example 1 – Source Control for Fish Other Than Molluscan Shellfish." The example illustrates the basic control for natural toxins by a primary processor receiving locally harvested grouper. It is provided for illustrative purposes only.

Natural toxins may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential species or process related hazards.

Example Only: See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving fresh fish - Grouper	Natural toxins - ciguatoxin	Grouper may not be received when a harvest location is under a regulatory or other ciguatoxin advisory, or for which there is information from a valid scientific source that ciguatoxin exists	Harvest vessel records to ensure harvest locations are not identified in a regulatory or other advisory, or locations where ciguatoxin exist.	Visual examination of harvest vessel records for harvest locations and compared with known ciguatoxin locations	Records for every lot of grouper received	Receiving employee with knowledge of harvest locations and hazard	Reject lot Discontinue use of the supplier until evidence is obtained that harvesting practices have changed through examination of harvest records compared to location intel	Receiving record	Review monitoring and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 – HARVEST AREA CONTROL FOR MOLLUSCAN SHELLFISH**

Set Critical Limits.

- All containers of shellstock received from a harvester must bear a tag identifying the:
  - Date and place of harvest (by state and site),
  - Type and quality 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);

OR

- For bulk shipments of shellstock where the shellstock is not containerized, the shellstock must be accompanied by a bill of lading or similar shipping document that contains the same information;

OR

- All containers of shellstock received from a processor must bear a tag identifying the processor who supplied the shellstock and that discloses the:
  - Date and place of harvest (by state and site),
  - Type and quantity of shellfish,

    AND
  - The certification number of the processor;

OR

- All containers of shucked molluscan shellfish must bear a label identifying the packer or repacker that identifies the:
  - Name,
  - Address,

    AND
  - Certification number of the packer or re-packer of the product;

AND

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

Note: The National Shellfish Sanitation Program (NSSP) allows for harvest of surf clams and quahogs in federal waters closed due to the risk of PSP utilizing the onboard screening dockside testing protocol. Refer to the NSSP for specific requirements.

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: Both primary and secondary processors of molluscan shellfish are required to implement source controls in their HACCP plans. Only the primary processor needs to apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters. The source controls listed in this critical limit are required under 21 CFR 123.28(c).

Establish Monitoring Procedures.

➢ **What Will Be Monitored?**

- Information listed on tags, or on the bill of lading, or similar shipping document accompanying bulk shipments of shellstock which includes at a minimum;
  - Date of harvest;
  - Location of harvest by state and site;
  - Quantity and type of shellfish;
  - Name of the harvester, name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority (for shellstock received directly from the harvester only);
  - Number and date of expiration of the harvester's license, where applicable;

AND

- Certification number of the shipper, where applicable.

AND

- Receiving information on whether the harvest area is authorized for harvest by a shellfish control authority or information regarding closures of federal harvest waters by an agency of the federal government.

AND

- The harvester's license.

OR

- Information declared on labels on containers of incoming shucked molluscan shellfish such as:
  - Name of the packer or repacker of the product;
  - Address of the packer or repacker of the product;

    AND
  - The certification number of the packer or re-packer of the product.

➢ How Will Monitoring Be Done?

- Visual examination of the harvest area location through harvest records to ensure they are not from areas under a restriction, advisory or prohibition from harvesting;

  AND
- Obtain assurance from shellfish control authorities from the state or country in which your shellstock are harvested that the harvest area is open for harvest.

➢ How Often Will Monitoring Be Done (Frequency)?

- Checking incoming tags:
  - Every container received;

  OR
- Checking the bill of lading or similar shipping document:
  - Every delivery received:

  OR
- Checking incoming labels:
  - At least three containers randomly selected from every lot received;

AND

- Checking licenses:
  - Every delivery received.

➢ Who Will Do the Monitoring?

- Any person with an understanding of the nature of the controls and closures.

Establish Corrective Action Procedures.

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

- Reject the lot.

AND

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

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

Establish a Recordkeeping System.

For shellstock:

- Receiving record(s) that documents:
  - Date of harvest;
  - Location of harvest by state and site;
  - Quantity and type of shellfish;
  - Name of the harvester, name of registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority (for shellstock received directly for the harvester only);
  - Number and date of expiration of the harvester's license, where applicable;

    AND
  - Certification number of the shipper, where applicable.

For shucked molluscan shellfish:

- Receiving records that documents:
  - Date of receipt;
  - Quantity and type of shellfish;

AND

- Name and certification number of the packer or re-packer.

Establish Verification Procedures.

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

TABLE 6-2

Control Strategy Example 2 – HARVEST AREA CONTROL FOR MOLLUSCAN SHELLFISH

This example table illustrates a hypothetical application of the control strategy just presented in "Control Strategy Example 2 – Harvest Area Control for Molluscan Shellfish." This example illustrates how a primary processor of shellstock oysters, could control natural toxins in shellstock oysters received directly from a harvester. It is provided for illustrative purposes only.

Natural toxins may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential species or process related hazards.

Example Only: See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5) Monitoring	(6)	(7)	(8)	(9)	(10)
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving shellstock	Natural toxins	All incoming shellstock must be tagged with the date and place of harvest, type and quantity of shell-fish, and name or registration num-ber of the harvest-er's vessel	Informa-tion on incoming shellstock tags	Visual checks	Every sack	Receiving employee	Reject untagged sacks; AND Discontinue use of the supplier until evidence is obtained that tagging practices have changed	Receiving record	Review monitoring and corrective action records within 1 week of preparation

(1)	(2)	(3)	(4)	(5) Monitoring	(6)	(7)	(8)	(9)	(10)
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
		All shellstock must be harvested from an Approved or Conditionally Approved area	Harvest site on tags	Visual checks; Ask the shellfish control authority from the state or country in which the shellstock are harvested whether the area is authorized for harvest	Every lot	Receiving employee	Reject lots from unapproved waters; AND Discontinue use of the supplier until evidence is obtained that harvesting practices have changed		
		All shellstock must be from a licensed harvester	Harvester's license	Visual check for number and expiration date	Every delivery from harvester	Receiving employee	Reject delivery from unlicensed harvesters; AND Discontinue use of the supplier until evidence is obtained that the harvester has secured a license		

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NOTES:

CHAPTER 7: Scombrotoxin (Histamine) Formation

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

UNDERSTAND THE POTENTIAL HAZARD.

Scombrotoxin (histamine) formation as a result of time and temperature abuse of certain species of fish can cause consumer illness. The illness is 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 the subject of Chapter 8.

Seafood-related scombrotoxin poisoning is primarily associated with the consumption of tuna, mahi-mahi, marlin, and bluefish. Table 3-2 (Chapter 3) identifies other species that are also capable of developing elevated levels of histamine when temperature abuse occurs.

The illness caused by the consumption of fish in which scombrotoxin has formed is most appropriately referred to as "scombrotoxin poisoning." The illness has historically been known by other names. Originally, the illness was termed "scombroid poisoning" because of its association with fish in the families Scombridae and Scomberesocidae. However, other species of fish are now known to cause the illness. The terms "histamine poisoning" and "histamine fish poisoning" have also been applied to the illness. However, because biogenic amines other than histamine have been associated with the illness, these terms also present difficulties. Nonetheless, this chapter refers to control measures to prevent the formation of histamine. It is expected that the methods of control used to inhibit the bacteria that result in histamine formation will also inhibit the bacteria that produce other biogenic amines.

Symptoms of scombrotoxin poisoning include tingling or burning in or around the mouth or throat; rash or hives on the upper body; drop in blood pressure; headache; dizziness; itching of the skin; nausea; vomiting; diarrhea; asthmatic-like constriction of the air passage; heart palpitation; and respiratory distress. Symptoms usually occur within a few minutes to a few hours of consumption and last from 12 hours to a few days.

- **Scombrotoxin (histamine) formation**

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

Histamine-forming bacteria are capable of growing and producing histamine over a wide temperature range. Growth of histamine is more rapid, however, at high-abuse temperatures (e.g., 70°F (21.1°C) or higher) 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, which is commonly associated with organoleptically detectable decomposition. Nonetheless, there are a number of opportunities for histamine to form under more moderate-abuse temperature conditions.

Once the enzyme histidine decarboxylase is present in the fish, 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 remains stable while in the frozen state and may be reactivated very rapidly after thawing.

Freezing may inactivate some of the enzyme-forming bacteria. Both the enzyme and the bacteria can be inactivated by cooking. However, once histamine is produced, it cannot be eliminated by heat (including retorting) or freezing. After cooking, recontamination of the fish with the enzyme-producing bacteria is necessary for additional histamine to form. For these reasons, histamine development is more likely in raw, unfrozen fish but should not be discounted in other product forms of scombrotoxin-forming fish species.

The kinds of bacteria that are associated with histamine development are commonly present in the saltwater environment. They naturally exist on the gills, on external surfaces, and in the gut of live, saltwater fish, with no harm to the fish. Upon death, the defense mechanisms of the fish no longer inhibit bacterial growth in the muscle tissue, and histamine-forming bacteria may start to grow, resulting in the production of histamine. Evisceration and removal of the gills may reduce, but not eliminate, the number of histamine-forming bacteria. Packing of the visceral cavity with ice may aid in chilling large fish in which internal muscle temperatures are not easily reduced. However, when done improperly, these steps may accelerate the process of histamine development in the edible portions of the fish by spreading the bacteria from the visceral cavity to the flesh of the fish.

With some harvesting practices, such as longlining and gillnetting, death may occur many hours before the fish is removed from the water. Under the worst conditions, histamine formation can already be underway before the fish is brought onboard the vessel. This condition can be further aggravated with certain tuna species that generate heat, resulting in internal temperatures that may exceed environmental temperatures and increasing the likelihood of conditions favorable to growth of enzyme-forming bacteria.

The potential for histamine formation is increased when the scombrotoxin-forming fish muscle is in direct contact with the enzyme-forming bacteria. This direct contact occurs when the fish are processed (e.g., butchering or filleting) and can be particularly problematic when the surface-to-volume ratio of the exposed fish muscle is large, such as minced tuna for salads. Even when such products are prepared from canned or pouch retorted fish, recontamination can occur during salad preparation, especially with the addition of raw ingredients. The mixing in of the bacteria throughout the product and the high surface-to-volume ratio can result in substantial histamine formation if time and temperature abuse occurs.

At least some of the histamine-forming bacteria are halotolerant (salt tolerant) or halophilic (salt loving). Some are more capable of producing histamine at elevated acidity (low pH). As a result, histamine formation is possible during processes such as brining, salting, smoking, drying, fermenting, and pickling until the product is fully shelf-stable. Refrigeration can be used to inhibit histamine formation during these processes.

A number of the histamine-forming bacteria are facultative anaerobes that can grow in reduced oxygen environments. As a result, reduced oxygen packaging (e.g., vacuum packaging, modified atmosphere packaging, and controlled atmosphere packaging) should not be viewed as inhibitory to histamine formation.

Histamine is water soluble (dissolves in water) and would not be expected in significant quantity in products such as fish oil that do not have a water component. However, histamine could be present in products such as fish protein concentrate that are prepared from the muscle or aqueous (water-based) components of fish tissue.

- **Controlling scombrotoxin (histamine) formation**

Rapid chilling of scombrotoxin-forming fish immediately after death is the most important element in any strategy for preventing the formation of scombrotoxin (histamine), especially for fish that are exposed to warm waters or air, and for tunas which generate heat in their tissues. Some recommendations follow:

- Fish exposed to air or water temperatures above 83°F (28.3°C) should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than 6 hours from the time of death; or
- Fish exposed to air and water temperatures of 83°F (28.3°C) or less should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than 9 hours from the time of death; or
- Fish that are gilled and gutted before chilling should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than 12 hours from the time of death; or
- Fish that are harvested under conditions that expose dead fish to harvest waters of 65°F (18.3°C) or less for 24 hours or less should be placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than the time limits listed above, with the time period starting when the fish leave the 65°F (18.3°C) or less environment.

Note: If the actual time of death is not known, an estimated time of the first fish death in the set may be used (e.g., the time the deployment of a longline begins).

TABLE 7-1

RECOMMENDED MAXIMUM TIME TO GET SCOMBROTOXIN-FORMING FISH INTO CHILLING MEDIUM ONBOARD HARVEST VESSELS TO PREVENT SCOMBROTOXIN FORMATION[1]

WHEN…		THEN, THE MAXIMUM TIME IN HOURS TO GET THE FISH INTO CHILLING MEDIUM (≤ 40°F) FROM THE TIME OF…	
THE WATER TEMPERATURE (°F) IS…	AND THE AIR TEMPERATURE (°F) IS…	DEATH OF THE FISH OR EARLIEST ESTIMATED TIME OF DEATH IS…	ONBOARD LANDING IS…
FOR UNEVISCERATED FISH:			
> 65	> 83	6	--
> 83	Any	6	--
> 65, but ≤ 83	≤ 83	9	--
≤ 65[2]	> 83	--	6
≤ 65[2]	≤ 83	--	9
FOR FISH EVISCERATED ONBOARD BEFORE CHILLING:			
> 65	Any	12	--
≤ 65[2]	Any	--	12

1. This table is a summary of the preceding recommendations. For complete understanding of the recommendations, refer to the text above.
2. Provided exposure of the fish in the water at 65°F or less is ≤ 24 hours.

The controls listed above for onboard chilling will prevent the rapid formation of the enzyme histidine decarboxylase. Once this enzyme is formed, control of the hazard is unlikely. It is important to recognize that the parameters listed above are intended to control scombrotoxin formation; these criteria may not effectively control the activity of other spoilage organisms, raising the possibility that fish may become adulterated because of decomposition (not a food safety hazard covered by the Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products regulation, 21 CFR 123, called the Seafood Hazard Analysis Critical Control Point (HACCP) Regulation in this guidance document) before scombrotoxin (histamine) is formed.

Further chilling toward the freezing point is also desirable to safeguard against the less common, longer term, lower temperature development of histamine. Additionally, the shelf life and quality of the fish are significantly compromised when product temperature is not rapidly dropped to near freezing.

Although it may be possible for a harvest vessel to completely avoid onboard chilling and still deliver fish to the processor within the time and temperature limitations recommended above for chilling the fish, this practice is discouraged. Failure to chill onboard may permit bacteria and enzymes, including those that form scombrotoxin (histamine), to increase unnecessarily.

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 the water after capture, such as those captured by a longline, may significantly limit the amount of time left for chilling and may allow some fish to heat up;
  - Large quantities of fish captured in a single fishing set, such as those captured on a purse seiner, 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 seawater or brine, a consequence of reduced contact area and heat transfer;
  - The quantity of ice or ice slurry and the capacity of refrigerated seawater or brine systems, as well as the physical arrangement of the fish in the chilling media, should be suitable for the quantity of catch.

Once chilled, the scombrotoxin-forming fish should be maintained as close as possible to the freezing point (or held frozen) until it is consumed. Exposure to temperatures above 40°F (4.4°C) should be minimized. The amount of post-harvest time at elevated temperatures (after proper chilling onboard the harvest vessel) to which a fish can be exposed (e.g., during processing, storage, and distribution) without adverse effects is dependent primarily upon whether the fish was previously frozen (e.g., onboard the harvest vessel) or heat processed sufficiently to destroy scombrotoxin-forming bacteria.

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 following cooking. Such recontamination may not be likely if the fish is processed under a conscientious sanitation program. However, addition of raw ingredients, employee contact, or poor sanitary conditions could reintroduce contamination. Further guidance is provided below:

- Scombrotoxin-forming fish that have not been previously frozen or heat processed sufficiently to destroy scombrotoxin-forming bacteria should not be exposed to

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 (21.1°C); or
- More than 8 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F (21.1°C).

- Scombrotoxin-forming fish that have been previously frozen, or heat processed sufficiently to destroy scombrotoxin-forming bacteria and are subsequently handled in a manner in which there is an opportunity for recontamination with scombrotoxin-forming bacteria (e.g., contact with fresh fish, employees, or introduction of raw ingredients), should not be exposed to 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 (21.1°C); or
  - More than 24 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F (21.1°C);
- Scombrotoxin-forming fish that have been heat processed sufficiently to destroy scombrotoxin-forming bacteria and enzymes and are not subsequently handled in a manner in which there is an opportunity for recontamination with scombrotoxin-forming bacteria (e.g., no contact with fresh fish, employees, or raw ingredients) are at low risk for further scombrotoxin (histamine) development.

TABLE 7-2

RECOMMENDED MAXIMUM HOURS OF EXPOSURE OF SCOMBROTOXIN-FORMING FISH TO AMBIENT TEMPERATURES GREATER THAN 40°F TO PREVENT SCOMBROTOXIN FORMATION AFTER PROPER ONBOARD HARVEST VESSEL CHILLING, FOR DIFFERING TEMPERATURE EXPOSURE AND PREVIOUS PROCESSING CONDITIONS[1]

WHEN THE AMBIENT TEMPERATURE (°F) OF EXPOSURE IS…	THEN, THE MAXIMUM HOURS OF EXPOSURE TIME FOR…	
	Fresh fish (not heat processed or previously frozen) is …	Previously frozen fish, or heat processed fish (that has been exposed to possible recontamination), is…
> 70 AT ANY TIME	≤ 4	≤ 12
≤ 70 DURING ENTIRE EXPOSURE	≤ 8	≤ 24

1. This table is a summary of the preceding recommendations. For complete understanding of the recommendations, refer to the text above.

- **Detection**

Sensory evaluation

Sensory evaluation is generally used to screen fish for indicators of spoilage that develop when the fish is exposed to time and temperature abuse. Odor in particular 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 preventing scombrotoxin (histamine) formation.

It is important to recognize that the Federal Food, Drug, and Cosmetic Act (the FFD&C Act) prohibits interstate commerce of adulterated foods (21 U.S.C. 331). Under the FFD&C Act, a food that is decomposed is considered adulterated (21 U.S.C 342). Accordingly, a fish or fishery product that is decomposed in whole or in part is prohibited from entering interstate commerce even if the type of decomposition may not lead to scombrotoxin (histamine) formation. You should distinguish between recommendations in this chapter for sensory screening, as a component of a HACCP control strategy for scombrotoxin formation, and your obligation to avoid otherwise violating the FFD&C Act with regard to the distribution of decomposed food.

Chemical testing

Chemical testing is an effective means of detecting the presence of histamine in fish flesh. However, the variability in histamine levels between fish and within an individual fish can be large, even in fish from the same harvest vessel. For this reason, a guidance level has been set of 50 ppm histamine in the edible portion of fish. If 50 ppm is found in one section of a fish or lot, there is the possibility that other sections may exceed 500 ppm.

Because histamine is generally not uniformly distributed in a fish or a lot, the validity of histamine testing is dependent upon the design of the sampling plan. The amount of sampling required to accommodate such variability of distribution is necessarily quite large. The method of collection of the fish sample is also critical. In large scombrotoxin-forming fish, the lower, anterior (forward) portion of the fish loin (not the belly flap) is likely to provide the best information about the histamine content of the fish. The number of samples (i.e., scombrotoxin-forming fish) necessary to make a judgment about a lot depends on the anticipated variability, but should not be fewer than 18 samples per lot, unless the lot contains less than 18 fish, in which case a sample should be collected from each fish.

Where samples are composited to reduce the number of analyses needed on a lot, it should be done in a manner that ensures meaningful results. No more than three samples should be composited, in order to minimize masking of problematic fish. Furthermore, the analytical method and instrument used should be capable of reliably detecting histamine at the lower levels that are necessary for composited samples (e.g., 17 ppm histamine in a three-sample composite, rather than 50 ppm in an uncomposited sample).

Combining additional indicators of conditions that can lead to histamine formation, such as sensory examination and internal temperature measurement, with histamine testing can provide better assurance of product safety. Observation for the presence of honeycombing (voids in the fish flesh) in cooked tuna loins intended for canning is a valuable means of screening for fish that have been exposed to the kinds of temperature abuse that can lead to histamine development. Any scombrotoxin-forming fish that demonstrate the trait should be destroyed or diverted to a non-food use.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether scombrotoxin (histamine) formation is a significant hazard at a processing step:

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 3-2 (Chapter 3) lists those species of fish that are generally known to be capable of producing elevated levels of histamine if temperature abused. Such species of fish have this capability because they contain naturally high levels of histidine. They also have this capability 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 onboard vessel 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, onboard 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), as evidenced by supporting data.

   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). In addition, you may need to exercise control to prevent pathogen growth or toxin formation when receiving a refrigerated (not frozen) raw or cooked product from another processor (see Chapter 12). The in-transit controls for secondary processors recommended in Chapter 12 are similar to those recommended in this chapter.

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

   Time and 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 and temperature abuse during the entire process. Information is provided above to help you assess the significance of time and temperature abuse that may occur in your process.

3. Can unsafe levels of histamine formation that are reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Scombrotoxin (histamine) 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 (histamine) formation can include:

   - Examining harvest vessel records to ensure that incoming fish were properly handled onboard the harvest vessel, including:
     - Rapidly chilling the fish immediately after death;

- Controlling onboard refrigeration (other than frozen storage) temperatures;
- Performing proper onboard icing;

- Testing incoming fish for histamine levels;
- Ensuring that incoming fish were handled properly during refrigerated transportation from the previous processor, including:
  - Controlling refrigeration temperatures during transit;
  - Performing 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 decomposition;
- Controlling refrigeration temperatures in your plant;
- Performing proper icing in your plant;
- Controlling the amount of time that the product is exposed to temperatures that would permit histamine formation during processing.

These preventive measures are ordinarily employed at receiving, processing, and storage steps.

- **Intended use**

Because of the heat stable nature of histamine, the intended use of the product is not likely to affect the significance of this hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for scombrotoxin (histamine) formation:

1. If scombrotoxin (histamine) formation is a significant hazard at the receiving step, you should identify receiving as a CCP for this hazard.

   a. If you are the primary processor of the scombrotoxin-forming fish (i.e., if you receive the fish directly from the harvest vessel) and have a relationship with the operator of the harvest vessel(s) from which you purchase fish that enables you to obtain documentation of onboard practices, you should identify the following preventive measures for control of this hazard:

      - Examining harvest vessel records to ensure that incoming fish were properly handled onboard the harvest vessel, including:
        - Rapidly chilling the fish immediately after death;
        - Controlling onboard refrigeration (other than frozen storage) temperatures;
        - Performing proper onboard icing;
      - Checking incoming fish to ensure that they are not at an elevated temperature at time of receipt; and,
      - Performing sensory examination of incoming fish to ensure that they do not show signs of decomposition.

      Example:

      A mahi-mahi processor that regularly purchases from the same harvest vessels should require harvest vessel records as a condition of purchase.

The processor should also check the internal temperatures of incoming fish and perform sensory examination of these fish. The processor should then set a CCP for histamine formation at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Harvest Vessel Control."

b. If you are the primary processor of the scombrotoxin-forming fish (i.e., if you receive the fish directly from the harvest vessel) and do not have a relationship with the operator of the harvest vessel(s) that enables you to obtain documentation of onboard practices, you should identify the following preventive measures for control of this hazard:

- Testing incoming fish for histamine levels;
- Checking incoming fish to ensure that they are not at an elevated temperature at time of receipt and,
- Performing sensory examination of incoming fish to ensure that they do not show signs of decomposition.

Example:

A canned tuna processor that purchases from a variety of harvest vessels should subject incoming fish from each harvest vessel to histamine testing, internal temperature checks, and sensory examination. The processor should then set a CCP for histamine formation at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Histamine Testing."

c. If you are a secondary processor of the scombrotoxin-forming fish (i.e., if you receive the fish from another processor), you should identify the following preventive measures for control of this hazard:

- Ensuring that incoming fish were properly refrigerated during transportation from the previous processor, by controlling refrigeration temperatures during transit or,
- Checking incoming fish to ensure that they are properly iced at time of receipt.

Example:

A tuna processor that receives fish from another processor should require evidence of temperature control throughout transit as a condition of receipt. The processor should then set a CCP for histamine formation at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 3 - Transit Control." This control strategy, in addition to "Control Strategy Example 1 - Harvest Vessel Control" or "Control Strategy Example 2 - Histamine Testing," may also be applicable if you are a primary processor and transport the fish by truck from your harvest vessel unloading site to your processing facility.

2. If scombrotoxin (histamine) formation is a significant hazard at one or more processing steps, you should identify the processing step(s) as a CCP for this hazard.

a. The preventive measure for this type of control is:

- Controlling the amount of time that the scombrotoxin-forming product is exposed to temperatures that would permit histamine formation during processing.

Example:

A mahi-mahi processor should control histamine formation by limiting exposure time and temperature of the product during processing. The processor should then set CCPs for histamine formation at the processing steps.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Processing Control." This control strategy is intended for processing at ambient and air-conditioned temperatures. "Control Strategy Example 5 - Storage Control" may be more appropriate for processing under refrigerated conditions.

3. If scombrotoxin (histamine) formation is a significant hazard at a storage step for raw material, in-process product, or finished product, you should identify the storage step(s) as a CCP for this hazard.

   a. The preventive measures for this type of control are:

      - Controlling refrigeration temperatures in your plant or,
      - Performing proper icing in your plant.

   Example:

   A mahi-mahi processor should control histamine formation by icing the product during raw material, in-process product, and finished product storage. The processor should then set CCPs for histamine formation at the storage steps.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 5 - Storage Control."

- **Likely CCPs**

  Following is further guidance on processing steps that are likely to be identified as CCPs for this hazard:

  - Receiving;
  - Processing, such as:
    - Thawing;
    - Brining and salting;
    - Smoking;
    - Heading and gutting;
    - Manual filleting and steaking;
    - Fermenting;
    - Pickling;
    - Drying;
    - Stuffing;
    - Mixing (e.g., salad preparation);
    - Portioning;
  - Packaging;
  - Final chilling after processing and packaging;
  - Storing raw material, in-process product, and finished product under refrigeration.

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 and temperature exposure.

- **Unlikely CCPs**

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

DEVELOP A CONTROL STRATEGY.

The following guidance provides examples of five control strategies for scombrotoxin (histamine) formation. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation. You may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

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

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Harvest vessel control	✓	
Histamine testing	✓	
Transit control	✓	✓
Processing control	✓	✓
Storage Control	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL**

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

Set Critical Limits.

The critical limits for this control strategy should include three components:

- Harvest vessel records;
- Sensory examination;
- Internal temperature measurements.

Harvest vessel records:

- All scombrotoxin-forming fish lots received are accompanied by harvest vessel records that show:
  - Fish exposed to air or water temperatures above 83°F (28.3°C) were placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not longer than 6 hours from the time of death;

    OR
  - Fish exposed to air and water temperatures of 83°F (28.3°C) or less were placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not longer than 9 hours from the time of death;

    OR
  - Fish that were gilled and gutted before chilling were placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not longer than 12 hours from the time of death;

    OR
  - Fish that were harvested under conditions that expose dead fish to harvest waters of 65°F (18.3°C) or less for 24 hours or less were placed in ice, or in refrigerated seawater, ice slurry, or brine of 40°F (4.4°C) or less, as soon as possible after harvest, but not more than the time limits listed above, with the time period starting when the fish left the 65°F (18.3°) or less environment;

    OR
  - Other critical limits for onboard handling (e.g., maximum refrigerated brine or seawater temperature, maximum fish size, maximum fish to brine/seawater/ ice ratio, maximum initial temperature of

the fish) necessary to achieve a cooling rate that will prevent development of an unsafe level of histamine in the specific species, as established through a scientific study.

Note: If the actual time of death is not known, an estimated time of the first fish death in the set may be used (e.g., the time the deployment of a longline begins). Table 7-1 provides a summary of the preceding recommended critical limits.

AND

- For fish held refrigerated (not frozen) onboard the vessel:
  - The fish were stored at or below 40°F (4.4°C) after cooling;

    OR
  - The fish were stored completely and continuously surrounded by ice after cooling;

AND

Sensory examination:

- Sensory examination of a representative sample of scombrotoxin-forming fish shows decomposition (persistent and readily perceptible) in less than 2.5% of the fish in the sample. For example, no more than 2 fish in a sample of 118 fish may show signs of decomposition. Note that the FFD&C Act prohibits interstate commerce of any decomposed fish whether or not the HACCP critical limit has been exceeded;

AND

Internal temperature measurements:

- For fish held iced or refrigerated (not frozen) onboard the vessel 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) onboard the vessel from 15 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) onboard the vessel from 12 to less than 15 hours after death:
  - The internal temperature should be 60°F (15.6°C) or below;

    OR
- For fish held iced or refrigerated (not frozen) onboard the vessel less than 12 hours after death:
  - The internal temperature should be sufficiently below water and air temperatures to indicate that appropriate chilling methods were implemented onboard the harvest vessel. Chilling of the fish should begin on the harvest vessel regardless of the time from death until off-loading from the vessel by the processor unless the environmental conditions (e.g., air and water temperatures) are below 40°F (4.4°C) from the time of death until off-loading from the vessel by the processor;

    OR
- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - Elapsed time from death and internal temperatures at the time of off-loading from the vessel by the processor should be consistent with cooling curves that will prevent development of an unsafe level of histamine in the specific species, as established through a scientific study.

Establish Monitoring Procedures.

» What Will Be Monitored?

Harvest vessel records containing the following information:

- Method of capture*;

  AND
- Where applicable to the critical limit, the

date and time of landing the fish onboard the harvest vessel;

AND

- Where applicable to the critical limit, the estimated earliest date and time of death for fish brought onboard in the fishing set (e.g., trawl, gillnet, longline, or purse seine);

AND

- Where applicable to the critical limit, the air and water temperatures at the time of landing the fish onboard the harvest vessel*;

AND

- Where applicable to the critical limit, the water temperature at the depth where dead fish may remain until harvest;

AND

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

AND

- Where applicable to the critical limit, the date and time cooling began and/or the date and time when the last fish in a fishing set (e.g., trawl, gillnet, longline, or purse seine) was placed in the cooling medium;

AND

- Where applicable to the critical limit, 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, maximum initial temperature of the fish);

AND

- For fish held iced or refrigerated (not frozen) onboard 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 ice that completely and continuously surrounds the fish.

(*These items may be documented by the primary (first) processor, on the receiving records, rather than by the harvest vessel operator, on the harvest vessel records, provided the primary processor has direct knowledge about those aspects of the harvesting practices and has made first-hand observations for each lot received. The vessel operator should document other onboard handling information. The primary processor should maintain all relevant information.)

AND

Sensory examination:

- Amount of decomposition in the lot;

AND

Internal temperature measurement:

- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - The internal temperature of a representative number of the largest fish in the lot at the time of off-loading from the harvest vessel, concentrating on any fish that show signs of having been mishandled (e.g., inadequately iced);

    AND

  - Date and time of off-loading.

    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 9 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 return of the vessels; the ambient water and air temperatures of the fishing grounds; and the adequacy of icing of the catch at the time of off-loading. 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.

» **How Will Monitoring Be Done?**

- For harvest vessel records:
  - Review controls documented in the records;

  AND
- For sensory examination:
  - Examine at least 118 fish, collected representatively throughout each lot (or the entire lot, for lots smaller than 118 fish). Additional fish should be examined if variability in fish-to-fish histamine content is expected to be high. Lots should consist of only one species of fish; for vessels delivering multiple species, testing should generally be done separately on each species. All fish within a lot should have a similar history of harvest. 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) onboard the vessel:
  - Use a temperature-indicating device (e.g., a thermometer) to measure the internal temperature of a representative number of the largest fish in each lot, concentrating on any 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 1,000 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 or lots of very small fish may require a larger sample size;

    AND
  - Visually determine the date and time of off-loading.

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

- Every lot of scombrotoxin-forming fish received.

» **Who Will Do the Monitoring?**

- For sensory examination:
  - Any person who is qualified by experience or training to perform the examination;

  AND
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- In the absence of harvest vessel records or when one of the harvester-related critical limits has not been met, or when the internal temperature critical limit at receiving has not been met:
  - Chill and hold the affected lot (i.e., fish of common origin) until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the lot, including any fish measured to have temperatures that exceeded the critical limit (or the entire lot for lots smaller than 60 fish). Reject the lot if any fish are found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited for analysis if the action point 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

- Reject the lot;

AND

- When the sensory examination critical limit has not been met:
  - Chill and hold the affected lot (i.e., fish of common origin) until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the lot, including all fish in the lot that show evidence of decomposition (persistent and readily perceptible odors) (or the entire lot for lots smaller than 60 fish), and reject the lot if any fish is found with histamine greater than or equal to 50 ppm;

    AND

  - If any fish in the lot are to proceed into commerce for food use, perform a sensory examination of all fish in the lot to ensure that no decomposed fish proceed;

    AND

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

    OR

  - Reject the lot.

AND

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

- Discontinue use of the supplier until evidence is obtained that the identified harvesting and onboard practices and controls have been improved.

Establish a Recordkeeping System.

- Harvest vessel records containing the information described above;

  AND

- Receiving records showing the date and time of off-loading;

  AND

- Results of sensory examination;

  AND

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

Establish Verification Procedures.

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

  AND

- Ensure that new sensory examiners receive training to calibrate their ability to identify decomposed fish and that all sensory examiners receive periodic refresher training;

  AND

- Where histamine testing is part of a corrective action plan, periodically verify the findings (e.g., by comparing results with those obtained using an Association of Official Analytical Chemists (AOAC) method);

  AND

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

    OR

  - Comparing the temperature reading on the device with the reading on a

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

OR

- Following the manufacturer's instructions;

AND

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

AND

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

AND

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

TABLE 7-3

CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Harvest Vessel Control." This example illustrates how a fresh mahi-mahi processor that receives the fish on ice directly from harvest vessels that use a hook and line technique (fish brought onboard alive) can control scombrotoxin formation. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving fresh mahi-mahi on ice from harvest vessels	Scombrotoxin formation	All lots received are accompanied by harvest vessel records that show (1) placement of fish on ice within 9 hours of death if the maximum exposure temperature does not exceed 83°F or within 6 hours if the maximum exposure temperature exceeds 83°F; (2) The fish were stored completely and continuously surrounded by ice after capture	Harvest vessel records	Review of controls documented in the records	Every lot received	Receiving supervisor	Reject the lot Discontinue use of the supplier until evidence is obtained that harvesting and onboard practices and controls have been improved	Harvester vessel records	Perform histamine analysis on 1 incoming lot every 3 months (18 fish per sample) Review monitoring, corrective action, and verification records within 1 week of preparation
		Less than 2.5% decomposition (persistent and readily perceptible) in the incoming lot	Amount of decomposition in the incoming lot	Sensory examination (118 fish per lot; or all fish in the lot if less than 118 fish)	Every lot received	Quality control staff		Receiving record	Provide sensory training for new fish examiners and annual training for all fish examiners Review monitoring, corrective action, and verification records within 1 week of preparation
		Internal temperatures of all fish are to meet the following criteria based on the time since the death of the fish: >24 hours → ≤ 40° 15 to < 24 hours → ≤ 50° 12 to < 15 hours→ ≤ 60° < 12 hours → below ambient air and water temperatures commensurate with size of fish and time since death	Internal temperature of the fish at time of off-loading from vessel; Date and time of off-loading	Digital thermometer (1 fish/1,000 pounds; minimum of 12 fish per lot)	Every lot received	Receiving supervisor		Receiving record	Check the digital thermometer for accuracy and damage and to ensure that it is operational before putting it into operation; perform these same checks daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING**

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

Set Critical Limits.

The critical limits for this control strategy should include three components:

- Histamine testing;
- Sensory examination;
- Internal temperature measurements.

Histamine testing:

- Analysis of a representative sample of scombrotoxin-forming fish shows less than 50 ppm histamine in all fish in the sample;

AND

Sensory examination:

- Sensory examination of a representative sample of scombrotoxin-forming fish shows decomposition (persistent and readily perceptible) in less than 2.5% of the fish in the sample. For example, no more than 2 fish in a sample of 118 fish may show signs of decomposition. Note that the FFD&C Act prohibits interstate commerce of any decomposed fish whether or not the HACCP critical limit has been exceeded;

AND

Internal temperature measurements:

- For fish held iced or refrigerated (not frozen) onboard the vessel 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) onboard the vessel from 15 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) onboard the vessel from 12 to less than 15 hours after death:
  - The internal temperature should be 60°F (15.6°C) or below;

  OR
- For fish held iced or refrigerated (not frozen) onboard the vessel less than 12 hours after death:
  - The internal temperature should be sufficiently below water and air temperatures to indicate that appropriate chilling methods were implemented onboard the harvest vessel. Chilling of the fish should begin on the harvest vessel regardless of the time from death until off-loading from the vessel by the processor, unless the environmental conditions (e.g. air and water temperatures) are below 40°F (4.4°C) from the time of death until off-loading from the vessel by the processor;

  OR
- For fish held iced or refrigerated (not frozen) onboard the vessel:
  - Elapsed time from death and internal temperatures at the time of off-loading from the vessel by the processor should be consistent with cooling curves that will prevent development of an unsafe level of histamine in the specific species, as established through a scientific study.

Establish Monitoring Procedures.

» What Will Be Monitored?

Histamine testing:

- Histamine content in the scombrotoxin-forming fish flesh;

AND

Sensory examination:

- Amount of decomposition in the scombrotoxin-forming fish lot;

AND

Internal temperature measurement:

- For scombrotoxin-forming fish held iced or refrigerated (not frozen) onboard the vessel:
  - The internal temperature of a representative number of the largest fish in the lot at the time of off-loading from the harvest vessel by the processor, concentrating on any fish that show signs of having been mishandled (e.g., inadequately iced);

    AND
  - Date and time of off-loading.

» How Will Monitoring Be Done?

- For histamine analysis:
  - Test a minimum of 18 fish, collected representatively throughout each lot (or the entire lot when there are fewer than 18 fish in the lot). Additional fish should be examined if variability in fish-to-fish histamine content is expected to be high. Lots should consist of only one species of fish; for vessels delivering multiple species, testing should generally be done separately on each species. Reject the lot if any fish are found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited 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
- For sensory examination:
  - Examine at least 118 fish, collected representatively throughout each lot (or the entire lot, for lots smaller than 118 fish). Additional fish should be examined if variability in fish-to-fish histamine content is expected to be high. Lots should consist of only one species of fish; for vessels delivering multiple species, testing should generally be done separately on each species. 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) onboard the vessel:
  - Use a temperature-indicating device (e.g., a thermometer) to measure the internal temperature of a representative number of the largest fish in each lot, concentrating on any 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 1,000 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 or lots of very small fish may require a larger sample size;

    AND
  - Visually determine the date and time of off-loading.

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

- Every lot of scombrotoxin-forming fish received.

» **Who Will Do the Monitoring?**

- For sensory examination and histamine testing:
  - Any person who is qualified by experience or training to perform the work;

  AND

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- When the histamine-level critical limit at the receiving step has not been met, reject the lot;

  AND

- When the internal temperature critical limit has not been met:
  - If histamine did not exceed 50 ppm in the initial testing:
    - Chill and hold the affected lot (i.e., fish of common origin) until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the lot, including any fish measured to have temperatures that exceeded the critical limit (or the entire lot for lots smaller than 60 fish). Reject the lot if any fish are found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited for analysis if the action point 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

    - Reject the lot;

  AND

- When the sensory examination critical limit has not been met:
  - If histamine did not exceed 50 ppm in the initial testing:
    - Chill and hold the affected lot (i.e., fish of common origin) until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the lot, including all fish in the lot that show evidence of decomposition (persistent and readily perceptible odors) (or the entire lot for lots smaller than 60 fish). Reject the lot if any fish are found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited for analysis if the action point 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

  - If any fish in the lot are to proceed into commerce for food use, perform a sensory examination of all fish in the lot to ensure that no decomposed fish proceed;

    AND

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

    OR

  - Reject the lot.

AND

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

- Discontinue use of the supplier until evidence is obtained that the identified harvesting and onboard practices have been improved.

Establish a Recordkeeping System.

- 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) onboard the vessel:
  - Internal temperatures of the fish.

Establish Verification Procedures.

- Periodically verify histamine findings (e.g., by comparing results with those obtained using an AOAC method or by analyzing proficiency samples);

  AND
- Ensure that new sensory examiners receive training to calibrate their ability to identify decomposed fish and that all sensory examiners receive periodic refresher training;

  AND
- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

    OR
  - Following the manufacturer's instructions;

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

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

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

TABLE 7-4

CONTROL STRATEGY EXAMPLE 2 - HISTAMINE TESTING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Histamine Testing." This example illustrates how a canned tuna processor that receives frozen tuna directly from the harvest vessel can control scombrotoxin formation. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., Clostridium botulinum growth and toxin formation).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving frozen tuna from harvest vessels	Scombrotoxin formation	Less than 50 ppm histamine in all fish in the sample	Fish flesh for histamine content	Histamine testing using the AOAC 977.13 method on a minimum of 18 fish per lot (36 fish from vessels with high variability of histamine detected between fish or when 1 of the first 18 fish exceeds 30 ppm histamine)	Every lot received	Quality assurance staff	Reject the lot; Discontinue use of the supplier until evidence is obtained that harvesting and onboard practices have been improved If the initial histamine sample was <50 ppm, perform histamine analysis on a min, of 60 fish, collected representatively from the lot and reject the lot if any fish contains ≥50 ppm histamine; and if all fish <50 ppm	Reports of histamine analysis	Do a quarterly comparison of histamine test results with AOAC method Review monitoring, corrective action, and verification records within 1 week of preparation
		Less than 3 decomposed fish (persistent and readily perceptible) in a 118-fish sample	Amount of decomposition in the incoming lot	Sensory examination (118 fish per lot, or all fish if lot is less than 118 fish)	Every lot received	Quality assurance staff	Conduct sensory evaluation of all fish in the lot, removing and destroying all decomposed fish Discontinue use of the supplier until evidence is obtained that harvesting and onboard practices have been improved	Sensory examination record	Provide sensory training for new fish examiners and annual training for all fish examiners Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL**

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

Set Critical Limits.

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

  OR
- For fish delivered under ice:
  - Fish are completely surrounded by ice at the time of delivery;

  OR
- For fish delivered under ice on an open-bed truck:
  - Fish are stored completely surrounded by ice;

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

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

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

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

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

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For scombrotoxin-forming fish delivered refrigerated (not frozen):
  - The internal temperature of the fish throughout transportation;

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

  OR
- For scombrotoxin-forming fish delivered under ice:
  - The adequacy of ice surrounding the product at the time of delivery;

  OR
- For scombrotoxin-forming fish delivered under ice on an open-bed truck:
  - The adequacy of ice surrounding the product at the time of delivery;

    AND
  - The internal temperature of the fish at time of delivery;

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

    AND
  - The internal temperature of the fish at the time of delivery;

OR

- For scombrotoxin-forming fish delivered refrigerated (not frozen) with a transit time of 4 hours or less:
  - The date and time fish were removed from a controlled temperature environment before shipment and the date and time delivered;

    AND
  - The internal temperature of a representative number of fish at the time of delivery.

» **How Will Monitoring Be Done?**

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

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

    OR
- For fish delivered under ice on an open-bed truck:
  - Make visual observations of the adequacy of ice surrounding the product in a representative number of containers (e.g., cartons and totes) from throughout the shipment, at delivery;

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

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

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

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

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

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

- Every scombrotoxin-forming fish lot received.

» **Who Will Do the Monitoring?**

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

OR

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Chill and hold the affected lot until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the lot, including any with temperatures that exceeded a critical limit and any fish observed to have been exposed to inadequate cooling media (or the entire lot for lots smaller than 60 fish). Reject the lot if any fish is found with histamine greater than or equal to 50 ppm.

  The fish collected for analysis may be composited if the action point 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

- Reject the lot.

AND

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

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

Establish a Recordkeeping System.

- Receiving records showing:
  - For continuous temperature monitoring:
- Printouts, charts, or readings from temperature-recording devices (e.g., temperature recorder);

  OR

  - For ice checks:
    - The number of containers examined and the sufficiency of ice for each;

      AND

    - The number of containers in the lot;

    OR
  - For chemical cooling media checks:
    - The number of containers examined and the frozen status of the cooling media for each;

      AND

    - The number of containers in the lot;

    AND
  - Results of internal product temperature monitoring, where applicable, including:
    - The number of containers examined and the internal temperatures observed for each;

      AND

    - The number of containers in the lot;

    AND
  - Date and time fish were initially removed from a controlled temperature environment and the date and time fish were delivered, when applicable.

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used

(e.g., product internal temperature) within the temperature range at which it will be used;

OR

- Following the manufacturer's instructions;

AND

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

AND

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

AND

- Check the accuracy of temperature-recording devices that are used for monitoring transit conditions upon receipt of each lot. The accuracy of the device can be checked by comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

AND

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

AND

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

TABLE 7-5

CONTROL STRATEGY EXAMPLE 3 - TRANSIT CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3 - Transit Control." This example illustrates how a fresh mahi-mahi secondary processor that receives the product by air under chemical coolant (gel packs) can control scombrotoxin formation. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving	Scombrotoxin formation	Adequate quantity of frozen gel packs to maintain the product at 40°F or less throughout transit; and	Quantity and frozen condition of gel packs	Visual observation of a minimum of 25% of shipping containers in the lot but not fewer than 12 containers (or all containers if lot has less than 12 containers)	Every lot received	Receiving clerk	Reject the lot Discontinue use of the supplier or carrier until evidence is obtained that transportation-handling practices have been improved	Receiving record	Check the thermometer for accuracy and damage, and to ensure that it is operational before putting into operation; perform these same checks daily at the beginning of operations, and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
		Internal temperatures of all fish at delivery are 40°F or below	Internal core temperature and a near-surface temperature of each fish	Digital thermometer for internal temperature of one fish in 25% of shipping containers but not fewer than 12 containers (or all containers if lot has less than 12 containers)	Every lot received	Receiving clerk	Reject the lot Discontinue use of the supplier or carrier until evidence is obtained that transportation-handling practices have been improved	Receiving record	

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

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

Set Critical Limits.

- During processing (e.g., butchering, cleaning, brining, salting, smoking, drying, fermenting, pickling, mixing, fermenting, stuffing, packing, labeling, and staging) of scombrotoxin-forming fish that have not been previously frozen or heat processed sufficiently to destroy scombrotoxin-forming bacteria:
    - 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 (21.1°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 (21.1°C).

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

OR

- During processing (e.g., thawing, butchering, cleaning, brining, mixing, fermenting, stuffing, packing, labeling, and staging) of scombrotoxin-forming fish or fishery products that have been (1) previously frozen or (2) heat processed sufficiently to destroy scombrotoxin-forming bacteria and are processed in a manner where there is an opportunity for recontamination with scombrotoxin-forming bacteria (e.g., contact with fresh fish, employees, or introduction of raw ingredients), such as in a tuna salad made from canned tuna with added raw ingredients:
    - 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 (21.1°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 (21.1°C).

Note: Only one of the two limits above should be selected. They should not be added for a total exposure of 36 hours.

Establish Monitoring Procedures.

» What Will Be Monitored?

- The length of time the scombrotoxin-forming fish are exposed to unrefrigerated conditions (i.e., above 40°F (4.4°C));

  AND
- The ambient temperatures during the exposure periods.

Note: If the critical limit is based on an assumption that temperatures may exceed 70°F (21.1°C), then only the length of exposure may need to be monitored.

» How Will Monitoring Be Done?

- Make visual observations of the length of time of product exposure to unrefrigerated conditions (i.e., above 40°F (4.4°C));

  AND
- Measure ambient air temperature, using:
    - A continuous temperature-recording device (e.g., a recording thermometer) located in the processing area;

      OR
    - A temperature-indicating device (e.g., a thermometer) located in the processing area.

Note: Where multiple processing locations are combined in a cumulative exposure control strategy, temperature monitoring may be needed in each of the processing locations.

Example:

A fresh tuna processor using raw material that was not previously frozen has identified a series of processing steps (i.e., from raw material cooler to finished product cooler) as CCPs for scombrotoxin formation. The processor establishes a critical limit of no more than 4 cumulative hours of exposure to unrefrigerated temperatures in excess of 40°F (4.4°C) during these processing steps. The processor uses a marked product to monitor the progress of the product through the processing steps. The time that the marked product is removed from refrigeration to the time the last of the marked product is placed in the finished product cooler is monitored visually and recorded. It is not necessary for the processor to measure temperature because the critical limit is based on an assumption that the product temperature may exceed 70°F (21.1°C).

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

- For exposure time:
  - At least every 2 hours;

  AND
- For temperature measurements:
  - For a continuous temperature-recording device:
    - Continuous monitoring during processing operations is accomplished by the device itself, with a visual check of the device at least once per lot or batch, but no less often than once per day;

    OR
  - For a temperature-indicating device:
    - At least every 2 hours.

» **Who Will Do the Monitoring?**

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

  OR
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Chill and hold the affected product until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the affected lot. Destroy the lot or divert it to a non-food use if any fish is found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited if the action plan 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
- Destroy the product;

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

AND

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

- Add ice to the product;

  OR
- Return the affected product to the cooler;

  AND

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

Establish a Recordkeeping System.

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

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) or a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

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

    OR
  - Doing a combination of the above if the device will be used at or near room temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

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

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

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

TABLE 7-6

CONTROL STRATEGY EXAMPLE 4 - PROCESSING CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4 - Processing Control." This example illustrates how a fresh bluefish processor that butchers, cleans, packs, labels, and boxes the fish at ambient temperature can control scombrotoxin formation. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Processing (butchering, cleaning, packaging, labeling, and boxing)	Scombrotoxin formation	The product is not out of refrigeration for more than 4 hours cumulatively	Time of product exposure to unrefrigerated conditions during processing operations	Visual tracking of time for a marked batch of product to move from raw material cold storage to final product cold storage	Every batch of fish removed from raw material cold storage for processing	Quality control supervisor	Ice and hold the affected batch in raw material cooler Perform histamine analysis on a minimum of 60 fish in the affected batch Destroy the entire batch if any fish exceeds 50 ppm histamine Modify the process, if necessary, to reduce delays	Processing record	Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 5 - STORAGE CONTROL**

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

Set Critical Limits.

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

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

Establish Monitoring Procedures.

» What Will Be Monitored?

- For refrigerated storage of scombrotoxin-forming fish:
  - The temperature of the cooler;

  OR
- For storage under ice of scombrotoxin-forming fish:
  - The adequacy of ice surrounding the product.

» How Will Monitoring Be Done?

- For refrigerated storage:
  - Measure cooler temperature using a continuous temperature-recording device (e.g., a recording thermometer);

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

» How Often Will Monitoring Be Done (Frequency)?

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

  OR
- For storage under ice:
  - Monitoring with sufficient frequency to ensure control.

» Who Will Do the Monitoring?

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

OR

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations.

  OR

- Chill and hold the affected product until histamine analysis is performed on a minimum of 60 fish collected from throughout each affected lot. Destroy the lot or divert it to a non-food use if any fish is found with histamine greater than or equal to 50 ppm. The fish collected for analysis may be composited if the action point 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

- Destroy the product;

  OR

- Divert the product to a non-food use.

AND

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

- Prevent further deviation:
  - Add ice to the product;

    OR

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

  AND

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

    OR

  - Make adjustments to the ice application operations.

Establish a Recordkeeping System.

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

    AND

  - Record of visual checks of recorded data;

  OR

- For storage under ice:
  - The number of containers examined and the sufficiency of ice for each;

    AND

  - The approximate number of containers in the cooler.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

    OR

  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the

history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

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

AND

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

AND

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

TABLE 7-7

CONTROL STRATEGY EXAMPLE 5 - STORAGE CONTROL

This table is an example of a portion of a HACCP plan using "Control Strategy Example 5 - Storage Control." This example illustrates how a fresh fish processor can control scombrotoxin formation. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Histamine formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Raw material and finished product cold storage (shared cooler)	Scombrotoxin formation	Maximum cooler temperature of 40°F	Cooler temperature	Time and temperature data logger	Continuous, with a visual check of recorded data once per day	Production supervisor	Ice and hold the affected product inside the cooler Check sufficiency of ice on the product two times per day until cooler is functioning reliably Perform histamine analysis on a minimum of 60 fish representative of the affected product Destroy all affected product if any fish exceeds 50 ppm histamine Adjust and repair cooler as needed	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; perform these checks daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

BIBLIOGRAPHY.

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

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NOTES:

CHAPTER 8: **Other Decomposition-Related Hazards**

Chapter 7 covers scombrotoxin poisoning in certain species of fish. This poisoning occurs 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 with consumption of a number of fish species. FDA also has received a number of consumer complaints concerning illnesses that are associated with the consumption of decomposed shrimp and salmon.

There are also some indications that chemicals formed when fats and oils in foods oxidize may contribute to long-term detrimental health effects.

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UNDERSTAND THE POTENTIAL HAZARD.

Environmental chemical contaminants and pesticides in fish pose a potential human health hazard. Fish can be harvested from waters that are contaminated by varying amounts of industrial chemicals, including heavy metals and pesticides. These contaminants may accumulate in fish at levels that can cause human health problems (e.g., carcinogenic and mutagenic effects). The hazard is most commonly associated with exposure over a prolonged period of time (chronic exposure). Illnesses related to a single exposure (one meal) are very rare. Concern for these contaminants primarily focuses on fish harvested from aquaculture ponds, freshwater bodies, estuaries, and near-shore coastal waters (e.g., areas subject to shoreside contaminant discharges), rather than from the open ocean. Environmental chemicals and pesticides may also accumulate in aquacultured fish through contaminated feed ingredients (e.g., pesticides in oil-containing feed ingredients derived from near-shore bait fish).

Although some pesticides have not been produced or used in the United States for many years (e.g., dichloro-diphenyl-trichloroethane (DDT) and polychlorinated biphenyls (PCBs)), many are very persistent and tend to accumulate in soil and sediments. Once pesticides are introduced into the environment, they may travel beyond their point of application or discharge.

Certain pesticides are applied directly to the water in aquaculture ponds to control weeds and algae and to eliminate fish and invertebrates. These products can be used legally only if they are registered with the U.S. Environmental Protection Agency (US EPA) and used according to conditions described on the label (40 CFR 180 and the "Guide to Drug, Vaccine, and Pesticide Use in Aquaculture," the Federal Joint Subcommittee on Aquaculture (*http://aquanic.org/jsa/wgqaap/drugguide/drugguide.htm*)).

Many contaminants accumulate in the edible fatty tissues of fish. Concentrations of these contaminants can vary considerably in individual fish of the same species from the same location, depending on factors such as their fat content, size, age, and gender.

In the case of components or extracts of whole fish (e.g., dietary supplements, dietary ingredients, and flavors), the component or extract may contain higher or lower concentrations of environmental chemical contaminants and pesticides than the whole fish from which it was derived. For example, organochlorine contaminants, such as PCBs, are oil soluble. When producing fish oil and fish meal, any PCBs present will become more concentrated in the oil fraction and less concentrated in the water fraction, as compared with the levels in the whole fish.

- **Control of chemical contaminants**

Federal tolerances and action levels are established for some of the most toxic and persistent contaminants that can be found in fish. These levels are listed in Table 9-1. State, tribal, local, or foreign authorities may use the federal tolerances or action levels to decide whether to issue local advisories to consumers recommending limits on consumption of all or certain species of locally harvested fish (some of which may be commercially important) or to close waters for commercial harvesting of all or certain species of fish.

In the case of molluscan shellfish, state, tribal, territorial 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 and not 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. In this context, molluscan shellfish include oysters, clams, mussels, and scallops.

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

Processors of seafood components and extracts may choose to control environmental chemical contaminants and pesticides at receipt (e.g., by screening raw materials). If contaminants in the raw material are present at unacceptable levels, processors may reject the product or choose to implement refining steps that reduce the contaminants to acceptable levels in the finished product. These steps may include distillation, absorption, and steam deodorization. You should validate the effectiveness of these refining steps at reducing environmental and chemical contaminants to an acceptable level and include appropriate controls in your Hazard Analysis Critical Control Point (HACCP) plan. No further information on these control measures is provided in this guidance document.

- **Tolerance and action levels**

Table 9-1, "Environmental Chemical Contaminants and Pesticides Tolerance and Action Levels," lists the tolerance and action levels that have been established for environmental chemical contaminants and pesticides in the edible portion of fish (wet weight).

TABLE 9-1

ENVIRONMENTAL CHEMICAL CONTAMINANTS AND PESTICIDES TOLERANCE AND ACTION LEVELS

Tolerance Levels

DELETERIOUS SUBSTANCE	LEVEL IN EDIBLE TISSUE	FOOD COMMODITY	REFERENCE
PCBs	2 ppm	All fish	21 CFR 109.30
Carbaryl	0.25 ppm	Oysters	40 CFR 180.169
Diquat	2 ppm	Fish	40 CFR 180.226
Diquat	20 ppm	Shellfish	40 CFR 180.226
Diuron and its metabolites	2 ppm	Farm-raised, freshwater finfish	40 CFR 180.106
Endothall and its monomethyl ester	0.1 ppm	All fish	40 CFR 180.293
Fluridone	0.5 ppm	Finfish and crayfish	40 CFR 180.420
Glyphosate	0.25 ppm	Fish	40 CFR 180.364
Glyphosate	3 ppm	Shellfish	40 CFR 180.364
2,4-D	0.1 ppm	Fish	40 CFR 180.142
2,4-D	1 ppm	Shellfish	40 CFR 180.142

Action Levels

DELETERIOUS SUBSTANCE	LEVEL IN EDIBLE TISSUE	FOOD COMMODITY	REFERENCE
Aldrin and dieldrin[1]	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[2]	0.3 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Chlordecone[2]	0.4 ppm	Crabmeat	"Compliance Policy Guide," Sec. 575.100
DDT, TDE, and DDE[3]	5 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Methylmercury[4]	1 ppm	All fish	"Compliance Policy Guide," Sec. 540.600
Heptachlor and Heptachlorepoxide[5]	0.3 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Mirex	0.1 ppm	All fish	"Compliance Policy Guide," Sec. 575.100

1. The action level for aldrin and dieldrin is for residues of the pesticides individually or in combination. However, in calculating a total, amounts of aldrin or dieldrin found at below 0.1 ppm are not counted.
2. Previously listed as Kepone, the trade name of chlordecone.
3. The action level for DDT, TDE, and DDE is for residues of the pesticides individually or in combination. However, in calculating a total, amounts of DDT, TDE, and DDE found below 0.2 ppm are not counted.
4. See Chapter 10 for additional information.
5. The action level for heptachlor and heptachlor epoxide is for the pesticides individually or in combination. However, in calculating a total, amounts of heptachlor and heptachlor epoxide found below 0.1 ppm are not counted.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether environmental chemical contaminants and pesticides are a significant hazard at a processing step:

1. Is it reasonably likely that unsafe levels of environmental chemical contaminants or pesticides will be introduced at this processing step (e.g., do such contaminants and pesticides come in on the raw material)?

   Tables 3-2 and 3-3 (Chapter 3) identify the species of fish for which environmental chemical contaminants and pesticides are 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. However, there may be circumstances 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 harvested from your area. You should be guided by the historical occurrence of environmental contaminants and pesticides, at levels above established tolerance and action levels, in fish from the area in which your fish are caught. This information may be available from federal, state, tribal, territorial, local, or foreign health or environmental authorities in the area where your fish are caught.

   If you are receiving fish, other than molluscan shellfish, from another processor, you would not need to identify environmental chemical contaminants and pesticides as a significant hazard. This hazard should have been fully controlled by the primary (first) processor.

2. Can unsafe levels of environmental chemical contaminants and pesticides that were introduced earlier be eliminated or reduced to an acceptable level at this processing step?

   Environmental chemical contaminants and pesticides should be considered a significant hazard at any processing step where a preventive measure is or can be used to eliminate the hazard or to reduce the likelihood of its occurrence to an acceptable level. Preventive measures for environmental chemical contaminants and pesticides can include:

   For wild-caught fish other than molluscan shellfish:

   - Making sure that incoming fish have not been harvested from waters that are closed to commercial harvest because of concentrations of environmental chemical contaminants or pesticides exceeding the federal tolerance or action levels;
   - Making sure that incoming fish have not been harvested (for commercial purposes) from the same waters that are under a consumption advisory by a state, tribal, territorial, local, or foreign regulatory authority based on a determination by the authority that fish harvested from these waters are reasonably likely to contain contaminants above the federal tolerance or action levels. Note that many consumption advisories are not based on such a determination.

   For aquacultured fish other than molluscan shellfish:

   - Reviewing, at time of receipt, the producer's lot-by-lot certification that harvest is from uncontaminated waters, coupled with appropriate verification;
   - Reviewing, at time of receipt, test results of fish tissue samples or production site water for those contaminants that

are reasonably likely to be present, and obtaining information on present land use practices in the area immediately surrounding the production area (tests and monitoring may be performed by the aquacultural producer, a state, tribal, territorial, local, or foreign authority, or a third-party organization);

- Conducting on-farm visits to the aquacultural producer to collect and analyze water or fish samples for those 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;
- Reviewing, at time of receipt, evidence (e.g., a third-party certificate) that the producer operates under a third-party-audited Quality Assurance (QA) program for environmental chemical contaminants and pesticides (e.g., the National Aquaculture Association's Fish Producers Quality Assurance Program);
- Conducting, at time of receipt, environmental chemical contaminant and pesticide testing of fish tissue for those contaminants that are reasonably likely to be present.

For molluscan shellfish, both aquacultured and wild caught:

- Checking incoming molluscan shellfish to ensure that containers 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.

These preventive measures are ordinarily employed either at the receiving step or at the pre-harvest step. In the case of an integrated operation, where fish cultivation and processing are performed by the same firm, it may be possible and desirable to exercise preventive measures early in the process (ideally when the cultivation site is selected), rather than at receipt of the fish at the processing plant. Such preventive measures will not be covered in this guidance document.

- **Intended use**

For environmental chemical contaminants and pesticides, it is unlikely that the intended use of the product will affect the significance of the hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for the hazard of environmental chemical contaminants and pesticides:

Is the raw material an aquacultured product other than molluscan shellfish?

1. If the raw material is an aquacultured product other than molluscan shellfish, do you have a relationship with the producer that enables you to visit the farm before receipt of the fish?

    a. If you have such a relationship with the producer, then you should identify the pre-harvest step as the CCP for environmental chemical contaminants and pesticides. The preventive measure for this type of control is:

        - Conducting on-farm visits to the aquacultural producer to collect and analyze water or fish samples for those 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:

    An aquacultured catfish processor that regularly purchases from the same

producers should visit the producers before the fish are harvested. The processor should collect and analyze water or fish samples for those environmental chemical contaminants and pesticides that are reasonably likely to be present and should review present land use at the pond site and in the adjacent areas. The processor should then set the CCP for environmental chemical contaminants and pesticides at the pre-harvest step.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - On-Farm Visits."

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

- Reviewing, at time of receipt, the supplier's lot-by-lot certification of harvesting from uncontaminated waters, coupled with appropriate verification.

Example:

An aquacultured shrimp processor that purchases raw material through various brokers should receive lot-by-lot certificates from the suppliers. The certificates would state that shrimp were not harvested from contaminated waters that would cause the levels in shrimp to exceed the established tolerance or action levels. The processor should combine this monitoring procedure with quarterly raw material testing for those environmental chemical contaminants and pesticides that are reasonably likely to be present for verification and should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Supplier's Certification."

- Reviewing, at time of receipt, test results of water or fish tissue samples for those contaminants that are reasonably likely to be present and obtaining information on the present land use practices in the area immediately surrounding the production area (the aquaculture producer, a state, tribal, territorial, local or foreign authority, or a third-party organization may perform tests and monitoring).

Example:

A farm-raised catfish processor purchases catfish from producers with which the processor has no long-term relationship. The processor requires all new suppliers to provide the test results of water samples or fish tissue 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 and whenever information on the land use change warrants a more frequent update (the aquaculture producer, a state, tribal, territorial, local or foreign authority, or a third-party organization may perform tests and monitoring). The processor should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 3 - Records of Testing and Monitoring."

- Conducting, at time of receipt, analysis of fish tissue for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

Example:

An aquacultured shrimp processor that purchases raw material through various brokers should screen all incoming lots of shrimp for those environmental chemical contaminants and pesticides that are reasonably likely to be used in the production area. The processor should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Chemical Contaminant Testing."

- Reviewing, at time of receipt, evidence (e.g., a continuing or lot-by-lot third- party certificate) that the producer operates under a third-party-audited QA program that covers environmental chemical contaminants and pesticides. The certificate should outline the audit steps and summarize the water and/or fish test results.

Example:

An aquacultured trout processor that regularly purchases raw trout from the same producer should obtain a third-party certificate, valid for 1 year (i.e., a continuing certificate), that attests that the producer operates under a QA program that controls environmental chemical contaminants and pesticides or should receive a lot-by-lot certificate issued by the third party. The processor should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 5 - QA Program."

Is the raw material molluscan shellfish (aquacultured or wild caught) or wild caught fish other than molluscan shellfish?

1. If the raw material is molluscan shellfish or wild-caught fish other than molluscan shellfish, you should identify the receiving step as the CCP for environmental chemical contaminants and pesticides. At the receiving step, you should exercise the following preventive measures:

   a. For wild-caught fish other than molluscan shellfish:

      - Making sure that incoming fish have not been harvested from waters that are closed to commercial harvest because of concentrations of environmental chemical contaminants or pesticides exceeding the federal tolerance or action levels;
      - Making sure that incoming fish have not been harvested from waters that are under a consumption advisory by a state, tribal, territorial, local, or foreign regulatory authority based on a determination by the authority that fish harvested from the waters are reasonably likely to contain contaminants above the federal tolerance or action levels.

      Example:

      A processor purchases bluefish directly from the harvester. The processor asks the harvester where the fish were caught. The processor then compares the harvest area location with the areas that are closed to commercial fishing by state or local regulatory authorities or that are under consumption advisories that include bluefish and that are based on the reasonable likelihood that a contaminant level in fish tissue will exceed a federal tolerance or action level. The processor should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 6 - Source Control for wild caught Fish Other Than Molluscan Shellfish."

b. For molluscan shellfish:

- 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.

Example:

A processor purchases oysters directly from the harvesters. The processor should check the harvest location on the tags attached to the sacks of oysters. The processor should then compare the harvest area location with information on closed waters and check the harvesters' state licenses. The processor should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 7 - Source Control for Molluscan Shellfish."

DEVELOP A CONTROL STRATEGY.

The following guidance provides seven control strategies for environmental chemical contaminants and pesticides. It is important to note that you may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

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

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
On-farm visit	✓	
Supplier's certification	✓	
Records of testing and monitoring	✓	
Chemical contaminant testing	✓	
QA program	✓	
Source control for wild caught fish other than molluscan shellfish	✓	
Source control for molluscan shellfish	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT**

Set Critical Limits.

- Environmental chemical contaminants and pesticides that are reasonably likely to be present in farm water may not be at levels so high that they are reasonably likely to result in concentrations in fish tissue above the established tolerance or action levels (refer to Table 9-1). Elevated concentrations of chemical contaminants in water can be an indication that they are reasonably likely to be present in the fish tissue. Note that US EPA has developed water quality guidance documents that may be suitable for evaluating water quality in local situations (*U.S. EPA Water Quality Standards Handbook,* Appendix I);

OR

- The levels of environmental contaminants and pesticides in fish tissue samples that are reasonably likely to be present may not exceed the established tolerance or action levels (refer to Table 9-1);

AND

- Agricultural and industrial practices in the area near the production site must not be reasonably likely to cause contamination

of the fish tissue above the established tolerance or action levels (refer to Table 9-1).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The levels of environmental chemical contaminant and pesticide residues found in water or in fish tissue for those contaminants that are reasonably likely to occur;

  AND

- Agricultural and industrial practices in the area near the production site.

» **How Will Monitoring Be Done?**

- Collect and analyze water samples or fish tissue samples from each production site;

  AND

- Ask questions about and observe agricultural and industrial practices in the area near the production site, such as:
  - Which types of crops, if any, are grown in the area near the production site?
  - What pesticides, if any, are used on these crops, how are they applied, and at what time of year?
  - What industrial and urban discharges, if any, enter the watershed surrounding the production site?

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

- For testing water:
  - Before first delivery from each production site;

  OR

- For testing fish tissue:
  - Before each delivery;

  AND

- For evaluating agricultural and industrial practices:
  - At least once per year for each production site.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Do not have the product shipped from the production site for processing.

AND

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

- Discontinue use of the supplier until evidence is obtained that the cause of the chemical contamination has been eliminated.

Establish a Recordkeeping System.

- Test results;

  AND

- On-site audit report.

Establish Verification Procedures.

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

TABLE 9-2

CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - On-Farm Visits." This example illustrates how an aquacultured catfish processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental chemical contaminants and pesticides may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, food and color additives, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Pre-harvest	Environmental chemical contaminants and pesticides	Levels of environmental chemical contaminants and pesticides in fish tissue may not exceed established tolerance and action levels for those contaminants that are reasonably likely to be present*	Environmental chemical contaminant and pesticide levels in fish tissue for those contaminants that are reasonably likely to be present*	Collect samples and analyze for environmental chemical contaminants and pesticides*	Before each harvest	Field agent will submit samples to the contract laboratory	Do not have the product shipped for processing Discontinue use of the supplier until evidence is obtained that the cause of the chemical contamination has been eliminated	Test results	Review monitoring and correction action records within 1 week of preparation
		Agricultural and industrial practices in the area near the pond must not be reasonably likely to cause contamination of the fish tissue above the established tolerances and action levels	Agricultural and industrial practices near the pond	Ask questions and observe agricultural and industrial practices	Once per year	Field agent	Do not have the product shipped for processing Discontinue use of the supplier until evidence is obtained that the cause of the chemical contamination has been eliminated	Field agent report	Review monitoring and correction action records within 1 week of preparation

* Note: This plan is for illustrative purposes only. An actual plan should specify (1) in the Critical Limits column: the environmental chemical contaminants and pesticides that are reasonably likely to be present and the critical limits to be applied to each contaminant; and (2) in the Monitoring columns: the contaminants for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each contaminant.

- **CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION**

Set Critical Limits.

- A certificate accompanying all lots received (lot by lot) that indicates that fish were not harvested from contaminated waters that could cause the levels in fish tissue to exceed the established federal tolerance and action levels (refer to Table 9-1).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Presence of a certificate indicating harvesting from uncontaminated waters.

» **How Will Monitoring Be Done?**

- Visual check for the presence of a certificate.

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

- Each lot received.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Reject the lot;

  OR

- Hold the lot until a certificate can be provided;

  OR

- Hold and analyze the lot for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

AND

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

- Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls.

Establish a Recordkeeping System.

- Copy of the certificate;

  AND

- Receiving record showing lots received and the presence or absence of a certificate.

Establish Verification Procedures.

- Visit all new aquacultured fish producers within the year and all existing fish suppliers at a predetermined frequency (e.g., 25% per year) to collect and analyze water or fish tissue samples, as appropriate, for those environmental chemical contaminants and pesticides that are reasonably likely to be present, 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 it for those environmental chemical contaminants and pesticides that are reasonably likely to be present;

  AND

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

TABLE 9-3

CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Supplier's Certification." This example illustrates how an aquacultured shrimp processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental chemical contaminants and pesticides may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, food and color additives, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving	Environmental chemical contaminants and pesticides	Certificate accompanying all lots received indicates that fish were not harvested from contaminated waters that could cause the levels in fish tissue to exceed the established federal tolerance and action levels	Presence of a certificate	Visual check	Each lot received	Receiving dock employee	Reject lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls	Copy of the certificate Receiving record	Review monitoring, corrective action, and verification records within 1 week of preparation Visit all new aquacultured fish producers within the year and 25% of existing suppliers each year to collect and analyze water samples, and review agricultural and industrial practices in the area

- **CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING**

Set Critical Limits.

- Reports of analyses of the water from all new suppliers that show that levels of those environmental chemical contaminants and pesticides that are reasonably likely to be present are not so high that they are reasonably likely to result in levels in the fish tissue that exceed the established federal tolerance and action levels (refer to Table 9-1). (The aquaculture producer, a state, tribal, territorial, local, or foreign authority, or a third-party organization may perform tests.) Note that US EPA has developed water quality documents that may be suitable for evaluating water quality in local situations (*U.S. EPA Water Quality Standards Handbook,* Appendix I);

  OR

- Reports of analyses of fish tissue for each delivery that show that levels of those environmental chemical contaminants and pesticides that are reasonably likely to be present are below the established federal tolerance and action levels (the aquaculture grower, a state, tribal, territorial, local, or foreign authority, or a third-party organization may perform tests);

  AND

- Reports from all suppliers that show that agricultural and industrial practices in the area near the aquaculture production site are not reasonably likely to cause contamination of fish tissue above the established federal tolerance or action levels (the aquaculture producer, a state, tribal, territorial, local, or foreign authority, or a third-party organization may perform monitoring).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Test results of water or fish tissue for those environmental chemical contaminants and pesticides that are reasonably likely to be present;

  AND

- Monitoring results for agricultural and industrial practices.

» **How Will Monitoring Be Done?**

- Visual check of test results and monitoring reports.

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

- For results of water testing:
  - All new suppliers;

  OR

- For results of fish tissue testing:
  - Each delivery;

  AND

- For reports of evaluation of agricultural and industrial practices:
  - At least once every year.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Reject the lot.

AND

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

- Discontinue use of the supplier until evidence is obtained that the supplier will comply with the testing and evaluation controls.

Establish a Recordkeeping System.

- Test results;

  AND

- Reports of evaluation of agricultural and industrial practices.

TABLE 9-4

CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3 - Records of Testing and Monitoring." This example illustrates how a farm-raised catfish processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental chemical contaminants and pesticides may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, food and color additives, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving	Environmental chemical contaminants and pesticides	Reports of analyses of the water from all new suppliers that show that levels of environmental chemical contaminants and pesticides that are reasonably likely to be present are not so high that they are likely to result in levels in fish tissue that exceed the established federal tolerance or action levels*	Reports of analyses showing levels of environmental chemical contaminants and pesticides in water samples for those contaminants that are reasonably likely to be present*	Visual check	At first delivery	Quality control staff	Reject the lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the testing and evaluation controls.	Test results	Review monitoring and corrective action records within 1 week of preparation
		Reports from all suppliers that show that agricultural and industrial practices in the area near the production site are not reasonably likely to cause contamination of fish tissue above the established tolerance or action levels	Reports of agricultural and industrial practices in the area near the production site	Visual check	Once per year	Quality control staff	Reject the lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the testing and evaluation controls	Reports of agricultural and industrial practices	Review monitoring and corrective action records within 1 week of preparation

* Note: This plan is for illustrative purposes only. An actual plan should specify (1) in the Critical Limits column: the environmental chemical contaminants and pesticides that are reasonably likely to be present and the critical limits to be applied to each contaminant; and (2) in the Monitoring columns: the contaminants for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each contaminant.

Establish Verification Procedures.

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

- **CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING**

Set Critical Limits.

- No lot may exceed the federal tolerance or action levels for those environmental chemical contaminants and pesticides that are reasonably likely to be present (refer to Table 9-1).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Fish tissue for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

» **How Will Monitoring Be Done?**

- Obtain samples and analyze for environmental chemical contaminants and pesticides.

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

- Each lot received.

» **Who Will Do the Monitoring?**

- Any person who is qualified by training or experience to perform the analyses.

Establish Corrective Action Procedures.

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

- Reject the lot.

AND

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

  - Discontinue use of the supplier until evidence is obtained that the cause of the chemical contamination has been eliminated.

Establish a Recordkeeping System.

- Test results.

Establish Verification Procedures.

- Periodically verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Chemists, or equivalent method, or by analyzing proficiency samples);

  AND

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

TABLE 9-5

CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4 - Chemical Contaminant Testing." This example illustrates how an aquacultured shrimp processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental chemical contaminants and pesticides may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, food and color additives, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving	Environmental chemical contaminants and pesticides	No lot of shrimp may exceed the established tolerance or action levels for environmental chemical contaminants and pesticides that are reasonably likely to be present*	Chemical residue levels in shrimp tissue that are reasonably likely to be present*	Obtain samples and analyze for environmental chemical contaminants and pesticides*	Each lot received	Receiving employee will submit sample to quality control staff	Reject the lot Discontinue use of the supplier until evidence is obtained that the cause of the chemical contamination has been eliminated	Test results	Annual methods comparison to AOAC methods Review monitoring and corrective action records within 1 week of preparation

* Note: This plan is for illustrative purposes only. An actual plan should specify (1) in the Critical Limits column: the environmental chemical contaminants and pesticides that are reasonably likely to be present and the critical limits to be applied to each contaminant; and (2) in the Monitoring columns: the contaminants for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each contaminant.

- **CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM**

Set Critical Limits.

- A certificate indicating that the producer operates under a third-party-audited QA program that covers environmental chemical contaminants and pesticides. The certificate may accompany each lot of incoming aquacultured fish or may be issued for each producer of incoming aquacultured fish as a continuing certification.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Certificate indicating operation under a third-party-audited QA program.

» **How Will Monitoring Be Done?**

- Visual check for the presence of a certificate.

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

- Each lot received is checked for the presence of a certificate. Certificates may be issued on continuing (not less often than annually) or lot-by-lot basis.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Reject the lot;

  OR

- Hold the lot until a certificate can be provided;

  OR

- Hold and analyze the lot for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

AND

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

- Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls.

Establish a Recordkeeping System.

- Third-party certificates;

  AND

- Records showing lots received and the presence or absence of a certificate.

Establish Verification Procedures.

- Review the third-party-audited QA program and results of audits annually;

  AND

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

TABLE 9-6

CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

This table is an example of a portion of a HACCP plan using "Control Strategy Example 5 - QA Program." This example illustrates how an aquacultured trout processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purpose only.

Environmental chemical contaminants and pesticides may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, food and color additives, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving	Environmental chemical contaminants and pesticides	Certificate indicating that the producer operates under a third-party-audited QA program that covers environmental chemical contaminants and pesticides	Presence of a third-party certificate	Visual check for the presence of a certificate	Each lot	Receiving dock employee	Reject the lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls	Certificate Receiving record	Review the third-party-audited QA program and results of audits annually Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL FOR WILD CAUGHT FISH OTHER THAN MOLLUSCAN SHELLFISH**

Set Critical Limits.

- No fish may be harvested from an area that is closed to commercial harvesting by state, tribal, territorial, local, or foreign authorities because of concentrations of environmental chemical contaminants or pesticides exceeding the federal tolerance or action levels;

  AND

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Location of harvest and whether the harvest area is subject to closure or consumption advisory.

» **How Will Monitoring Be Done?**

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

  AND

- Ask the state, tribal, territorial, local, or foreign authorities in which your fish are harvested whether there are closures or consumption advisories that apply to the areas from which your fish are harvested.

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

- Every lot received.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Reject the lot;

  OR

- For fish harvested from an area under a consumption advisory based on federal tolerance or action levels:
  - Sample the lot and analyze it for the appropriate environmental chemical contaminant or pesticide. Reject the lot if the results exceed the federal tolerance or action level.

AND

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

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

Establish a Recordkeeping System.

- Receiving records that document the location and whether the harvest area is subject to closure or consumption advisory.

Establish Verification Procedures.

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

TABLE 9-7

CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL FOR WILD CAUGHT FISH OTHER THAN MOLLUSCAN SHELLFISH

This table is an example of a portion of a HACCP plan using "Control Strategy Example 6 - Source Control for Wild Caught Fish Other Than Molluscan Shellfish." This example illustrates how a wild caught bluefish processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental contaminants and pesticides from the harvest area may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., scombrotoxin (histamine), metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving	Environmental chemical contaminants and pesticides	No fish may be harvested from an area that is closed to commercial harvesting by state, or local authorities because of concentrations of environmental chemical contaminants or pesticides exceeding the federal tolerance or action levels No fish may be commercially harvested from an area that is under a consumption advisory by a state, local, 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 tolerance or action levels	Location of harvest and whether the harvest area is subject to closure or consumption advisory	Ask the harvester for the harvest location, and ask state and local authorities the status of the area	Each lot received	Receiving dock employee	Reject the lot Discontinue use of the supplier until evidence is obtained that harvesting practices have changed	Receiving record	Review monitoring and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 7 - SOURCE CONTROL FOR MOLLUSCAN SHELLFISH**

Set Critical Limits.

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

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

OR

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

OR

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

AND

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

AND

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

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The information contained on tags on containers of incoming shellstock or on the bill of lading or other similar shipping document accompanying bulk shipments of shellstock and whether the harvest area is authorized for harvest by a shellfish control authority;

AND

- The license of the harvester;

OR

- The information contained on labels on containers of incoming shucked molluscan shellfish.

» **How Will Monitoring Be Done?**

- Perform visual checks;

AND

- Ask the relevant shellfish control authority whether the harvest area is authorized for harvest.

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

- For checking tags:
  - Every container;

AND

- For checking harvester licenses:
  - Every delivery;

OR

- For checking labels:
  - At least three containers randomly selected from throughout every lot.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Reject the lot.

AND

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

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

Establish a Recordkeeping System.

For shellstock:

- Receiving record that documents:
  - Date of harvest;

    AND
  - Location of harvest by state and site;

    AND
  - Quantity and type of shellfish;

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

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

    AND
  - Certification number of the shipper, where applicable.

For shucked molluscan shellfish:

- Receiving record that documents:
  - Date of receipt;

    AND
  - Quantity and type of shellfish;

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

Establish Verification Procedures.

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

TABLE 9-8

CONTROL STRATEGY EXAMPLE 7 - SOURCE CONTROL FOR MOLLUSCAN SHELLFISH

This table is an example of a portion of a HACCP plan using "Control Strategy Example 7 - Source Control for Molluscan Shellfish." The example illustrates how a processor of shellstock oysters received directly from a harvester can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental contaminants and pesticides from the harvest area may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., natural toxins and pathogens from the harvest area).

Example Only
See Text for Full Recommendations

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

BIBLIOGRAPHY.

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

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NOTES:

CHAPTER 10: **Methylmercury**

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

As with previous editions of the "Fish and Fishery Products Hazards and Controls Guidance," this fourth edition does not contain advice on Hazard Analysis Critical Control Point (HACCP) controls for methylmercury, except where federal, state, local, or foreign authorities close certain waters to commercial harvesting as described in Chapter 9.

NOTES:

CHAPTER 11: AQUACULTURE DRUGS

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

UNDERSTAND THE POTENTIAL HAZARD

This chapter concerns the potential food safety hazard of animal drug residues in aquaculture products.

The primary purpose of aquaculture is to produce animals and plants for human consumption. Aquaculture is defined as farming of both animals and plants (including crustaceans, finfish, mollusks, amphibians, reptiles, seaweeds, and algae) in a natural or controlled environment. The term farming implies some form of intervention in the breeding and rearing process to increase and expand production, such as regular stocking, feeding, protection from predators, improvement of water quality, and enhancement of animal health conditions including prophylactic and treatment activities. Aquaculture can occur in freshwater, coastal, and marine environments, including inland ponds, tanks, reservoirs, rivers, lakes, estuaries, bays, fjords, and the open sea.

Note: Aquaculture plants (seaweed and algae) are not covered by the Seafood HACCP regulation.

There are numerous diseases currently associated with aquaculture species, and new ones are consistently emerging. In addition, outbreaks of diseases can be significantly accentuated in aquaculture operations due to the animals' proximity to each other, high population densities, frequently changing environmental conditions, and other stressors.

The most common reasons for the use of animal drugs in aquaculture are:

- to treat, control or prevent disease,
- to control parasites,
- to affect reproduction and growth,
- to provide tranquilization/sedation (e.g., for weighing, harvest), and
- for skeletal marking of fish fry (larvae) and fingerlings.

The food safety hazard associated with the use of animal drugs occurs during activities listed above, which can be performed at any stage of aquaculture operation. The use of unapproved drugs or misuse of approved drugs in farm-raised fish may result in residues in edible tissue and poses a potential risk to human health upon long-term exposure. These substances may be toxic, allergenic, mutagenic, or carcinogenic, may contribute to the development of antimicrobial resistance in pathogens that affect humans and animals, or may be a combination of these adverse effects.

Residue is defined by FDA Center for Veterinary Medicine (CVM) as any compound or metabolite of a compound that is present in edible tissues from food animals because of the use of a compound in or on animals. Residues can be from the compound itself, its metabolites, or any other substances formed in or on food as a result of the compound's use. The metabolism of some drugs varies according to species, and the toxic character of a compound in one animal species is not necessarily the same as that in others.

• Animal Drugs for Use in Aquaculture

According to the Federal Food, Drug, and Cosmetic Act, a drug is defined as "an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals and an article (other than food) intended to affect the structure or any function of the body of man or other animals" (FD&C Act Sec.201.(g)(1)(B) & (C)).

As required by the Federal Food, Drug, and Cosmetic Act, an animal drug must be approved by FDA before a drug sponsor can legally sell the drug. During this pre-market review, the agency evaluates information submitted by the sponsor to make sure the drug is safe and effective for its intended use and that the drug is properly manufactured and adequately labeled and packaged. The drug's labeling should ensure the information remains truthful, complete, and not misleading. A drug for use in food animals, whether it is for direct medication or use in or on medicated feed, can be legally marketed and used in the US if it has been approved through:

- New Animal Drug Application (NADA), or
- Abbreviated New Animal Drug Application (ANADA), or
- Conditional New Animal Drug Application (CNADA).

An alternative to the new animal drug approval process is the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index). The Index provides legal marketing status for certain drugs that have had their safety and effectiveness affirmed through another FDA review process (FD&C Act, Section 572). Drugs listed on the Index are only available for new animal drugs intended for use in:

- nonfood-producing minor species for which there is the certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals, and
- a hatchery, tank, pond, or other similar contained man-made structure in an early, nonfood life stage of a food-producing minor species, where safety for humans is demonstrated (e.g. larva, fry, fingerlings) (21 CFR 516.111).

In addition, under certain conditions authorized by FDA, unapproved new animal drugs may be used by experts, qualified by scientific training and experience, to investigate their safety and effectiveness if requirements of an Investigational New Animal Drug (INAD) exemption stated in21 CFR 511 are met.

Each approval pathway mentioned above has different requirements, but they all lead to legal marketing status of the drug for which safety has been fully evaluated. For more information refer to New Animal Drug Application Guidance documents at https://www.fda.gov/animal-veterinary/guidance-industry/new-animal-drug-application-guidances.

All drugs should be used judiciously, particularly drugs considered as "medically important" antimicrobials. Antimicrobials are essential for protecting human and animal health and should not be used in food-producing animals for production uses, such as to enhance growth or improve feed efficiency. They are deemed "medically important" because the antimicrobial or a member of that class of antimicrobials is also used to treat human disease, and such treatment might not be effective if the pathogenic bacteria become resistant to the drugs' therapeutic effect. The antimicrobial-resistant bacteria can be spread to humans through the food supply. Refer to CVM website for more information https://www.fda.gov/animal-veterinary/antimicrobial-resistance/judicious-use-antimicrobials

Relatively few drugs have been approved for aquaculture in the US. This factor may lead to the inappropriate use of unapproved drugs, general purpose chemicals, or approved drugs in a manner that deviates from the labeled instructions.

When a drug is approved by the FDA Center for Veterinary Medicine (CVM), the conditions of the approval are listed on the label or in the labeling (21 CFR 514.1). These conditions specify the species or group of species (e.g., freshwater-reared salmonids) for which the drug is approved for use; indications (disease or other circumstances) for use; dosage regimen; route of administration; and other limitations, including withdrawal period. The labeled withdrawal period must be followed to ensure that no harmful drug residues are present in the edible tissue of the animal when harvested for human consumption and offered for sale. Tolerances for some drug residues in the edible tissue have been established (21 CFR 556). In addition to the regulation(s), specific tolerance levels may also be found in Appendix 5 of this guidance document.

Effective January 1, 2017, all medically important antimicrobials intended for use in or on animal feed or in water for food-producing animal species require either a Veterinary Feed Directive (VFD) (21 CFR 558.6) or a prescription (Rx) (21 CFR 520). The use of a VFD or Rx drug is permitted only under the professional supervision of a licensed veterinarian. To be lawful, a VFD must be issued by a licensed veterinarian operating in compliance with all applicable licensing and practice requirements, including issuing the VFD in the context of a valid

Veterinarian-Client-Patient Relationship (VCPR) as defined in 21 CFR 530.3(i).

The increasing threat of antimicrobial resistance to both human and animal health compelled the FDA to remove production uses of medically important antibiotics and implement a requirement for veterinary oversight of their uses. Over-the-counter (OTC) antibiotics have been transitioned to VFD or Rx marketing status. A licensed veterinarian should be trained to understand not only when these medications are needed, but also what is the appropriate drug, dose, duration, and administration method for therapy. This requirement is aimed to help preserve a supply of effective antibiotics for situations of true need to protect animal and human health, and, in turn, food safety.

○ Extra-label Drug Use (ELDU)

The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) allows veterinarians to prescribe **approved** new animal or human drugs for uses other than those on the approved label. This is called "extra-label drug use" (ELDU**) The FDA defines extra-label drug use as "Actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease and other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from labeled withdrawal period based on these different uses." (21 CFR 530.3)**. However, a veterinarian must not pursue the use of certain FDA-prohibited drugs in food-producing animals listed in 21CFR 530.3.

Furthermore, AMDUCA does not permit veterinarians to prescribe the extra-label use of medicated feeds. ELDU is limited to situations when there are no approved treatment options available, and the health of an animal is threatened or when suffering or death may result from failure to treat the affected animals. If a veterinarian determines that extra-label use of medicated feed is necessary and the only option, this use has to be consistent with all considerations described in Compliance Policy Guide Sec. 615.115 " Extralabel Use of Medicated Feeds for Minor Species." The reader is strongly encouraged to be familiar with all considerations. Only a licensed veterinarian may legally prescribe a drug under ELDU conditions.

An extra-label prescription must be for therapeutic purposes only and must not be used for production enhancement. As defined in 21CFR 530.3(h), a veterinarian is a person licensed by a U.S. state or territory, to practice veterinary medicine.

NOTE: Farmers in foreign countries should consult their country's competent authority for information on prescription requirements, disease treatment options, and technical support. The OIE Aquatic Animal Health Code defines a veterinarian as a person with appropriate education, registered or licensed by the relevant regulatory authority of a country to practice veterinary medicine/science in that country.

The extra-label use restrictions are fully explained in 21 CFR Part 530, FDA CVM Program Policy and Procedures Manual 1240.4210, and CPG 615.115.

○ Unapproved Animal Drugs

FDA has serious concerns about unapproved animal drugs (any drug not approved or conditionally approved in the United States). These drugs have not been reviewed by FDA and may not meet the agency's strict standards for safety and effectiveness. Unapproved animal drugs also may not be properly manufactured or properly labeled. They can potentially put the health of animals and people at risk, and their use is strictly prohibited. Any amount of residues in domestic or imported aquaculture products from an unapproved new animal drug would cause the product to be adulterated (FD&C Act 402(a)(2)(C)(ii)).

Imported aquaculture product would be denied entry into the United States if residue of an unapproved new animal drug is identified, even if the levels of residues are considered safe by a country where the new animal drug is lawfully used. The only exception is if there is an Import Tolerance in place for this compound in that particular tissue. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug Availability Act of 1996 (ADAA), provides a basis for legally marketing food of animal origin that is imported into the United States and contains residues of animal drugs that are not approved or conditionally approved in the United States (unapproved new animal drugs). The ADAA granted the FDA the authority to establish or revoke tolerances for residues of such unapproved new animal drugs

present in imported, animal-derived food products. Refer to CVM's current list of import tolerances established for unapproved new animal drugs in imported food.

Information on the laws, regulations, guidance, and policies pertaining to drugs and the new animal drug approval process can be found on FDA's internet website, https://www.fda.gov/animal-veterinary.

To ensure unapproved drugs do not get into aquaculture products directly or inadvertently, farmers and the other facilities along the supply chain should implement a food safety and disease prevention and verification program based on the principles of Good Aquaculture Practices (GAqPs), current Good Manufacturing Practices (CGMPs) and Hazard Analysis and Critical Control Point (HACCP), where applicable.

However, according to the US FDA Seafood HACCP Regulation (21 CFR 123), it is the responsibility of the seafood processor to have an adequate strategy in place that effectively controls the aquaculture drug hazard.

- **APPROVED ANIMAL DRUGS FOR AQUACULTURE**

Animal Drugs for aquacultured food fish must meet human food safety standards assessed during the approval process. When a fish producer (farmer) or hatchery manager uses an approved drug for food fish as directed on the label, the treated fish are safe to eat.

The FDA-approved animal drugs for use in aquaculture, with information on their approved sponsor/supplier, species for which the approval has been granted, required withdrawal periods, and other conditions are listed below. Additional details on provisions of use (e.g., administration route, dosage level) can be obtained from the Code of Federal Regulations (CFR) as cited below; the labeling for the drug; and the FDA CVM Website, (the Animal Drugs @ FDA database: https://animaldrugsatfda.fda.gov/).

FDA's determination that these veterinary products are approved aquaculture drugs does not exempt facilities from complying with other federal, state, tribal, territorial, and local environmental requirements. For example, in the United States, facilities using these substances would still be required to comply with the National Pollutant Discharge Elimination System requirements.

- **Route of Administration: Immersion (Refer to Appendix 11 for additional information such as indicated use, contraindication, tolerance levels, and extra-label use for the following aquaculture drugs)**

- Chloramine-T powder
- Formalin
- Hydrogen peroxide
- Oxytetracycline hydrochloride
- Tricaine methanesulfonate (MS-222)

- **Route of Administration: Injectable (Refer to Appendix 11 for additional information such as indicated use, contraindication, tolerance levels, and extra-label use for the following aquaculture drug)**

- Chorionic gonadotropin

- **Route of Administration: Medicated Articles/Feeds (Refer to Appendix 11 for additional information such as indicated use, contraindication, tolerance levels, and extra-label use for the following aquaculture drugs)**

- Florfenicol
- Oxytetracycline dihydrate
- Sulfamerazine
- Ormetoprim/Sulfadimethoxine combination

- **UNAPPROVED ANIMAL DRUGS FOR AQUACULTURE**

Animal drugs not evaluated and approved by CVM are not recognized as safe under any condition of intended use. It is reasonable to expect that the application of unapproved aquaculture drugs may result in unsafe levels of residues and render the food adulterated.

- **FDA high enforcement priority unapproved aquaculture drugs**

FDA CVM has identified a number of drugs and families of drugs historically **used in fish without the FDA approval** that are of high enforcement priority. Those drugs may have an impact on the safety of fish products for consumers because they are:

- known or suspected carcinogens;
- known or suspected mutagens;
- known or suspected serious toxicants; and/or
- antimicrobials that might be a factor in the emergence of antimicrobial resistance (AMR)

to drugs used in human medicine as well as in veterinary medicine.

The following compounds are **examples of unapproved drugs** that have been recognized as of human health concern (this list is not inclusive):

- Chloramphenicol;
- Nitrofurans;
- Fluoroquinolones;
- Quinolones (Oxolinic Acid, Flumequine, Nalidixic Acid);
- Malachite Green and metabolite;
- Gentian (Crystal) violet and metabolite;
- Isoeugenol;
- Avermectins;
- Sulfonamides;
- Trimethoprim;
- Steroids and Hormones.

○ Drugs prohibited from extra-label use

The following drugs and families of drugs are prohibited for extra-label use in food-producing animals including fish, i.e., actual use or intended use of a drug in an animal in a manner that is not consistent with the FDA approved provisions of use and approved labeling (21 CFR 530.41(a)):

- Chloramphenicol;
- Clenbuterol;
- Diethylstilbestrol (DES);
- Dimetridazole, Ipronidazole, and other Nitroimidazoles;
- Furazolidone, and Nitrofurazone;
- Fluoroquinolones;
- Glycopeptides.

None of these drugs and family of drugs has been approved for use in fish.

○ FDA low regulatory priority unapproved aquaculture drugs

Due to the broad definition of drug in the FD&C Act, many compounds that satisfy the conditions of the definition are considered drugs. CVM has identified several unapproved drugs used in aquaculture that are considered low-risk products when used in fish for human consumption. These drugs are also called "low regulatory priority."

The agency will exercise regulatory discretion in cases of the use of low regulatory priority compounds in fish if the following conditions are met:

- the substances are used for the stated indications;
- the substances are used at the stated levels;
- the substances are used according to good management practices;
- the product is of an appropriate grade for use in food animals; and
- use of these products is not likely to result in an adverse effect on the environment.

The agency's enforcement position on the use of these compounds **should not be considered** as FDA approval or 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.

In addition, the FDA's determination that these compounds are new animal drugs of low regulatory priority does not exempt facilities from complying with other federal, state, tribal, territorial, and local environmental requirements. For example, in the United States, facilities using these compounds would still be required to comply with the National Pollutant Discharge Elimination System requirements.

The following list identifies unapproved new animal drugs of low regulatory priority and provides their indicated use and usage levels (CVM's Policy and Procedures Manual Attachment: "Enforcement Priorities for Drug use in Aquaculture" Guide 1240.4200 https://www.fda.gov/media/70193/download) Refer to Appendix 12 for indicated use for each of the following:

- Acetic acid
- Calcium chloride
- Calcium oxide
- Carbon dioxide gas
- Fuller's earth
- Garlic (whole form)
- Ice
- Magnesium sulfate
- Onion (whole form)
- Papain
- Potassium chloride
- Povidone iodine
- Sodium bicarbonate
- Sodium chloride
- Sodium sulfite
- Thiamine hydrochloride
- Urea and tannic acid

○ FDA Import Tolerances for residues of unapproved new animal drugs present in imported seafood

The following tolerances have been established for residues of new animal drugs that have not been approved in the US in imported seafood in order to allow the product be lawfully sold in the US:

FDA Import Tolerances for Residues of Unapproved New Animal Drugs in Imported Seafood

Requester	Drug	Species	Import Tolerance for Drug Residues in Edible Tissue	Year Established
Zoetis Inc.	Hexaflumuron	Salmonids	0.5 ppm for hexaflumuron in muscle with adhering skin	2021
Intervet Inc	Emamectin	Salmonids	100ppb for emamectin B1a in muscle with adhering skin	2019
ACD Pharmaceuticals	Benzocaine	Atlantic salmon and rainbow trout	50ppb benzocaine in muscle with adhering skin	2018
Novartic Animal Health USA, Inc.	Lufenuron	Salmonids	1.35pm lufenuron in muscle/adhering skin	2016
FVG Ltd.	Azamethiphos	Salmonids	0.02ppm azamethiphos in muscle/ adhering skin	2016
Skretting Agricultural Research Center	Teflubenzuron	Atlantic salmon	0.5ppm teflubenzuron in muscle/ adhering skin	2014

The most current list of Import Tolerances is available at https://www.fda.gov/animal-veterinary/import-exports/import-tolerances.

Additional information on aquaculture-related topics can be obtained from FDA/CVM at: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/Aquaculture/default.htm.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT

The following guidance will assist you in determining whether animal drugs used in aquaculture operations are a significant food safety hazard at a processing step:

1. **Is it reasonably likely that unsafe levels of residues of aquaculture drugs will be introduced at this processing step?**

   NOTE: A "residue" means any compound present in edible tissues that results from the use of a drug, and includes the drug, its metabolites, and any other substance formed in or on food because of the drug's use (21 CFR 530.3)

   - Under ordinary circumstances, if you are a primary (first) processor, it **would be** reasonably likely that unsafe levels of residues of aquaculture drugs could enter the process at the receiving of raw material step of any type of aquaculture species, including:
     - Finfish;
     - Crustaceans;
     - Other aquatic food animals, such as frogs, snails, alligators.
   - Under ordinary circumstances, it **would be** reasonably likely that unsafe levels of residues of aquaculture drugs could be introduced during aquatic holding (e.g., live lobster, crab in tanks) or transport of live fish.
   - 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 **unless** they are kept live in holding tanks.

   If you are receiving fish (other than live fish) from another processor, you might not need to identify aquaculture drugs as a significant hazard. The primary (first) processor should have appropriate measures in place to adequately control this hazard. However, the prudent secondary processor might request records from the supplying primary processor demonstrating that the product has been processed in compliance with the HACCP

regulation, and the hazard of aquaculture drugs has been addressed by the primary processor. Documentation may include but is not limited to, test results for drug residues reasonably likely to be present, HACCP monitoring records reflecting monitoring of aquaculture drug hazard approach, reports from the primary processor visits to the raw material supplier(s), etc. It is recommended that the secondary processor keep all relevant records in files.

2. Can unsafe levels of residues of aquaculture drugs that are reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

The presence of animal drug residues in aquacultured products is associated with their use during the various stages of production, i.e. at the hatchery, on the farm and/or during holding and/or transport of live fish. This significant hazard occurs prior to the receipt of the raw material and should be considered by a primary processor at any processing step, but at the receiving of raw material step in particular. It is recommended that the primary processor has an understanding of aquaculture in general and more specifically about the operations associated with the products they process, what potential animal drugs may be used on farms and what control activities suppliers of raw material (farmer, middleman, collector) may have taken, in order to employ the appropriate preventive measure early in the process to eliminate the hazard of animal drug residues or to reduce the likelihood of its occurrence.

- **Preventive measures**

- Preventive measures for the hazard of aquaculture drugs used in aquaculture operations are ordinarily employed at either the processor receiving step or at the farm before harvest (commonly called the "pre-harvest step"). They can include the following activities and should be coupled with an appropriate verification strategy:
    - Before receiving any raw material, the processor or an informed representative conducts a visit at the farm, holding, or transport facility to evaluate the existing conditions and practices that can contribute to a potential risk of the aquaculture drug hazard. This will include:
        - a review of any program or strategy the farm implements (e.g., Good Aquaculture Practices (GAqPs)/ Best Management Practices (BMPs), or
        - a record and document review of the farm activities and procedures to control or minimize the risk of aquatic animal' diseases, including monitoring and maintaining of good water quality, managing animal feeding and feed storage, maintaining records of use and storage of animal drugs, medicated feed and other compounds (e.g., probiotics, vitamins, water conditioners).

      This review should be conducted to ensure that all products used on the farm are in conformance with FDA regulations, guidance, and labeling instructions.
    - Reviewing, at the time of receipt of each lot of the raw material, the appropriate farm(s) or other supplier's drug usage records. This should include a list of all drugs used on the farm(s) and withdrawal times for each drug used (i.e. the date when the drug was started and stopped being used or administered), and when the raw material was harvested or collected from the site. All drugs should be used in conformance with applicable FDA regulations, guidance and labeling instructions.
    - Reviewing, at the time of receipt of each lot of the raw material, a signed certification or declaration from the farmer or other supplier (middleman, broker, collector) that clearly states that no unapproved animal drugs were used during production, holding or transport of the lot of raw material delivered to the processor. If approved animal drugs were used, the certification or declaration should list all drugs used on the farm(s) and state that all drugs were approved by the FDA and were used in conformance with applicable FDA regulations, guidance, and labeling instructions.
    - Conducting, at the time of receipt of each lot of the raw material, residue testing for approved drugs used on the farm and unapproved drugs that the processor may have knowledge to be potentially administered and are considered a high enforcement priority for species received;
    - Reviewing, at the time of receipt of the raw material, evidence that the raw material

supplier/ farm operates under a competent third-party farm certification program. The evidence can be lot by-lot or continuing a third-party certificate, or a copy of documentation indicating that the farm is listed on an accessible, secure and valid web site administered by the third-party. The program can be administered and verified by a government competent authority or a private third-party entity.

The third-party farm certification program should include:

- Adequate controls for the aquaculture drug hazard and specifically address controls and preventive measures in place to reduce the risk of disease outbreaks and the use of animal drugs on the farm.
- The application of a biosecurity program designed to mitigate the risk factors for disease emergence and good aquaculture management practices that prevent and minimize the impact of diseases on animal health.
- A system in place that adequately documents animal drug use in compliance with FDA regulation, guidance, and labeling instructions.

While the third-party is administering preventative measures to control the aquaculture drug hazard, it remains the responsibility of the processor to evaluate the adequacy of the third-party control program. The processor should evaluate the adequacy of the third-party program implemented on the farm through a verification audit or inspection once a grow-out cycle, or at least once a year.

- Preventive measures for the control of aquaculture drugs used during the holding of aquatic animals (e.g., lobster pounds) and live transport can include controlled application of animal drugs in a manner consistent with:
  - Established withdrawal periods;
  - Labeled instructions for use;
  - Conditions for extra-label use of FDA-approved drugs under a licensed veterinarian's supervision and in accordance with FDA regulations and guidance;
  - Conditions specified in the FDA list of low regulatory priority unapproved aquaculture drugs;
  - Conditions of an INAD exemption meeting the criteria under 21 CFR.

- Verification

  Each HACCP plan is required to have a verification step for all CCPs identified by the processor. Under ordinary circumstances, it is reasonably likely to expect the verification step for the aquaculture drug hazard to include an appropriate aquaculture drug testing strategy. The strategy should include collecting and testing raw material from each farm and/ or supplier (whether testing is done at the production site, at receiving, in-process, or the end product). The number of samples and frequency of testing, type of drugs selected for testing, and analytical methods used will depend on the product processed. However, the overall strategy should be sufficient to demonstrate that the critical limit established is effective and working properly to control the aquaculture drug hazard. The verification activities may be carried out by competent individuals within a company, a qualified laboratory, third-party experts, or a regulatory agency. This strategy can vary according to a variety of factors and may need to be revised and adjusted.

  The following can be considered when developing or re-evaluating an appropriate, representative aquaculture drug verification testing strategy;

- What approved animal drugs are typically used in your area and on the species of fish you process?
- What unapproved animal drugs or chemical compounds may potentially be used in your area on species of fish you process? Government, academia, third-party, or industry experts may be helpful in obtaining this information.
- Does the farm establish their own aquaculture drug testing program? Determine who collects and analyzes the samples, what type of drugs are tested for, and what analytical methods are used.
- Is the supplying farm registered or approved by a government regulatory agency or listed by a third-party certification body? If so, do they collect and analyze samples for drug residues during farm visits or inspections and share results?
- What is the compliance history of drug use and testing from a given farm, has product ever been tested positive for an unapproved drug or

do you have a long history of compliance and negative test results from this farm?
- What is your relationship with the farm; do you own it, is it part of the same company and raw material is regularly tested?
- Has the farm ever had a disease outbreak? If so, how recent and did they use any animal drugs for treatment?
- Does the farm ever use animal drugs; if no, do they have documentation to verify this information?
- Have you or your representative ever seen any animal drugs stored on the farm?

○ Animal Drug Residues, Processing and Intended Use of the Final Seafood Product

Drug residue levels in aquaculture products are not normally expected to be significantly affected during common food processing activities (e.g., washing, sorting, grading, packing, fileting, breading, cooking, brining, and freezing) or preparation techniques (e.g., cooking, baking, grilling or microwaving). Therefore, it is unlikely that any typical processing or intended use of the final product will eliminate or reduce to an acceptable level the aquaculture drug hazard.

IDENTIFY CRITICAL CONTROL POINTS

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for the hazard of aquaculture drugs.

Is the hazard the result of the use of aquaculture drugs during the raising of fish (i.e., aquaculture) or during aquatic holding (e.g., lobster pounds) or transport of live fish?

- **RAISING FISH IN AN AQUACULTURE OPERATION**

  If the hazard is the result of the use of drugs during the raising of fish in an aquaculture operation, do you have a relationship, association or agreement with the farmer that enables you to visit the farm before receipt of the fish?

A. If you have such a relationship or agreement with the farmer, then you might identify a pre-harvest step as the CCP for the hazard of aquaculture drugs. The preventive measure for this type of control can include:

a. PROCESSOR'S ON-FARM VISITS

Conducting an on-farm visit to review farming conditions, including the farm's aquaculture drug use program.

A person representing the processor that is trained in aquaculture food safety should conduct a general inspection of each supplying farm at least once per grow-out cycle or more as needed. A report should be made for each visit carried out at each individual farm.

The report should include:

- date of the visit,
- name of person visiting the farm,
- observations (some observation suggestions are provided below), and
- areas that need improvement or correction.

The reports should be kept as part of the processor's HACCP records. The processor should have a procedure in place to document any follow-up enhancement or corrective steps taken by the farmer.

During a farm visit, the processor or representative should evaluate the farm's overall food safety and disease prevention program or strategy and history of animal drug use. Preventing diseases is an important element of controlling the aquaculture drug hazard, considering that the predominant reason for the use of unapproved or misuse of approved animal drugs is to treat (or attempt to treat) the diseased animals. The focus should be on ensuring that only FDA approved animal drugs and chemicals are used on the farm, that the drugs were administered correctly, in accordance with labeling instructions and/or according to a licensed veterinarian, and that the farm has the appropriate records to document their use (e.g., type of drug, indication for use (disease), dosage, a path the drug was administered, period of use, the withdrawal times).

The disease prevention strategy should include an effective biosecurity program and implementing good aquaculture practices that minimize the need for therapeutic agents such as antibiotics and other disease control veterinary medicinal products and chemical compounds.

A food safety and disease prevention program can be developed and administered voluntarily by the farm or can be required by a government competent authority regulation (e.g., mandatory Good Aquaculture Practices, Best Management Practices, farm registration/certification programs), or be a part of a third-party certification program. All of these programs should be designed to reduce the risk of disease and ensure that the product the processor receives does not contain unsafe levels of approved drugs or unapproved drug residues.

The processor may want to develop and use a checklist to document observations made while conducting a farm visit. The following are some specific components the processor should consider:

- Determine what drugs and/or medicated feed the farm uses;
- Determine if any compounds other than drugs were used for improving fish health and enhancing production (e.g., probiotics, vitamins, water conditioners);
- Examine records of any drugs and/or medicated feed used for each rearing unit (e.g., pond, cage) and the documented appropriate administration and withdrawal period information (e.g., when the drug was started and stopped, and how much time passed between the last drug treatment and fish harvest);
- Verify that the farmer has a copy of prescription or Veterinary Feed Directive (VFD) issued by a licensed veterinarian for drugs and/or medicated feed used on the farm;
- Examine records of feed source and feeding monitoring;
- Evaluate storage of drugs and/or medicated feed and regular feed;
- Evaluate storage of probiotics, vitamins, water conditioners;
- Evaluate storage of toxic chemicals including fuels, lubricants, pesticides, and other agriculture chemicals.
- Evaluate the farm's biosecurity program. The program should identify biosecurity vulnerabilities on the farm and set up internal and external barriers to control acknowledged risks that help to prevent disease outbreaks and minimize the risk of introducing, spreading, or transmitting diseases, including viruses.

  Biosecurity measures taken on the farms should be outlined in standard operating procedures (SOPs). SOPs should be implemented, followed constantly, reviewed periodically, and amended whenever necessary. For example, the program may comprise:

  - implementing stock source program, e.g., use only specific or listed pathogen-free post-larva or fry,
  - proper treatment of source water,
  - restriction on physical access to the farm site, e.g., fence around the farming site,
  - control of entry and movement of peoples and vehicles,
  - prevention of wild and domestic animals' access,
  - sanitary measures for people entering the farm, i.e., properly located and installed foot and hand dips, protective clothing,
  - sanitary measures for vehicles entering the farm,
  - using only properly clean and sanitized tools and equipment,
  - pest control management.
- Evaluate the farm's disease or best management practice program:
  - list of the potential diseases associated with the species and the farming area,
  - monitoring for early signs or symptoms of disease,
  - procedure in case of disease outbreak (e.g., name and contact information for assistance, quarantine process of the infected animals and area, disposal of dead animals, disinfection of the infected area, water, and other appropriate areas before reuse or discharge into the environment).
- Review the farm's records of monitoring of water quality parameters such as dissolved oxygen, pH, ammonia, etc. that aid the animals' health;
- Evaluate the general sanitation on the farm, including properly located and installed toilets for workers, disposal of trash or rubbish, etc.;

- Determine storage of equipment (e.g., harvest nets, aerators), machinery fuels or oils;
- Determine if the water and ice used at harvest comes from potable water and containers are cleaned and disinfected;
- Observe harvest practices, if possible;
- Review the farm production lot identification system e.g., a unique code per farm location, harvested pond, harvest date, transport and delivery, etc.;
- Review training provided to the farm employees.

The farm visit should be coupled with appropriate verification to ensure that the strategy implemented at the farm is operative and effective, and the aquaculture drug hazard is adequately controlled. This strategy should also include testing for aquaculture drug residues reasonably likely to be present.

Example 1:

This control approach is a control strategy referred to in this document as "Control Strategy Example 1 - On-Farm Visits."

A primary processor of aquacultured tilapia that regularly purchases from the same grower should visit the grower before the fish are harvested and review farming conditions, including drug usage practices and records. In addition, the processor could also choose to receive a supplier's certificate that states all drugs used were approved by the FDA and that all drugs were used in conformance with applicable FDA regulations, guidance, and labeling instructions.

The processor should combine this control approach and monitoring procedure with an appropriate aquaculture drug verification testing strategy that is sufficient to demonstrate that the critical limit is effective and working properly to control the aquaculture drug hazard and should set the CCP at the pre-harvest step.

B. If you do not have such a relationship or agreement with the farmer, then you should identify the receiving step as the CCP for the hazard of aquaculture drugs. At the receiving step, you could exercise one of the following preventive measures:

a. SUPPLIER'S CERTIFICATION OR LETTER OF GUARANTEE

Reviewing, at time of receipt, the supplier's (farmer or middleman/ collector) lot-by-lot certification or letter of guarantee indicating all drugs and chemicals were approved and used properly.

This control measure should be coupled with a proper verification including an appropriate aquaculture drug verification testing strategy that is sufficient to demonstrate that the critical limit is effective and working properly to control the hazard.

Example 2:

This control approach is a control strategy referred to in this document as "Control Strategy Example 2 - Supplier's (Farm or Middleman) Certification or Letter of Guarantee."

1. A primary processor of aquaculture shrimp that purchases shrimp raw material directly from a contract farm should receive lot-by-lot certificates/ letters of guarantee from the farmer. The certificate/letter should state that all drugs used were approved by the FDA and were used in conformance with applicable FDA regulations, guidance, and labeled instructions. The processor should combine this control strategy and monitoring procedure with an appropriate aquaculture drug verification testing strategy that is sufficient to demonstrate that the critical limit is effective and working properly to control the aquaculture drug hazard and should set the CCP at receiving.

2. A primary processor of aquaculture shrimp that purchases shrimp raw material from a number of farms through a middleman or collector should request to 1) receive a lot-by-lot certificate/letter of guarantee from each farm the raw

material was collected from that states that all drugs used were approved by the FDA and were used in conformance with applicable FDA regulations, guidance and labeled instructions, 2) request that the middleman or collector provides a list of farms he bought shrimp from with affiliated lot numbers. This would allow him to trace the product back to a farm and pond level. The processor should combine this control strategy and monitoring procedure with an appropriate aquaculture drug verification testing strategy that is sufficient to demonstrate that the critical limit is effective and working properly to control the hazard and should set the CCP at receiving.

b. PROCESSOR'S PRE-QUALIFIED SUPPLIER PROGRAM

Managing a Pre-qualified Supplier Program and List and reviewing, at the time of receipt, that the farm is on the Pre-qualified Supplier List and presence of supplier certificate or letter of guarantee.

Refer to conducting an on-farm visit for examples of criteria that should be included in the pre-qualified program (pages 9-11). This control measure should be coupled with a proper verification, including an appropriate aquaculture drug verification testing strategy that is sufficient to demonstrate that the critical limit is effective and working properly to control the hazard.

Example 3:

This control approach is a control strategy referred to in this document as "Control Strategy Example 3 – Processor's Pre-qualified Supplier Program"

A primary processor of aquaculture shrimp regularly purchases shrimp raw material from a number of farms that have been pre-qualified according to the processors established criteria. The processor maintains a list of the names of all farms that have been pre-qualified.

The processor or his trained and competent agent conducts a visit at a farm and evaluates the level of compliance with the pre-qualification requirements before placing the supplier on the pre-qualified list.

The processor ensures that each farm has adequate controls in place to control the aquaculture drug hazard (refer to conducting on-farm visit for examples of criteria that could be considered in the pre-qualified program). **The processor should have a description of their pre-qualified established criteria on file. The processor should also maintain reports of their farm visit, verifying that the farm met the pre-qualified established criteria.**

The processor should check at the time of the raw material receipt:1) if the supplier currently participates in the processor's pre-qualified program and is listed on the pre-qualified list, and 2) request a lot-by-lot or continuing certificate/letter of guarantee from each farm that states that the farm complies with the processor's pre-qualified program criteria and all drugs used were approved by the FDA and were used in conformance with applicable FDA regulations, guidance and labeled instructions.

The processor should combine this control strategy and monitoring procedure with an appropriate aquaculture drug verification testing strategy that is sufficient to demonstrate that the critical limit is effective and working properly to control the hazard and should set the CCP at receiving.

c. FARM'S RECORDS OF DRUG USE

Reviewing, at time of receipt of raw material, drug usage records on the farm.

This control measure should be coupled with an appropriate verification.

Example 4:

This control approach is a control strategy referred to in this document as "Control Strategy Example 4 - Records of Drug Use."

A primary processor of aquaculture shrimp that purchases raw material shrimp from a contract farm or multiple farms through various middlemen or collectors should receive drug usage records from all the farmers when the raw material is delivered. The records must allow the processor to determine that the farmer has only used aquaculture drugs approved by the FDA and were used in conformance with applicable FDA regulations, guidance, and labeled instructions.

Additionally, the processor should receive a lot-by-lot certificate stating that any INAD used was used in conformance with the food use authorization requirements. The processor should combine this control strategy and monitoring procedure with an appropriate aquaculture drug verification testing strategy that is sufficient to demonstrate that the critical limit is effective and working properly to control the hazard. The processor should set the CCP at receiving.

d. DRUG RESIDUE TESTING BY PROCESSOR

Conducting at time of receipt, drug testing on all lots for the presence of unapproved drugs considered as a high risk to human health and any approved drugs used on the farm.

It is recommended that testing is performed using quantitative analytical methods that measure residue concentration in the edible tissue. However, the testing can also be performed using the commercially available rapid screening test, e.g., ELISA, that would indicate the presence of a drug, family, or class of drugs. If the rapid screening test reveals that a drug residue is present, further testing with a quantitative method to confirm the result and follow-up with the supplier could be necessary.

NOTE: A limited number of rapid screening tests for aquaculture drugs are available. Tests may not be suitable to assay for all drugs that might be used in aquaculture species. Processors should be cautioned that tests that have not been validated may be unreliable. These tests may fail to detect a residue (false negative) or may give false positive results. Processors should ensure that the tests that they intend to use are appropriate for the species and tissue to be tested, are obtained from a reputable supplier, and have been validated. Special attention should be paid to test kit storage conditions and expiration dates as they may affect their performance and reliability.

Example 5:

This control approach is a control strategy referred to in this document as "Control Strategy Example 5 - Drug Residue Testing."

A primary processor of aquaculture tilapia that purchases raw material tilapia through various brokers should screen all incoming lots of tilapia with a series of validated rapid tests that target the families of drugs that are reasonably likely to be used during grow-out (e.g., chloramphenicol, nitrofurans, fluoroquinolones, sulfonamides). The processor should set the CCP at receiving.

e. THIRD-PARTY FARM CERTIFICATION PROGRAM

Reviewing, at time of receipt, evidence (e.g., continuing or lotby-lot third-party certificate, web-site listing) that the producer operates under a competent third-party farm certification program that covers biosecurity, disease prevention measures, and aquaculture drug use.

Each supplier should be assigned a unique code/number for the purpose of identification.

The third-party farm certification program can be administered by a government competent authority, a single individual, an organization, or other private entity that is acting separately and independently from the processor. Through the certification, the third-party would affirm that they have assessed, audited, inspected, or otherwise determined that an aquaculture farm has met their program requirements and controls the aquaculture drug hazard.

Processors who rely on the third-party farm certification of their raw material supplier should be knowledgeable of issues associated with aquaculture seafood and

the potential sources of contamination with animal drugs and other chemicals used on the farm for treatment or prevention of diseases. They should have expectations for the controls to be included in the third-party certification program criteria. It is the responsibility of the processor to determine the competency of the third-party and its program. The processor may seek technical assistance from an aquaculture food safety expert or consultant to determine the competency of a third-party and its certification program.

There are several factors that affect the health issues of fish and contribute to their diseases and illnesses. The major cause of the spread of diseases and pathogens into aquaculture systems has been mainly through the movement of animals, feed, broodstock, and seeds. The effective health management program needs to cover all levels of aquaculture activities from the production unit, such as ponds, tanks, cages, etc. as well as the entire farm and the area where the farm operates.

The strategy of a third-party program often includes two components: 1) fish health management practices to prevent diseases, and 2) assurance that in case of necessary drug treatments, only FDA approved animal drugs properly acquired (e.g., a veterinarian prescription), are administered, and that the farmer maintains adequate records of all drugs used.

Some third-party certification programs implement Good Aquaculture Practices (GAqPs), Best Management Program (BMP), or other similar programs to control the aquaculture drug hazard at farms. These preventative programs use a holistic approach to address the root cause or need for farmers to use antibiotics or chemicals by implementing practices that prevent or minimize the risk of diseases and keep the animals healthy until harvest. They also include a food safety component to ensure only approved drugs are used and support it with proper documentation.

While there are a variety of ways the third-party may choose to control the aquaculture drug hazard on the farm, it is important that they verify the program is effective and working. The third-party program should evaluate and provide reasonable confidence that the farm operation is managed responsibly, farming practices meet the established criteria, and the food safety of the product is not compromised.

The credible third-party farm certification program should address three main areas: biosecurity, good animal health practices, and disease contingency plan. The following elements should be included.

1. A system for maintaining records that document:

    - The source of inputs such as feed, seed, animal drugs and antibiotics, additives, chemicals that are:
        - approved by the proper authorities
        - properly used
        - properly stored
        - properly labeled and identified.
    - Type, concentration, dosage, method of administration, and withdrawal times (if applicable) of chemicals, animal drugs, probiotics, water conditioners, and the reason for their use:
    - Monitoring of grow-out water quality
    - Monitoring of sanitary conditions on the farm
    - Transaction documentation
    - Training received and provided to workers.

2. Biosecurity controls for workers and visitors:

    - Perimeter fencing, netting, or other structures intended to keep animals or unauthorized personnel out of the farm
    - Monitoring access and movement on the farm
    - A cleaning and sanitizing program for employees, any equipment used on the farm, trucks or visitors entering the farm
    - Restricted access of farm and domestic or wild animals including pets to the grow-out area
    - Using pathogen-free or disease-resistant post larva, fry, or fingerlings to minimize the risk of introducing

diseases.

3. Training of workers:

    - Health and hygienic practices
    - Handling and/or administering veterinary medicines, probiotics, water treatment chemical compounds, disinfectants, and other substances.
    - Recognize the early onset signs or symptoms of the potential diseases identified in the farm's disease contingency plan.

4. Traceability of stock and product.

    The farm should be able to identify the hatchery or origin of all products they produce and the eventual buyer, purchaser, destination or outcome of their product.

5. Monitoring and management of water quality and growing area controls to prevent the spread or introduction of disease or contamination within and between aquaculture facilities and the natural environment.

6. Monitoring and maintaining records of the source of all water and ice used on the farm during and after harvest on the animals or on food contact surfaces, e.g., to clean totes, tubs, or other containers for transport of animals.

7. Waste and pollution management controls.

8. Fish health and welfare programs monitoring the health of seed, broodstock, and fish populations on the farm and the prevention of disease:

    - Properly implement and manage controls of the sources of broodstock and seed for culture (larvae, post larvae, fry and, fingerling, etc.) to reduce the risk of carryover of potential human health hazards (e.g., residues of antimicrobials, parasites, etc.) into the growing stocks.
    - Controls to assure that aquaculture activities are conducted in a manner to maintain the health and welfare of farmed aquatic animals, e.g., minimize stress, and maintain a healthy culture environment at all phases of the production cycle.
    - Controls of the usage, proper labeling/identification, and storage for veterinary medicinal products, probiotics, water treatment chemical compounds, disinfectants, and other substances to prevent contamination of growing areas or improper and/or unapproved use.
    - Control of diseases with animal drugs and antimicrobials based on an accurate diagnosis.
    - Use only approved drugs that are specific to control or treatment of disease. In some cases, drugs may only be prescribed and distributed by a licensed veterinarian.
    - All animal drugs and chemicals or medicated feeds must be used according to the instructions of the manufacturer or veterinarian instruction with particular attention to withdrawal periods.
    - Animal drugs should be used in accordance with practices that consider both domestic requirements and the requirements of the country(ies) of intended consumers. Banned, non-registered, and/or not permitted antimicrobial agents, medicinal products for veterinary use, and/or chemicals must not be used in aquaculture production, transportation, or product processing.

9. Written Disease Contingency Plan:

    - Developed by the appropriate aquaculture expert(s) knowledgeable about the aquatic diseases associated with the species and the farming area or location.
    - Identify the potential diseases in the plan.
    - Training program for the farmworkers to recognize the early onset signs or symptoms of the potential diseases identified.
    - Procedure in case of disease outbreak

- The name and contact information (including 24hr emergency) for assistance to:
  - diagnose the disease;
  - conduct the appropriate diagnostic or laboratory analysis;
  - prescribe and provide the appropriate treatment plan.
- Quarantine process of the infected animals and area, disposal of dead animals,
- Disinfection of the infected area, water, and other appropriate areas before reuse or discharge into the environment.

Third-Party Farm Reports

The third-party farm certifier should develop a report from each inspection or audit and make it available to the processor. The report should include:

- General observations related to farm compliance with the program criteria including drug controls (records of use, test results)
- Any deficiencies observed, and corrective actions needed
- Deadline for completion of the corrective actions
- Discussion and comments with the farm management.

Third-Party Verification of Animal Drug Controls on the Farm

The third-party should implement a verification step for oversight of animal drugs administered at the farm to ensure the control strategy is properly implemented and effective. The verification should include both farm audits or inspections and analytical testing for approved animal drug residues used on the farm to ensure that no harmful residues are present. The prudent third-party certifier should also include testing for unapproved drugs of concern that may have an impact on the safety of fish products for consumers.

Processor Evaluation of Third-Party

The processor should evaluate the third-party certification program periodically (e.g., once a year or once during the grow-out cycle) to determine if the necessary safety points are addressed in the certification scheme and whether a certification scheme is implemented in accordance with described criteria. The processor should consider the assessment of inspection or audit reports and any analytical test results.

Reports of poor farm performance may necessitate more frequent audits or inspections, and any positive test for unapproved animal drugs may mean destroying product, investigation of the root cause, the need for corrective actions, or stopping the use of the third-party.

Example 6:

This control approach is a control strategy referred to in this document as "Control Strategy Example 6 – Third-party Farm Certification Program"

A primary processor of aquaculture trout that regularly purchases the raw material from a third-party certified farm should obtain evidence (continuing or lot by-lot third- party certificate, web-site listing) that the farm operates under a qualified third-party farm certification program. The certificate or evidence should be valid for the dates of the grow-out period and in case of a continuing certification for one (1) year. The certification should attest that the program the farm operates under covers aquaculture food safety components, specifically proper drug use during the grow-out period for that specific species. The processor should set the CCP at receiving of the trout raw material.

HOLDING

If the hazard is by reason of aquatic holding (e.g., lobster pounds), then you should identify the holding step as the CCP for aquaculture drugs. The preventive measure for this type of control is:

- Applying animal drugs in a manner consistent with:
  - Established withdrawal times;
  - Labeled instructions for use;
  - Conditions for extra-label use of FDA-approved drugs under a licensed veterinarian's supervision and in accordance with FDA regulations and guidance;

- Conditions specified in the FDA "low regulatory priority" aquaculture drug list;
- Conditions of an INAD food use authorization granted by FDA.

Example 7:

This control approach is a control strategy referred to in this document as "Control Strategy Example 7 - Control During Holding."

A primary processor that uses oxytetracycline in the holding of live lobster in a lobster pound should use the drug as a medicated feed in accordance with labeled instructions and should document the withdrawal time of 30 days before selling. The processor should set the CCP at holding.

- **TRANSPORT**

A. If the hazard results from transportation of live fish, then the processor should identify the receiving step as the CCP for aquaculture drugs. In this case, the processor should **refer to the guidance described in Control Strategy Examples 2 through 6**.

Example:

A primary processor that receives live tilapia from a broker on the broker's truck should receive a lot-by-lot certificate from the broker. The certificates should state that all drugs were used in conformance with the applicable FDA regulations, guidance, and labeled instructions. The processor should combine this monitoring procedure with an appropriate aquaculture drug verification testing strategy and should set the CCP at receiving.

B. If live transportation is on the processor's own truck, he should identify the transportation step as the CCP and **refer to Control Strategy Example 7 for guidance**.

Example:

A primary processor that receives live tilapia from the farmer on the processor's own truck and uses drugs to control animal health during transportation (e.g., carbon dioxide as an anesthetizing agent at levels appropriate for the purpose) should control drug use during transportation and should set the CCP at transportation.

DEVELOP A CONTROL STRATEGY

This section provides examples of seven control and verification strategies for aquaculture drug hazards. You may select a control strategy that is different from those which are suggested, provided that it complies with the requirements of the applicable US FDA food safety laws, regulations, and guidance.

While aquaculture drugs are predominately used at the hatchery, farm, during holding, or live transportation, it is the responsibility of the primary processor to have a strategy in place that effectively controls the aquaculture drug hazard.

Aquaculture, as an industry, varies widely around the world. This includes the species farmed; the production methods; the type of feed used; the availability and use of approved and unapproved drugs; the prevalence of diseases; and whether the processor can source raw material directly from farm or through middleman/collector or auction houses. In addition, the governmental regulatory structure, implementation, and oversight of food safety prevention programs at the production and processing level might differ from country to country.

Consequently, there are several factors the processor should consider when determining the appropriate control and verification strategy that would be suitable for the particular process and product. It is important to understand that the processor should have sufficient evidence and documentation to support the hazard control and verification strategy chosen to implement.

Some factors to consider may include:

- When developing the control strategy, the processor should take into consideration the source of raw material, particularly if it is procured from a middleman/collector, at an auction, or from a foreign primary processor.
- The processor should be able to trace back the raw material to a specific pond or cage, farm, farm cluster, and/or growing area.
- Regardless of the control strategy chosen, the processor should implement testing of the product for residues of animal drugs (and their metabolites) as a verification step. Information on the number of samples and frequency of testing, type of drugs to be tested, analytical methods, and the laboratory conducting testing should be sufficient to document that the critical limit identified in the HACCP plan is effective

and working properly. The processor should include all suppliers of the raw material in his testing strategy.

- If a rapid screening test kit (e.g., ELISA) is used for the product testing, the processor should ensure that the test kit is purchased from a reputable supplier, is intended for detection of a specific drug and/or metabolite(s), is properly stored, and is used before the expiration date. All test records should be kept for review.
- If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment.
- Processors and suppliers should review and keep records of aquaculture drug residue test results conducted by the country's government regulatory authority.
- The processor should conduct a comprehensive follow-up investigation along with corrective actions when an unapproved drug residue is found in product during their own check or when an importer or foreign government notifies the processor that an unapproved drug residue was detected in the product. The result of the investigation should be recorded and retained in the files.
- The processor, government regulatory authority, or a credible third-party should verify through farm visits, farmer's interviews, or other means that the farmer is, in fact, implementing any identified farm food safety control scheme or program they are participating in.
- Examples may include verifying that the farm is actually implementing a food safety program; the farmer or identified representative is actually signing the supplier's certificate; a third-party, competent authority, or a farmers' own food safety program is being implemented and is effective; and any third-party certificate is legitimate (i.e., not counterfeit) and current.
- Processors in countries that have and implement a robust, regulatory government food safety prevention and verification program on aquaculture farms should consider including this information when developing their HACCP aquaculture drug control strategy.
- Processors vertically integrated or commercially connected with a feed mill, hatchery, or farm(s) should consider including this information when developing the HACCP aquaculture drug control strategy.
- Records should be kept to support and document all decisions leading to development of the HACCP plan.

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

CONTROL STRATEGY	APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
On farm visit	✓	
Supplier's certification/ letter of guarantee	✓	✓
Processor's Pre-qualified Supplier Program	✓	✓
Records of drug use	✓	✓
Drug residue testing	✓	✓
Third-Party Farm Certification Program	✓	✓
Control During holding/ transport	✓	✓

The primary (first) processor is required to have control measures in place to adequately control this hazard. However, the prudent secondary processor might request certification from the supplying primary processor, demonstrating that the product has been processed in compliance with the HACCP regulation, and the hazard of aquaculture drugs has been addressed by the primary processor. The secondary processor might also request additional information, e.g., records of test results for drug residues reasonably likely to be present, HACCP monitoring records of aquaculture drug hazard, a supplier certificate or letter of guarantee, a third-party certification or reports from the primary processor's visit to the raw material supplier. It is recommended that the secondary processor keeps these records.

If the secondary processor uses imported aquaculture products for further processing, he should consider implementing one of the affirmative steps listed under 21CFR 123.12 "Special Requirements For Imported Products"

or use another means to verify that the original primary processor controlled the aquaculture drug hazard.

- **CONTROL STRATEGY EXAMPLE 1 – ON-FARM VISITS**

Set Critical Limits

Conduct an on-farm visit to review general farm conditions and any farm management and biosecurity programs (e.g., Good Aquaculture Practices, Best Management Practices) in place to minimize the risk of diseases and to determine whether the animal drugs and other chemicals are used appropriately and in compliance with FDA regulation, guidance, and labeling. Aquaculture drugs are used on food-producing fish only if they have been:

- Approved by FDA or granted a conditional approval by FDA and used in accordance with all labeled conditions;

  OR

- Approved by FDA and if used in an extra-label manner administered under a licensed veterinarian's supervision in accordance with FDA regulations and guidance;

  OR

- Present on the most current FDA's list of low regulatory priority aquaculture drugs and used according to the provisions described on that list;

  OR

- Used in compliance with FDA established Import Tolerance.

  OR

- Used in food fish as an INAD subject to an investigational new animal drug exemption under 21 CFR Part 511, and used according to the requirements of that food use authorization;

  AND

- Verified by the presence of a certificate from the producer indicating that
  - any investigational new animal drug used on the farm is subject to an investigational new animal drug exemption under 21 CFR Part 511, and fish intended for human consumption are subject to a food use authorization,

    AND

  - the INAD is used in the fish according to the food use authorization requirements.

Establish Monitoring Procedures

➢ What Will Be Monitored?

- Written and signed report from on-site farm visit conducted within a grow-out cycle of the harvest and shipment of fish to the processor confirming that only FDA approved drugs in accordance with all label conditions have been used;

  AND

- Certificate indicating proper INAD usage, if applicable.

➢ How Will Monitoring Be Done?

- Review on-site farm visit report surveying the farm husbandry practices and procedures and showing a proper drug usage (refer to pages 9-11 for more information on on-site farm visits).

➢ How Often Will Monitoring Be Done (Frequency)?

- At least once per grow-out cycle for each aquaculture farm site.

➢ Who Will Do the Monitoring?

- Assigned employee who has training and understanding of aquaculture food safety and drug use controls for food-producing fish.

Establish Corrective Action Procedures

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

- Reject the product if the on-site visit document is not present or not current

  OR

- Isolate and hold until the on-site farm document is provided and /or the farm lot(s) in question

are sampled and tested for potential drug residues.
- Do not buy the product or have the product shipped from the production site to a feed or food processor.

AND

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

- Discontinue use of the supplier/farm until evidence is obtained that the farm food safety and disease prevention strategy is in place and farming conditions have been improved and drug use and treatment practices have changed.

Establish a Recordkeeping System

- On-site farm visit report evaluating farming conditions;

  AND

- On-farm drug usage program and procedures;

  AND

- Certificate of proper use under an INAD exemption meeting the criteria under 21 CFR 511, if applicable.

Establish Verification Procedures

- Collect a representative number of samples of the raw material from each farm, in-process product, or finished product in order to verify that the farm is not using unapproved drugs or misusing approved drugs and analyze for those drug residues that are reasonably likely to be present. Specify drugs for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each drug;

  AND

- If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Collaboration (AOAC) International or equivalent method, or by analyzing proficiency samples;

  AND

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

TABLE 11-1

Control Strategy Example 1 – ON-FARM VISITS

This table is an example (**for illustrative purposes only**) of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - On-Farm Visits." This example illustrates how a primary processor of farm-raised tilapia can control aquaculture drugs. **An actual plan should specify under the Verification step: the aquaculture drugs for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each drug. This information can be provided in a footnote or in a separate document**.

Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides).

Example Only See Text for Full Recommendations

TABLE 11-1

Control Strategy Example 1 – ON-FARM VISITS

(1)	(2)	(3)	(4)	(5) Monitoring	(6)	(7)	(8)	(9)	(10)
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Pre-harvest	Aqua-culture drugs	1. Farm visit to review farming conditions including evaluation of the farm's aquaculture drug use and disease prevention strategy 2. Aquaculture drugs are used on fish only if the drugs have been: a. approved by FDA or granted conditional approval by FDA and used in accordance with all labeled conditions; b. approved by FDA and if used in an extra-label manner administered under a licensed veterinarian's supervision in accordance with FDA regulations and guidance; c. present on the list of low regulatory priority aquaculture drugs and used in accordance with the provisions in the list; OR d. used in food fish as an INAD in accordance with the requirements of the food use. authorization; OR e. used in compliance with FDA established Import Tolerance.	Written and signed report from on-site farm visit conducted within a grow-out cycle of the harvest and shipment of fish to the processor. AND Certificate indicating proper INAD usage, if applicable	Review on-site farm visit document showing proper drug usage Visual check for INAD certificate, if applicable	At least once per grow-out cycle for each aquaculture farm	Assigned employee trained in aquacul-ture food safety	Reject the product if the report not present or not current OR Isolate and hold until on-site visit report provided or the farm lot in question is sampled and tested for potential drug residues AND Do not have the product shipped from the production site for processing. AND Discontinue use of the supplier until evidence is obtained that drug treatment practices have changed	On-site visit report including on-farm drug usage program and procedures Certificate of INAD usage, if applicable	Collect a representative number of samples of the raw material from each farm or finished product and analyze for those drug residues that are reasonably likely to be present AND If testing is performed in the processor's laboratory periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using AOAC or equivalent methods) AND Review monitoring, verification, and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION**

Set Critical Limits

A written and signed certificate or letter of guarantee provided by the farmer or other supplier(s), e.g., middleman or collector for each lot of incoming raw material declaring that aquaculture drugs are used on fish only if they have been:

- Approved by FDA or granted a conditional approval by FDA and used in accordance with all labeled conditions;

  OR

- Approved by FDA and if used in an extra-label manner administered under a licensed veterinarian's supervision in accordance with FDA regulations and guidance;

  OR

- Present on the most current FDA's list of low regulatory priority aquaculture drugs and used according to the provisions described on that list;

  OR

- Used in compliance with FDA established Import Tolerance.

  OR

- Used in food fish as an INAD subject to an investigational new animal drug exemption under 21 CFR Part 511 and used according to the requirements of that food use authorization.

NOTE: If a raw material is outsourced from countries with known problems of use of unapproved drugs and other unsafe chemicals during the raising of fish, the prudent processor makes sure that the product meets food safety requirements and is in compliance with US FDA laws and regulations. The processor may consider implementation of affirmative steps listed under 21CFR 123.12 Special Requirements for Imported Products.

Establish Monitoring Procedures

➢ What Will Be Monitored?

- Presence of a certificate signed by the farmer or authorized farmer's representative, or another supplier (e.g., middleman, collector) indicating proper drug usage.
- If applicable, presence of certificate from the producer indicating that any investigational new drug used in fish intended for human consumption is subject to an investigational new animal drug exemption under 21 CFR Part 511 and that the INAD is used according to the requirements of the food use authorization.

➢ How Will Monitoring Be Done?

- Visual check for the presence of a certificate or letter of guarantee of proper drug use.

➢ How Often Will Monitoring Be Done (Frequency)?

- Each lot received.

➢ Who Will Do the Monitoring?

- Any person who has training and understanding of the principles of the controls.

Establish Corrective Action Procedures

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

- Reject the lot;

  OR

- Hold the lot until a certificate can be provided;

  OR

- Hold and analyze the lot for those aquaculture drugs that are reasonably likely to be present.

  NOTE: If testing is performed, the following specific information should be recorded: the protocol for sample collection, aquaculture drugs for which analyses were conducted, and the analytical method used for each drug.

AND

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

- Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls.

Establish a Recordkeeping System

- Copy of certificates or letters of guarantee;

  AND

- Receiving record showing lots received and the presence or absence of a certificate or letter of guarantee of proper drug use.

  AND

- Certificate of proper use under an INAD exemption meeting the criteria under 21 CFR 511, if applicable.

Establish Verification Procedures

- Collect a representative number of samples of the raw material from each farm, in-process product, or finished product and analyze for those drug residues that are reasonably likely to be present. Specify drugs for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each drug;

  AND

- If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Collaboration (AOAC) International (https://www.aoac.org/about-aoac-international/) or equivalent method, or by analyzing proficiency samples;

  AND

- If raw material collected and delivered by a middleman, request a list of farms he bought shrimp from with affiliated lot's numbers.

  AND

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

TABLE 11-2

Control Strategy Example 2 – SUPPLIER'S CERTIFICATION OR LETTER OF GUARANTEE

This table is an example (**for illustrative purposes only**) of a portion of a HACCP plan using "Control Strategy Example 2 - Supplier's Certification." This example illustrates how a primary processor of farm-raised shrimp can control aquaculture drugs. **An actual plan should specify under the Verification step: the aquaculture drugs for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each drug. This information can be provided in a footnote or in a separate document.**

Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides).

Example Only: See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Aquaculture Drugs	Certificate or letter of guarantee indicating proper drug usage for all lots of incoming pond- raised shrimp	Presence of a certificate or letter of guarantee indicating proper drug usage Certificate indicating proper INAD usage, if applicable	Visual Check	Each Lot received	Receiving employee trained in aquaculture food safety	Reject the lot if certificate or letter of guarantee is absent Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls	Producer's drug usage certificate or letter of guarantee Certificate of INAD usage, if applicable Receiving record	Collect a representative number of samples of the raw material from each farm and analyze for those drug residues that are reasonably likely to be present If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using AOAC or equivalent methods) If raw material collected and delivered by a middleman, request a list of farms he bought shrimp from with affiliated lot numbers. Review monitoring, verification, and corrective action records within 1 week of preparation

- **CONTROL STRATEGY 3 -PROCESSOR'S PRE-QUALIFIED SUPPLIER PROGRAM**

Set Critical Limits

All supplying farms participate in the processor's described and documented pre-qualified supplier program and are on the supplier/vendor list at the time of raw material delivery;

AND

A written and signed certificate or letter of guarantee provided by the farmer (continuing or lot-by-lot) declaring compliance with the processor's pre-qualification requirements and confirming that aquaculture drugs are used on fish only if they have been:

- Approved by FDA or granted a conditional approval by FDA and used in accordance with all labeled conditions;

  OR

- Approved by FDA and if used in an extra-label manner administered under a licensed veterinarian's supervision in accordance with FDA regulations and guidance;

  OR

- Present on the most current FDA's list of low regulatory priority aquaculture drugs and used according to the provisions described on that list;

  OR

- Used in compliance with an established Import Tolerance.

  OR

- Used in food fish as an INAD subject to an investigational new animal drug exemption under 21 CFR Part 511 and used according to the requirements of that food use authorization.

Establish Monitoring Procedures

➢ What Will Be Monitored?

- Presence of farm(s) on the processor's pre-qualified list;

  AND

- Presence of a certificate/letter of guarantee signed by the farmer or farmer's representative declaring that the lot was produced in compliance with the processor's program requirements.

➢ How Will Monitoring Be Done?

- Visual check that farm(s) are on the processor's supplier/vendor list;

  AND

- Visual check for the presence of a certificate or letter of guarantee.

➢ How Often Will Monitoring Be Done (Frequency)?

- Each lot received.

➢ Who Will Do the Monitoring?

- Any person who has an understanding of the principles of the controls.

Establish Corrective Action Procedures

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

- Reject the lot if the farm is not on the processor's pre-qualified list

  OR

- If the farm on the processor's pre-qualified list did not provide a certificate or letter of guarantee:
  - Reject the lot;

    OR

  - Hold the lot until a certificate can be provided;

    OR

  - Hold and analyze the lot for those aquaculture drugs that are reasonably likely to be present.

AND

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

- Do not accept the raw material from the farm not on the processor's pre-qualified list

  AND

- Conduct on-farm evaluation to ensure that the supplier complies with the processor's pre-qualified program

  AND

- Discontinue use of the supplier until evidence is obtained that the supplier will comply with the processor's pre-qualified program requirements.

Establish a Recordkeeping System

- The processor's current list of pre-qualified farms

  AND

- Receiving records showing lot received and presence or absence of a certificate or letter of guarantee;

  AND

- The processor inspection report of pre-qualified farms

  AND

- Copy of testing results for aquaculture drugs that are reasonably likely to be present, if applicable.

Establish Verification Procedures

- Conduct on-site visits of farms participating in the processor's pre-qualification program to evaluate their compliance regularly (at minimum, once per grow-out period). Refer to conducting on-farm visit for examples of criteria that should be included in the pre-qualified program.

  AND

- Review the processor's pre-qualified list weekly to ensure it is up to date.

  AND

- Collect a representative number of samples of the raw material from each farm and analyze for those drug residues that are reasonably likely to be present:

  NOTE: If testing is performed, the following specific information should be recorded: the protocol for sample collection; aquaculture drugs for which analysis were conducted, and the analytical method used for each drug.

  AND

- If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Collaboration (AOAC) International (https://www.aoac.org/about-aoac-international/) or equivalent method, or by analyzing proficiency samples;

  AND

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

TABLE 11-3

CONTROL STRATEGY EXAMPLE 3 - PROCESSOR'S PRE-QUALIFIED SUPPLIER PROGRAM

This table is an example (**for illustrative purposes only**) of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 3 – Processor's Pre-Qualified Supplier Program." This example illustrates how a primary processor of farm-raised shrimp can control aquaculture drugs. **An actual plan should specify under the Verification step: the aquaculture drugs for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each drug. This information can be provided in a footnote or in a separate document.**

Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides).

Example Only: See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Aquaculture drugs	All supplying farms participate in the processor's pre-qualified supplier program and are on the supplier/vendor list.	Presence of the farm on the Pre-qualified Supplier List	Visual check	Each lot	Receiving employee trained in aquaculture food safety	Reject the product Do not accept the raw material from non-prequalified supplier	The current list of prequalified suppliers	Conduct on-site visits of farms participating in the processor's pre-qualification program to evaluate their compliance regularly (at minimum, once per grow-out period). Review the processor's pre-qualified list weekly to ensure it is up to date. Collect a representative number of samples of the raw material from each farm and analyze for those drug residues that are reasonably likely to be present

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Aquaculture drugs	A signed certificate or letter of guarantee (continuous or lot-by-lot) declaring compliance with the processor's pre-qualification requirements and confirming that aquaculture drugs are used on fish only if they have been: • Approved by FDA or granted a conditional approval by FDA and used in accordance with all labeled conditions; OR • Approved by FDA and if used in an extra-label manner administered under a licensed veterinarian's supervision in accordance with FDA regulations and guidance; OR • Present on the most current FDA's list of low regulatory priority aquaculture drugs and used according to the provisions described on that list; OR • Used in compliance with an established Import Tolerance. OR • Used in food fish as an INAD according to the requirements of that food use authorization	Presence of a certificate or letter of guarantee Certificate indicating proper INAD usage, if applicable	Visual check	Each lot	Receiving employee trained in aquaculture food safety	If the farm on the processor's pre-qualified list: Reject the lot OR Hold the lot until a certificate can be provided; OR Hold and analyze the lot for those aquaculture drugs that are reasonably likely to be present. Conduct on-farm evaluation to ensure that the supplier complies with the processor's pre-qualified program AND Discontinue use of the supplier until evidence is obtained that the supplier will comply with the processor's pre-qualified program requirements.	Receiving records showing lot received and presence or absence of a certificate or letter of guarantee Copy of testing results for aquaculture drugs that are reasonably likely to be present, if applicable Certificate of INAD usage, if applicable	If testing is performed in the processor's laboratory periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using AOAC or equivalent methods) Review monitoring, verification, and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 4 - RECORDS OF DRUG USE**

Set Critical Limits

Records of drug usage for each delivery from each farm that show aquaculture drugs were used only if the drugs have been:

- Approved by FDA or granted conditional approval by FDA and used in accordance with all labeled conditions;

  OR

- Approved by FDA and if used in an extra-label manner administered under a licensed veterinarian's supervision in accordance with FDA regulations and guidance;

  OR

- Present on the most current FDA's list of low regulatory priority aquaculture drugs and used according to the provisions described on that list;

  OR

- Used in compliance with FDA established Import Tolerance.

  AND

- A lot-by-lot certificate from the farmer indicating that any investigational new animal drug (INAD) used in fish intended for human consumption is subjected to an investigational new animal drug exemption under 21 CFR Part 511 and that the INAD is used according to the food use authorization requirements.

Establish Monitoring Procedures

➢ What Will Be Monitored?

- Records of on-farm drug use;

  AND

- Certificate indicating proper INAD usage.

➢ How Will Monitoring Be Done?

- Visual check of drug use records and INAD certificate of proper use.

➢ How Often Will Monitoring Be Done (Frequency)?

- Each lot received.

➢ Who Will Do the Monitoring?

- Any person who has an understanding of the principles of the controls.

Establish Corrective Action Procedures

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

- Reject the lot

AND

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

- Discontinue use of the supplier until evidence is obtained that drug treatment practices have changed and/or the producer will comply with the certification controls.

Establish a Recordkeeping System

- Records of drug usage on the farm;

  AND

- Certificate of proper use under an INAD exemption meeting the criteria under (21CFR Part 511), if applicable.

Establish Verification Procedures

- Collect a representative number of samples of the raw material from each farm, in-process product, or finished product, and analyze for those drug residues that are reasonably likely to be present. Specify drugs for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each drug;

  AND

- If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical

Collaboration (AOAC) International (https://www.aoac.org/about-aoac-international/) or equivalent method, or by analyzing proficiency samples;

AND

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

TABLE 11-4

Control Strategy Example 4 – RECORDS OF DRUG USE

This table is an example (**for illustrative purposes only**) of a portion of a HACCP plan using "Control Strategy Example 4 - Records of Drug Use." This example illustrates how a farm-raised shrimp processor can control aquaculture drugs. **An actual plan should specify under the Verification step: the aquaculture drugs for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each drug. This information can be provided in a footnote or in a separate document.**

Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., chemical contaminants).

Example Only: See Text for Full Recommendations

TABLE 11-4

Control Strategy Example 4 – RECORDS OF DRUG USE

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Aquaculture drugs	Drug usage records for each delivery that show that drugs were used on fish only if the drugs have been: • Approved by FDA or granted conditional approval by FDA and used in accordance with all labeled conditions; • Approved by FDA and if used in an extra-label manner administered under a licensed veterinarian's supervision in accordance with FDA regulations and guidance; • Present on the most current FDA's list of low regulatory priority aquaculture drugs and used according to the provisions described in the list Used in food fish in compliance with an established Import Tolerance.	Records of on-farm drug usage from each farm	Visual check	Each lot received	Receiving trained employee in aquaculture food safety	Reject the lot Discontinue use of the supplier until evidence is obtained that drug use and treatment practices have changed	Farmer's drug usage records Receiving record	Collect a representative number of samples of the raw material from each farm and analyze for those drug residues that are reasonably likely to be present. If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using AOAC or equivalent methods). Review monitoring, verification, and corrective action records within 1 week of preparation

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Aquaculture drugs	Lot-by-lot certificate from the producer indicating that any investigational new aquaculture drug (INAD) used in fish intended for human consumption is used according to the requirements of the food use authorization, if applicable	Certificate indicating proper INAD usage, if applicable	Visual check	Each lot received	Receiving trained employee in aquaculture food safety	Reject the lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification requirements	Certificate of INAD usage Receiving record	Collect a representative number of samples of the raw material from each farm and analyze for those drug residues that are reasonably likely to be present. If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using AOAC or equivalent methods). Review monitoring, verification, and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 5 - DRUG RESIDUE TESTING**

Set Critical Limits

- No fish may contain residues of an unapproved drug (other than for those with an established import tolerance, those used under an INAD according to the requirements of the food use authorization, or used in accordance with the criteria specified in the list of low regulatory priority aquaculture drugs);

  AND

- No fish may contain residues of an approved drug that is above FDA established tolerance level for that drug.

Establish Monitoring Procedures

➢ What Will Be Monitored?

- Fish edible portion for those drug residues that are reasonably likely to occur.

➢ How Will Monitoring Be Done?

- Obtain a representative number of samples from the lot of raw material supplied by each farm and test for drugs using validated analytical methods.

➢ How Often Will Monitoring Be Done (Frequency)?

- Each lot received.

➢ Who Will Do the Monitoring?

- Any person who is qualified by training or experience to perform the analyses.

Establish Corrective Action Procedures

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

- Reject the lot.

AND

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

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

Establish a Recordkeeping System

- Results of testing conducted to control the hazard (critical limit)

AND

- Results of verification testing

Establish Verification Procedures

- If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Collaboration (AOAC) International (https://www.aoac.org/about-aoac-international/) or equivalent method, or by analyzing proficiency samples;

  AND

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

TABLE 11-5

Control Strategy Example 5 – DRUG RESIDUE TESTING

This table is an example (**for illustrative purposes only**) of a portion of a HACCP plan using "Control Strategy Example 5 - Drug Residue Testing." This example illustrates how a primary processor of farm- raised Tilapia can control aquaculture drugs.

An actual plan should specify in the:

1. **Critical Limits: the aquaculture drugs that are reasonably likely to be present and the critical limits to be applied to each drug; and**
2. **Verification steps: the aquaculture drugs for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each drug.**

This information can be provided in a footnote or in a separate document.

Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides).

Example Only: See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Aquaculture drugs	1. No fish may contain residues of unapproved drugs (other than those with an established import tolerance, those used under an INAD subject to an investigational new animal drug exemption under 21 CFR Part511 according to requirements of the food use authorization, or those included on the list of low regulatory priority aquaculture drugs) 2. No fish may contain residues of an approved drug that is above FDA tolerance for that drug	Fish edible portion for drug residues	Obtain samples and analyze for drugs using validated analytical methods	Each lot received	Quality assurance personnel	Reject the lot Discontinue use of the supplier until evidence is obtained that drug treatment practices have changed	Analytical testing results to control hazard (critical limit) and verification	If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using AOAC or equivalent methods) Review monitoring, verification, and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 6 – Third-party Farm Certification Program**

Set Critical Limits.

Documentation indicating that the aquaculture farm operates under a third-party farm certification program. The program should include adequate controls for the aquaculture drug hazard, and measures implemented prevent this hazard from occurring (i.e., biosecurity and disease prevention plan). The third-party farm certification program with the food safety component can be administered and verified through a qualified government competent authority or a private third-party entity (A list of third-party certification bodies that have been accredited under the FDA's voluntary Accredited Third-Party Certification Program is available at the FDA Data Dashboard https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program-public-registry-accredited-third-party-certification).

The documentation confirming that a farm operates under a third-party certification program and implements adequate controls for the aquaculture drug hazard may include:

- a valid certificate that accompanies each lot of incoming aquacultured product, or
- a valid certificate issued for each farm by a third-party declaring that the farm currently operates continually under their program (the continuing certification), and
- a copy of documentation indicating that the farm is listed on an accessible secure and valid web site administered by the competent authority or third-party (real-time listing).

Each farm/supplier should be assigned a unique code/number for the identification purpose.

NOTES:

1. Overall, a third-party farm program should provide reasonable assurances that the farm operation is managed responsibly, the farming practices meet the established criteria, and there is a high level of confidence in the safety of the product.

   The focus of an effective aquaculture farm food safety program should be on ensuring that only approved animal drugs and chemicals are used on the farm and that they are administered or applied correctly and in compliance with US FDA regulations. A disease prevention strategy should also be a part of the program. This includes requiring farms to have an effective biosecurity program and implementing good aquaculture practices that minimize the need for therapeutic agents, such as antibiotics and other disease control compounds that may not be approved for use in fish. Refer to pages 13-16 for more information and examples of criteria to be included in a third-party farm certification program.

2. While a farm may be under a third-party certification program, it remains the processor's responsibility to ensure and verify their products do not contain unapproved animal drug residues and/or residues of drugs approved by the FDA do not exceed tolerance levels established for those drugs by the FDA.

Establish Monitoring Procedures.

➢ What Will Be Monitored?

- Certificate/documentation indicating that the farm operates under a third-party farm certification program.

➢ How Will Monitoring Be Done?

- Visual check for presence of a certificate/documentation.

➢ How Often Will Monitoring Be Done (Frequency)?

- Each lot received must be checked for the presence of certificate or documentation that the farm operates under a third-party farm certification program. Documents may be issued on a lot-by-lot or continuing basis (i.e., at least once during each grow-out period).

➢ Who Will Do the Monitoring?

- Any person who has training, knowledge and understanding of aquaculture food safety and fundamentals of the third-party farm certification program.

Establish Corrective Action Procedure.

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

- Reject the lot;

  OR

- Hold the lot until the documentation/certificate can be provided;

  OR

- Hold and analyze the lot for those aquaculture drugs that are reasonably likely to be present.

  NOTE: If testing is performed, the following specific information should be recorded: the protocol for sample collection; aquaculture drugs for which analyses were conducted, and the analytical method used for each drug.

AND

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

- Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls.

Establish a Recordkeeping System

- Third-party farm certificate or a copy of online farm listing;

  AND

- Receiving record showing lots received and presence or absence of a certificate/online farm listing.

  AND

- Testing results for aquaculture drugs that are reasonably likely to be present, showing the third-party program criteria are effective as applicable.

  AND

- A report of evaluation of the third-party farm certification program with emphasis on the food safety component of aquaculture drugs use.

Establish Verification Procedures

- Evaluate the adequacy of the food safety component identified in the third-party farm certification program initially and at least once a year to determine if:
  - the program addresses the aquaculture drug food safety hazard and
  - the program is properly implemented and verified.

  NOTE: See pages 13-16 for description of criteria that should be included in a third-party farm certification program.

  AND

- Review results of farm inspection and verification audits conducted by the third-party food safety program and any testing for drug residues carried out on the farm at least annually;

  AND

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

TABLE 11-6

CONTROL STRATEGY EXAMPLE 6 – THIRD-PARTY CERTIFICATION PROGRAM

This table is an example (**for illustrative purposes only**) of a portion of a HACCP plan using "Control Strategy Example 6 – Third Part Farm Certification Program." This example illustrates how an aquacultured trout processor can control aquaculture drugs.

Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants).

Example Only: See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Aquaculture drugs	Documentation/ certificate that the farm operates under the qualified third-party farm certification program and adequately addresses aquaculture drug hazard.	Presence of a third-party certificate OR Documentation showing the farm listing on the third-party website (e.g. a government administered program)	Visual check	Each lot	Receiving trained employee in aquaculture food safety and the third-party documentation requirements for this critical limit	Reject the lot OR Hold the lot until the documentation/ certificate can be provided OR Hold and analyze the lot for those aquaculture drugs that are reasonably likely to be present. AND Discontinue use the supplier until evidence is obtained that the supplier complies with the documentation requirements	Third-party farm certificate or a copy of online farm listing by the third-party entity Receiving record Testing results for aquaculture drugs that are reasonably likely to be present, if applicable Report of the third-party program evaluation	Evaluate the adequacy of the third- party farm certification program food safety component and its implementation initially and at least once a year. Review results of farm inspection and verification audits conducted by the third-party and test results carried out on the farm, at least annually Review monitoring, verification, and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 7 - CONTROL DURING HOLDING**

Set Critical Limits

Aquaculture drugs are used on food fish only if they have been:

- Approved by FDA or granted a conditional approval by FDA and used in accordance with all labeled conditions;

  OR

- Approved by FDA and used in an extra-label manner under a licensed veterinarian's supervision in accordance with FDA regulations and guidance;

  OR

- Present on the most current FDA's list of low regulatory priority aquaculture drugs and used according to the provisions described in the list;

  OR

- Used in food fish as an INAD subject to an investigational new animal drug exemption under 21 CFR Part 511, and used according to the requirements of the food use authorization;

  OR

- Used in food fish in compliance with an established Import Tolerance for the drug.

Establish Monitoring Procedures

➢ What Will Be Monitored?

- Type of aquaculture drug used;

  AND

- Date and quantity of drug use;

  AND

- Any other conditions of drug usage that are relevant to:
  - Established withdrawal period;
  - Labeled instructions;
  - Extra-label use of an FDA-approved drug administered under a veterinarian's supervision in accordance with FDA regulations and guidance;
  - Conditions specified in the FDA list of low regulatory priority aquaculture drugs;

    OR

  - Requirements of the INAD food use authorization, if applicable;

  AND

- Date of distribution of the finished product.

➢ How Will Monitoring Be Done?

- Visually, observe and record drug use and finished product distribution.

➢ How Often Will Monitoring Be Done (Frequency)?

- Every time aquaculture drugs are used during holding or transportation;

  AND

- Every time the finished product is distributed.

➢ Who Will Do the Monitoring?

- Any person who has an understanding of principles of the controls.

Establish Corrective Action Procedures

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

- Destroy the product if unapproved drug residues detected;

  OR

- For approved/conditionally approved drug with an established tolerance level or import tolerance level:
  - hold the product until the mandatory withdrawal period has been met and until the drug residue level is below the established tolerance. These corrective actions should be verified by collecting and analyzing a representative number of samples of the product, using an appropriate analytical method.

AND

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

- Modify drug use practices.

Establish a Recordkeeping System

- Drug use records;

  AND

- Records indicating date of distribution of the finished product.

  AND

- Results of verification testing for residues of drug used during holding or transport.

Establish Verification Procedures

- Test the product for residues of drug used during holding before distribution
- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete, and any critical limit deviations that occurred were appropriately addressed.

TABLE 11-7

Control Strategy Example 7 – CONTROL DURING HOLDING

This table is an example (**for illustrative purposes only**) of a portion of a HACCP plan using "Control Strategy Example 7 - Control During Holding." This example illustrates how a processor that holds live lobster in a lobster pound can control aquaculture drugs.

Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants, pesticides and natural toxins).

Example Only: See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
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 and withdrawal time	Visual observation of drug use and records	Every time aquaculture drugs are used	Production trained employee	Destroy the lot when unapproved drugs are used Hold the product Collect a sample of the finished product and analyze for residues of drug used (oxytetracycline) Release the product if the drug residue level is below the tolerance (2 ppm) Hold the product if the drug residue level exceeds the tolerance and retest Modify drug use practices	Drug use record	Test the product for residues of drug used during holding before distribution Review monitoring and corrective action records within 1 week of preparation
			Date of finished product distribution	Visual check of product distribution and records	Every time finished product is shipped	Shipping supervisor		Shipping record	

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We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA verified the website addresses for the references it makes available as hyperlinks on the Internet copy of this Guidance. FDA is not responsible for any subsequent changes to Non- FDA Web site references after April 2018.

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NOTES:

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

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

UNDERSTAND THE POTENTIAL HAZARD.

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

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

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

Managing time and temperature of exposure

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

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

Presence of pathogenic bacteria

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

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

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

Pathogenic bacteria growth

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

Consider:

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

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

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

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

Infective dose

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

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

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

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

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

Levels of pathogenic bacteria

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

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

Practical considerations for unrefrigerated processing

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

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

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

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

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

- **Strategies for control of pathogenic bacteria**

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

- Managing the amount of time that food is exposed to temperatures that are favorable for pathogen growth and toxin production (covered generally in this chapter; for *Clostridium botulinum* (*C. botulinum*), in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16) or by retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (hereinafter, the Low-Acid Canned Foods (LACF) Regulation);
- Killing pathogenic bacteria by processes that retain the raw product characteristics (covered in Chapter 17);
- Controlling the amount of moisture that is available for pathogen growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the amount of moisture that is available for pathogen growth (water activity) in the product by formulation (covered in Chapter 13);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the level of acidity (pH) in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by Chapter 13 for refrigerated acidified products);
- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 4).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether pathogenic bacteria growth and toxin formation as a result of time and temperature abuse is a significant hazard at a processing step:

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

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

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

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

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

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

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

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

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

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

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

   Pathogenic bacteria growth and toxin formation due to time and temperature abuse should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measures that can be applied for pathogenic bacteria growth and toxin formation due to time and temperature abuse include:

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

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

- **Intended use**

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

  FDA is not aware of any HACCP controls that exist internationally for the control of pathogenic bacteria in fish and fishery products that are customarily fully cooked by the consumer or end user before consumption, other than a rigorous sanitation regime as part of a prerequisite program or as part of HACCP itself. The Fish and Fishery Products regulation, 21 CFR 123 (called the Seafood HACCP Regulation in this guidance document) requires such a regime. The proper application of sanitation controls is essential because of the likelihood that pathogenic bacteria can be introduced into fish and fishery products through poor handling practices by the aquaculture producer, the fisherman, or the processor.

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

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

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

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

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for pathogenic bacteria growth and toxin formation as a result of time and temperature abuse:

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

   Example:

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

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

   However, there are two important limitations to this strategy:

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

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

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

   Example:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

  These products are not heated during processing to a temperature that destroys pathogenic bacteria. They are often consumed without cooking. Examples include: cold-smoked fish, raw oysters, clams and mussels, and raw finfish (when the processor has knowledge or has reason to know that the product will be consumed without a process sufficient to kill pathogens of public health concern or where the processor represents, labels, or intends for the product to be so consumed).

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

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

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

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

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

- **Time and temperature profile**

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

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

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

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

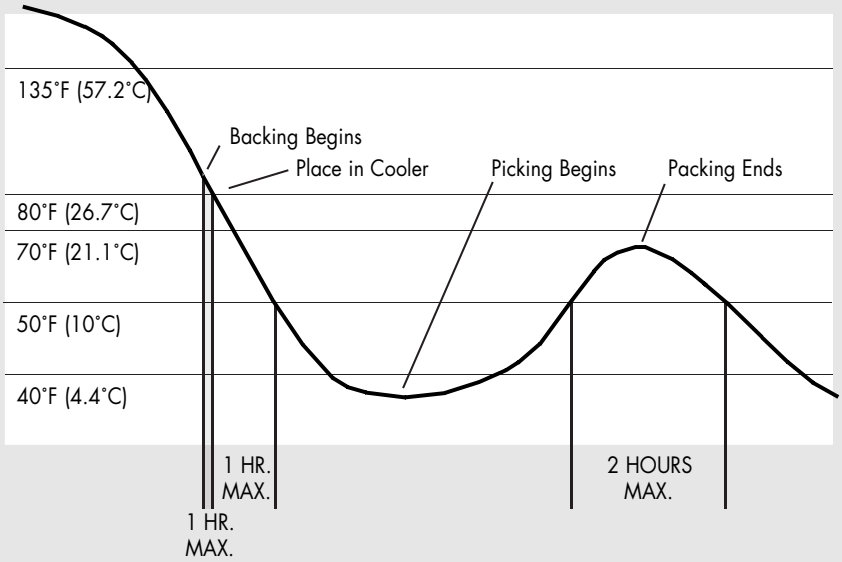
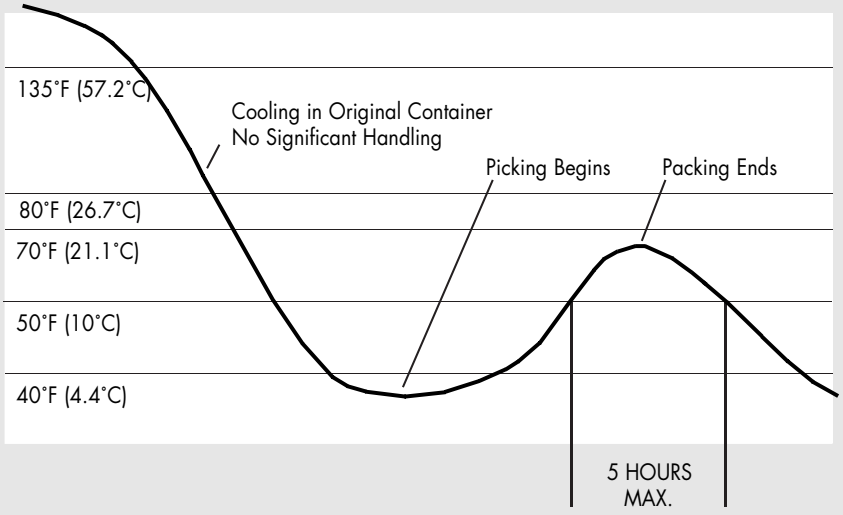


FIGURE 12-2: Internal Temperature Profile — Blue Crabmeat Processing
Cooling After Cook in Original Container With No Significant Handling During Cooling



DEVELOP A CONTROL STRATEGY.

The following guidance provides examples of four control strategies for pathogenic bacteria growth and toxin formation. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation. You may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

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

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Transit control		✓
Refrigerated storage and refrigerated processing control	✓	✓
Cooling after cooking control	✓	✓
Unrefrigerated processing control	✓	✓

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

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

Set Critical Limits.

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

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

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

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

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

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

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

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

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

OR

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

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

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

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

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

» **How Will Monitoring Be Done?**

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

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

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

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

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

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

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

- Every lot received.

» **Who Will Do the Monitoring?**

- For continuous temperature-recording devices:

- Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have consistently been met, may be performed by any person who has an understanding of the nature of the controls;

OR

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

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

OR

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

OR

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

OR

- Reject the lot.

AND

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

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

Establish a Recordkeeping System.

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

    AND

    - Visual check of recorded data;

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

    AND

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

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

    AND

    - The number of units in the lot;

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

AND

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

AND

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

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

      OR
    - Comparing the temperature reading on the device to the reading on a known accurate reference device (e.g., a thermometer traceable to standards of the National Institute of Standards and Technology (NIST)) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

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

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

  AND
- Check the accuracy of temperature-recording devices that are used for monitoring transit conditions upon receipt of each lot. The accuracy of the device can be checked by comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

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

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

TABLE 12-1

CONTROL STRATEGY EXAMPLE 1 - TRANSIT CONTROL

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

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

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receiving pasteurized crabmeat	Pathogenic bacteria growth and toxin formation	All lots received are accompanied by truck records that show temperature was maintained at or below 40°F	Temperature of truck refrigerated compartment	Digital time and temperature data logger	Continuous, with visual review and evaluation of temperature monitoring records for each shipment	Receiving employee	Reject the shipment Discontinue use of the supplier or carrier until evidence is obtained that the identified transportation-handling practices have been improved	Data logger printout	Check accuracy of the temperature data logger upon receipt of each lot Review monitoring, corrective action, and verification records within 1 week of preparation

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

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

Set Critical Limits.

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

OR

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

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

OR

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

» **How Will Monitoring Be Done?**

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

OR

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

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

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

OR

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

» **Who Will Do the Monitoring?**

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

  OR
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

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

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

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

  OR
- Destroy the product;

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

AND

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

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

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

    OR
  - Freeze the product;

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

    OR
  - Make adjustments to the ice application operations.

Establish a Recordkeeping System.

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

    AND
  - Record of visual checks of recorded data;

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

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

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

      OR
    - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

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

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

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

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

TABLE 12-2

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

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

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

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Finished product cooler	Pathogenic bacteria growth and toxin formation	Finished product containers completely surrounded with ice	Adequacy of ice	Visual observation	Each case immediately before shipping	Production employee	Re-ice the product Hold and evaluate based on total time and temperature exposure	Ice storage record	Check internal temperature of iced crabmeat weekly Review monitoring, corrective action, and verification records within 1 week of preparation

TABLE 12-3

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

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

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

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Finished product cooler	Pathogenic bacteria growth and toxin formation	Cooler maintained at or below 40°F	Cooler temperature	Digital time and temperature data logger	Continuous, with visual check of recorded data once per day	Production employee	Move to alternate cooler and/or add ice Hold and evaluate based on total time and temperature exposure	Data logger printout Record or visual checks	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

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

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

Set Critical Limits.

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

  AND

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

  OR

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

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

  OR

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

» **How Will Monitoring Be Done?**

- Clock;

  AND

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

  OR

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

  OR

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

Example:

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

Example:

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

Example:

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

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

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

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

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

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

» **Who Will Do the Monitoring?**

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

  OR
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

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

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

  OR
- Destroy the product;

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

AND

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

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

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

  OR
- Make adjustments to the ice application operation.

Establish a Recordkeeping System.

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

OR

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

    AND
  - Record of visual checks of recorded data;

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

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) or temperature- recording device (e.g., a time and temperature data logger) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

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

    OR
  - Doing a combination of the above if the device will be used at or near room temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

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

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

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

TABLE 12-4

CONTROL STRATEGY EXAMPLE 3 - COOLING AFTER COOKING CONTROL

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

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

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Cooked crab cooler	Pathogenic bacteria growth and toxin formation	Crabs cooled from 135°F to 70°F in 2 hours and 70°F to 40°F in 4 more hours	Length of cooling cycle	Clock	Start marked batch Approximately every 2 hours during cooking	Production supervisor	Destroy product Make adjustment or repairs to cooler	Production record	Check the dial thermometer for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
			Cooked crab internal temperature	Dial thermometer in marked batches of cooked crabs					

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

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

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

Set Critical Limits.

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

For raw, ready-to-eat products:

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

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

  OR

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

    OR

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

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

For cooked, ready-to-eat products:

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

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

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

  OR

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

OR

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

OR

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

OR

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

OR

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

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

Example:

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

Example:

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

TABLE 12-5

CUMULATIVE TIME AND TEMPERATURE CRITICAL LIMITS

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

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

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

    OR
  - The ambient temperature of the processing area;

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

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

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

» **How Will Monitoring Be Done?**

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

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

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

Example:

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

Example:

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

Example:

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

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

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

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

    OR
  - Every batch.

» **Who Will Do the Monitoring?**

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

  OR
- For temperature-indicating devices and clocks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

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

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

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

  OR
- Destroy the product;

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

AND

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

- Add ice to the product;

  OR
- Return the affected product to the cooler;

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

Establish a Recordkeeping System.

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

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) or temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

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

OR

- Doing a combination of the above if the device will be used at or near room temperature;

OR

- Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature and product internal temperature) within the temperature range at which it will be used;

AND

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

AND

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

AND

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

AND

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

TABLE 12-6

CONTROL STRATEGY EXAMPLE 4 - UNREFRIGERATED PROCESSING CONTROL

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

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

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Backing, in-process cooler, picking, and packing	Pathogenic bacteria growth and toxin formation	Exposure time (i.e., time at internal temperatures above 50°F but below 135°F) during backing, in-process cooler, picking, and packing should be limited to 4 hours, as long as no more than 1 of those hours is above 70°F	The length of time of product exposure to unrefrigerated conditions (i.e., above 40°F)	Visual observation of marked containers using a clock	Start marked container approximately every 2 hours during backing, in-process cooler, picking, and packing	Production supervisor	Immediately ice product or move to cooler Hold and evaluate based on total time and temperature exposure	Production record	Check the dial thermometer for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, verification, and corrective action records within 1 week of preparation
			The product internal temperature during the exposure period	Dial thermometer					

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

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

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NOTES:

CHAPTER 13: **Clostridium botulinum Toxin Formation**

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

UNDERSTAND THE POTENTIAL HAZARD.

Clostridium botulinum (*C. botulinum*) toxin formation can result in consumer illness and death. It is the toxin responsible for botulism. About 10 outbreaks of foodborne botulism occur annually in the United States, from all sources. Symptoms include: weakness, vertigo, double vision, difficulty in speaking, swallowing and breathing, abdominal swelling, constipation, paralysis, and death. Symptoms start from 18 hours to 36 hours after consumption. Everyone is susceptible to intoxication by *C. botulinum* toxin; only a few micrograms of the toxin can cause illness in a healthy adult. Mortality is high; without the antitoxin and respiratory support, death is likely.

This chapter covers the hazard of *C. botulinum* growth and toxin formation as a result of time and temperature abuse during processing, storage, and distribution.

- **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 level of acidity (pH) in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by this chapter for refrigerated acidified products);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the introduction of pathogenic bacteria after the pasteurization process and after the cooking process performed immediately before reduced oxygen packaging (covered in Chapter 18);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 4);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in this chapter; and for *Staphylococcus aureus (S. aureus)* in hydrated batter mixes, in Chapter 15);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16), or retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (hereinafter, the Low-Acid Canned Foods (LACF) Regulation));
- Killing pathogenic bacteria by processes that retain the raw product characteristics (covered in Chapter 17).

- **Formation of *C. botulinum* toxin**

When *C. botulinum* grows, it can produce a potent toxin, one of the most poisonous naturally occurring substances known. The toxin can be destroyed by heat (e.g., boiling for 10 minutes), but, because of its potency, you should not rely on this as a means of control.

The strains of *C. botulinum* can be divided into two groups, the proteolytic group (i.e., those that break down proteins) and the non-proteolytic 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 non-proteolytic group includes *C. botulinum* type E and some of types B and F.

The vegetative cells of all types of *C. botulinum* are easily killed by heat. However, *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 non-proteolytic group (i.e., they require a canning process to be destroyed). Table A-4 (Appendix 4) provides guidance about the conditions under which the spores of the most heat-resistant form of non-proteolytic *C. botulinum*, type B, are killed. However, there are some indications that substances that may be naturally present in some products (e.g., dungeness crabmeat), such as lysozyme, may enable non-proteolytic *C. botulinum* to more easily recover after heat damage, resulting in the need for a considerably more stringent process to ensure destruction.

C. botulinum is able to produce toxin when a product in which it is present is exposed to temperatures favorable for growth for sufficient time. Table A-1 (Appendix 4) provides guidance about the conditions under which *C. botulinum* and other pathogenic bacteria are able to grow. Table A-2 (Appendix 4) provides guidance about the time necessary at various temperatures for toxin formation to occur.

Packaging conditions that reduce the amount of oxygen present in the package (e.g., vacuum packaging and modified atmosphere packaging) extend the shelf life of a product by inhibiting the growth of aerobic spoilage bacteria. There is a safety concern with these products because there is an 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 non-proteolytic 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. You should expect that at some point during storage, distribution, display, or consumer handling of refrigerated foods, safe refrigeration temperatures will not be maintained (especially for the non-proteolytic group). Surveys of retail display cases indicate that temperatures of 45 to 50°F (7 to 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 non-proteolytic *C. botulinum* are inhibited or destroyed (e.g., smoked fish, pasteurized crabmeat, and pasteurized surimi), a normal refrigeration temperature of 40°F (4.4°C) is appropriate because it will limit the growth of proteolytic *C. botulinum* and other pathogens that may be present. Even in pasteurized products where non-proteolytic *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 and pasteurized surimi), a storage temperature of 40°F (4.4°C) is still appropriate because of the potential for survival through the pasteurization process and recovery of spores of non-proteolytic *C. botulinum*, aided by naturally occurring

substances, such as lysozyme. In this case, refrigeration serves as a prudent second barrier.

However, in reduced oxygen packaged products in which refrigeration is the sole barrier to outgrowth of non-proteolytic *C. botulinum* and the spores have not been destroyed (e.g., vacuum-packaged refrigerated raw fish, vacuum-packaged refrigerated unpasteurized crayfish meat, and reduced oxygen packaged unpasteurized dungeness crabmeat), the temperature should be maintained below 38°F (3.3°C) from packing to consumption. Ordinarily you, as a processor, can ensure that temperatures are maintained below 38°F (3.3°C) while the product is in your control. However, the current U.S. food distribution system does not ensure the maintenance of these temperatures after the product leaves your control.

The use of a Time-Temperature Indicator (TTI) on each consumer package may be an appropriate means of overcoming these problems in the distribution system for reduced oxygen packaged products in which refrigeration is the sole barrier to outgrowth of non-proteolytic *C. botulinum* and in which the spores have not been destroyed. A TTI is a device that monitors the time and temperature of exposure of the package and alerts the consumer or end user if a safe exposure limit has been exceeded. If a TTI is used, it should be validated to ensure that it is fit for its intended purpose and verified that it is functional at the time of use. It should be designed to alert the consumer (e.g., a color change) that an unsafe time and temperature exposure has occurred that may result in *C. botulinum* toxin formation. Additionally, the alert should remain perpetually visible after it has been triggered, regardless of environmental conditions that could reasonably be expected to occur thereafter. Skinner, G. E., and J. W. Larkin in "Conservative prediction of time to *Clostridium botulinum* toxin formation for use with time-temperature indicators to ensure the safety of foods," Journal of Food Protection, 61:1154-1160 (1998), describe a safe time and temperature exposure curve ("Skinner-Larkin curve") that may be useful in evaluating the suitability of a TTI for control of *C. botulinum* toxin formation in reduced oxygen packaged fish and fishery products.

Alternatively, products of this type may be safely marketed frozen, with appropriate labeling to ensure that it is held frozen throughout distribution. For some reduced oxygen packaged products, control of *C. botulinum* can be achieved by breaking the vacuum seal before the product leaves the processor's control.

The guidance in this chapter emphasizes preventive measures for the control of non-proteolytic strains of *C. botulinum* in products that are contained in reduced oxygen packaging. As was previously described, this emphasis is because such an environment extends the shelf life of a refrigerated product in a way that, under moderate temperature abuse, favors *C. botulinum* growth and toxin formation over aerobic spoilage. It is also possible for both non-proteolytic and proteolytic *C. botulinum* to grow and produce toxin in a product that is not reduced oxygen packaged and is subjected to severe temperature abuse. This is the case because of the development within the product of microenvironments that support its growth. However, this type of severe temperature abuse of refrigerated products is not reasonably likely to occur in the processing environment of most fish or fishery products and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulation, 21 CFR 110, requires refrigeration of foods that support the growth of pathogenic microorganisms.

- **Sources of *C. botulinum***

C. botulinum can enter the process on raw materials. The spores of *C. botulinum* are very common. They have been found in the gills and viscera of finfish, crabs, and shellfish. *C. botulinum* type E is the most common form found in freshwater 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.

Because spores are known to be present in the viscera, any product that will be preserved by salting, drying, pickling, or fermentation should be eviscerated prior to processing (see the "Compliance Policy Guide," Sec. 540.650). Without evisceration, toxin formation is possible during the process, even with strict control of temperature. Evisceration of fish is the careful and complete removal of all internal organs in the body cavity without puncturing or cutting them, including gonads. If even a portion of the viscera or its contents is left behind, the risk of toxin formation by *C. botulinum* remains. Uneviscerated small fish, less than 5 inches in length (e.g., anchovies and herring sprats), for which processing eliminates preformed toxin, prevents toxin formation during processing and that reach a water phase salt content of 10% in refrigerated finished products, or a water activity of below 0.85 in shelf-stable finished products, or a pH of 4.6 or less in shelf-stable finished products, are not subject to the evisceration recommendation.

Note: The water phase salt content of 10% is based on the control of *C. botulinum* type A and proteolytic types B and F.

Note: The water activity value of below 0.85 is based on the minimum water activity for toxin production of *S. aureus*.

- **Reduced oxygen packaging**

A number of conditions can result in the creation of a reduced oxygen environment in packaged fish and fishery products. They include:

- Vacuum, modified, or controlled atmosphere packaging. These packaging methods generally directly reduce the amount of oxygen in the package;
- Packaging in hermetically sealed containers (e.g., double-seamed cans, glass jars with sealed lids, and 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 and packaging techniques prevent the entry of oxygen into the container. Any oxygen present at the time of packaging (including oxygen that may be added during modified atmosphere 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 (in the final package) of at least 10,000 cc/m^2/24 hours at 24ºC can be regarded as an oxygen-permeable packaging material for fishery products. The oxygen transmission rate of packaging material is listed in the packaging specifications that can be obtained from the packaging manufacturer.

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. Particular care should be taken in determining the safety of a packaging material for a product in which the spoilage organisms have been eliminated or significantly reduced by processes such as high pressure processing. The generally recommended 10,000 cc/m^2/24 hours at 24ºC transmission rate may not be suitable in this case.

Use of an oxygen-permeable package may 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 or the use of oxygen scavengers in the packaging.

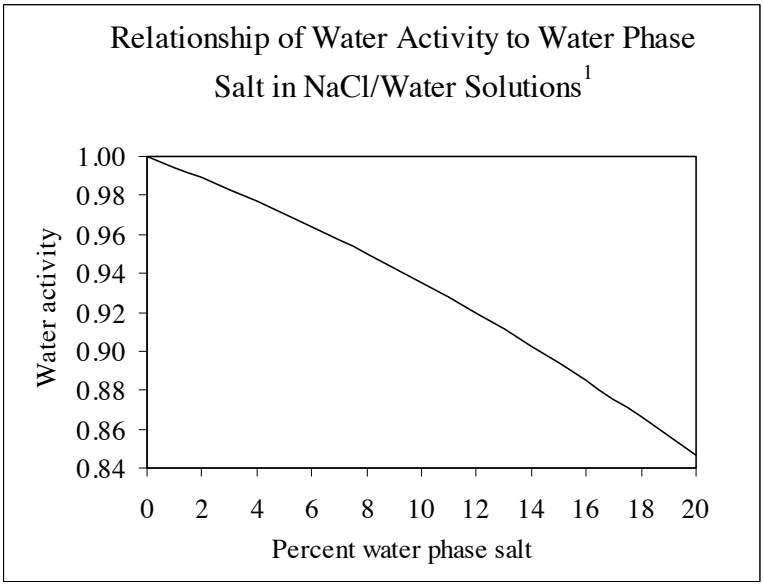
- **Control of *C. botulinum***

There are a number of strategies to prevent *C. botulinum* growth and toxin formation during processing, storage, and distribution of finished fish and 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). This strategy is covered by the LACF Regulation, 21 CFR 113, and these controls are not required to be included in your Hazard Analysis Critical Control Point (HACCP) plan;

- Controlling the level of acidity (pH) in the finished product to 4.6 or below, to prevent growth and toxin formation by *C. botulinum* types A, B, E, and F (e.g., shelf-stable acidified products). This strategy is covered by the Acidified Foods regulation, 21 CFR 114, and 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) to 0.85 or below by drying, to prevent growth and toxin formation by *C. botulinum* types A, B, E, and F and other pathogens that may be present in the product (e.g., shelf-stable dried products). This strategy is covered by Chapter 14;
- Controlling the amount of salt in the product to 20% water phase salt (wps) or more, to prevent the growth of *C. botulinum* types A, B, E, and F and other pathogens that may be present in the product (e.g., shelf-stable salted products). This strategy is covered in this chapter. Water phase salt is the concentration of salt in the water-portion of the fish flesh and calculated as follows: (% NaCl X 100)/(% NaCl + % moisture) = % NaCl in water phase. The relationship between percent water phase salt and water activity in fish is described in the following graph.



1. This relationship is generally valid for fish products when salt (sodium chloride) is the primary means of binding water. The specific food matrix and the use of other salts or water binding agents could affect the exact relationship. If you intend to use this relationship in your control strategy, you should determine the exact relationship in your product by conducting a study.

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 non-proteolytic types B and F, and then minimizing the risk of recontamination by controlling seam closures and cooling water, and next 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 and some pasteurized surimi-based products). Pasteurization is covered in Chapter 16, controlling recontamination after pasteurization is covered in Chapter 18, and controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter;
- Heating the product sufficiently to destroy the spores of *C. botulinum* type E and non-proteolytic types B and F, and then minimizing the risk of recontamination by hot filling the product into the final container in a sanitary, continuous, closed filling system and controlling seam closures and cooling water, and next 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 (e.g., vacuum packed soups, chowders, and sauces). Specialized cooking processes are covered in Chapter 16, prevention of recontamination after specialized cooking processes is covered in Chapter 18, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;
- Controlling the amount of moisture that is available in the product (water activity) to 0.97 or below to inhibit the growth of *C. botulinum* type E and non-proteolytic types B and F by drying, 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 (e.g., refrigerated dried fish). Drying is covered in Chapter 14, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;
- Controlling the level of pH to 5 or below, salt to 5% wps or more, moisture (water activity) to 0.97 or below, or some combination of these barriers, in the finished product sufficiently to prevent the growth of *C. botulinum* type E and non-proteolytic types B and F by formulation, 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). Controlling the growth of non-proteolytic *C. botulinum* through formulation is covered in this chapter, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in 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, sufficiently to prevent the growth of *C. botulinum* type E and non-proteolytic types B and F, 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). Controlling the growth of non-proteolytic *C. botulinum* through salting and smoking is covered in this chapter, controlling the growth of proteolytic *C. botulinum* through

refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;

- Controlling the amount of salt in the finished product, in combination with heat damage from pasteurization in the finished product container, sufficiently to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F, 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). Controlling the growth of non-proteolytic *C. botulinum* through a combination of salt and heat damage is covered in this chapter, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12.

Examples of *C. botulinum* control in specific products:

- **Refrigerated (not frozen), 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 non-proteolytic 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 non-proteolytic types B and F. Note that nitrites should be used only in salmon, sable, shad, chubs, and tuna, according to 21 CFR 172.175 and 21 CFR 172.177 , and should not exceed a level of 200 ppm in salmon, sable, shad, chubs and 10 ppm in tuna.

  In hot-smoked products, heat damage to the spores of *C. botulinum* type E and non-proteolytic 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 numbers of spoilage organisms are significantly reduced. This is important because spoilage organisms must be present to inhibit the growth and toxin formation of *C. botulinum* type E and non-proteolytic 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, and 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 non-proteolytic types B and F is made even more complex by the fact that adequate salt levels are not usually achieved during brining. Proper drying during smoking 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 growth and toxin formation by *C. botulinum*.

  This chapter covers the control procedures described above.

You should ordinarily restrict brining, dry salting, and smoking loads to single species and to fish portions of approximately uniform size. This restriction minimizes the complexity of controlling the operation. You should treat brine to minimize microbial contamination or periodically replace it as a good manufacturing practice control.

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 should 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. Controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12.

- **Refrigerated (not frozen), reduced oxygen packaged, pasteurized fishery products**

  Refrigerated, reduced oxygen packaged, pasteurized fishery products fall into two categories: (1) those which are pasteurized in the final container; and (2) those which are cooked in a kettle and then hot filled into the final container in a continuous, closed filling system (e.g., heat-and-fill soups, chowders, and sauces). In both cases, ordinarily the heating process should be sufficient to destroy the spores of *C. botulinum* type E and non-proteolytic 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)) should be maintained during storage and distribution to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F. Refrigeration also serves as a prudent second barrier because of the potential survival through the pasteurization process and recovery of spores of non-proteolytic *C. botulinum*, aided by naturally occurring substances, such as lysozyme. Cooking and pasteurization are covered in Chapter 16, and controlling the growth of *C. botulinum* through refrigeration is covered in this chapter.

  In the second category of products, filling the product into the final container while it is still hot in a continuous, closed 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 non-proteolytic types B and F. This control strategy applies to products such as soups, chowders, and sauces that are filled directly from the cooking kettle, where the risk of recontamination is minimized. It may not apply to products such as crabmeat, lobster meat, or crayfish meat or to 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 follow: fish and fishery products generally (e.g., surimi-based products, soups, or sauces) pasteurized to a minimum cumulative total lethality of $F_{194°F}$ ($F_{90°C}$) = 10 minutes, where z = 12.6°F (7°C) for temperatures less than 194°F (90°C), and z = 18°F (10°C) for temperatures above 194°F (90°C); blue crabmeat pasteurized to a minimum cumulative total lethality of $F_{185°F}$ ($F_{85°C}$) = 31 minutes, where z = 16°F (9°C); and dungeness crabmeat pasteurized to a minimum cumulative total lethality of $F_{194°F}$ ($F_{90°C}$) = 57 minutes, where z = 15.5°F

(8.6°C). Equivalent processes at different temperatures can be calculated using the z values provided.

EXAMPLES OF PROPERLY PASTEURIZED PRODUCTS

PRODUCT	MINIMUM CUMULATIVE TOTAL LETHALITY	Z VALUE
Fish and fishery products generally (e.g., surimi-based products, soups, or sauces)	$F_{194°F}$ ($F_{90°C}$) = 10 minutes	12.6°F (7°C), for temperatures less than 194°F (90°C) 18°F (10°C) for temperatures above 194°F (90°C)
Blue crabmeat	$F_{185°F}$ ($F_{85°C}$) = 31 minutes	16°F (9°C)
Dungeness crabmeat	$F_{194°F}$ ($F_{90°C}$) = 57 minutes	15.5°F (8.6°C)

In some pasteurized surimi-based products, salt, in combination with a milder pasteurization process, in the finished product container works to prevent growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F. An example of a properly pasteurized surimi-based product in which 2.4% wps 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.

- **Refrigerated (not frozen), reduced oxygen packaged pickled fish, salted fish, caviar, and similar products**

  In pickled fish, salted 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 non-proteolytic types B and F is controlled by one of the following:

  - 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%;
  - 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, prevents the growth of *C. botulinum* type E and non-proteolytic 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 non-proteolytic types B and F during storage and distribution. These control procedures are covered in this chapter.

  You should ordinarily restrict brining and pickling loads to single species and to fish portions of approximately uniform size. This restriction minimizes the complexity of controlling the operation. You should treat brine to minimize microbial contamination or periodically replace it as a good manufacturing practice control.

  The controls discussed above 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 should, 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. Controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the

growth of other pathogenic bacteria through refrigeration is covered in Chapter 12.

- **Refrigerated (not frozen), reduced oxygen packaged raw, unpreserved fish and unpasteurized, cooked fishery products**

  For refrigerated, reduced oxygen packaged raw, unpreserved fish (e.g., refrigerated, vacuum-packaged fish fillets) and refrigerated, reduced oxygen packaged, unpasteurized, cooked fishery products (e.g., refrigerated, vacuum-packaged, unpasteurized crabmeat, lobster meat, or crayfish meat), the sole barrier to toxin formation by *C. botulinum* type E and non-proteolytic 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 (3.3°C). As was previously noted, maintenance of temperatures below 38°F (3.3°C) after the product leaves your control and enters the distribution system cannot normally be ensured. The use of a TTI on the smallest unit of packaging (i.e., the unit of packaging that will not be distributed any further, usually consumer or end-user package) may be an appropriate means of overcoming these problems in the distribution system. This chapter provides controls for the application of TTIs for packaging.

  If you intend to package these products in a reduced oxygen package and you do not intend to apply a TTI on each consumer package, you should evaluate the effectiveness of other preventive measures, either singularly, or in combination, that may be effective in preventing growth and toxin formation by *C. botulinum*. Such evaluation is customarily accomplished by conducting an inoculated pack study 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."

- **Frozen, reduced oxygen packaged raw, unpreserved fish and unpasteurized, cooked fishery products**

  For frozen, reduced oxygen packaged raw, unpreserved fish (e.g., frozen, vacuum-packaged fish fillets) and frozen, reduced oxygen packaged, unpasteurized, cooked fishery products (e.g., frozen, vacuum-packaged, unpasteurized crabmeat, lobster meat, or crayfish meat), the sole barrier to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution is freezing. Because these products may appear to the retailer, consumer, or end user to be intended to be refrigerated, rather than frozen, labeling to ensure that they are held frozen throughout distribution is critical to their safety.

  Controls should be in place to ensure that such products are immediately frozen after processing, maintained frozen throughout storage in your facility, 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"). Frozen, reduced oxygen packaged products that are customarily cooked by the consumer or end user in the frozen state (e.g., boil-in-bag products and frozen fish sticks) need not be labeled to be thawed under refrigeration. For purposes of hazard analysis, other frozen products that do not contain the "keep frozen" statement should be evaluated as if they will be stored refrigerated because the consumer or end user would not have been warned to keep them frozen.

  Control procedures to ensure that product is properly labeled with "keep frozen" instructions are covered in this chapter.

- **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 *C. botulinum* types A, B, E, and F should be destroyed after the product is placed in the finished product container (covered by the LACF Regulation, 21 CFR 113) or (2) a barrier, or combination of barriers, should be in place that will prevent growth and toxin formation by *C. botulinum* types A, B, E, and F, and other pathogens that may be present in the product. Suitable barriers include:

  - 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 20%. Note that this value is based on the maximum salt level for growth of *S. aureus*, covered in this chapter;
  - Reducing the amount of moisture that is available for growth (water activity) to below 0.85 (e.g., by adding salt or other substances that bind the available water). Note that this value is based on the minimum water activity for growth and toxin formation of *S. aureus*, covered in this chapter;
  - Adding sufficient acid to reduce the pH to 4.6 or below. This barrier is covered by the Acidified Foods regulation, 21 CFR 114, and these controls are not required to be included in your HACCP plan;
  - Drying the product sufficiently to reduce the water activity to 0.85 or below. Note that this value is based on the minimum water activity for growth and toxin formation of *S. aureus*, covered in Chapter 14.

  Note: A heat treatment, addition of chemical additives, or other treatment may be necessary to inhibit or eliminate spoilage organisms (e.g., mold) in shelf-stable products.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether *C. botulinum* toxin formation is a significant hazard at a processing step:

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 to occur are those that may result in the formation of a reduced oxygen packaging environment. These are discussed in the section "Understand the potential hazard," under the heading, "Reduced oxygen packaging."

2. Can growth and toxin formation by *C. botulinum* that is reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   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 the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur.

   Preventive measures for *C. botulinum* toxin formation during finished product distribution and storage are discussed in the section, "Understand the potential hazard," under the heading, "Control of *C. botulinum*."

- **Intended use**

Because of 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.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for *C. botulinum* toxin formation:

1. Is there an acidification step (equilibrium pH of 4.6 or below), a drying step, an in-package pasteurization step, a combination of cook and hot-fill steps, or a retorting step (commercial sterility) in the process?

    a. If there is, you should 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, control should be provided for time and temperature exposure during finished product storage and distribution of the following products:

    - Products pasteurized in the final container to kill *C. botulinum* type E and non-proteolytic 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 and pasteurized surimi);
    - Products cooked to kill *C. botulinum* type E and non-proteolytic types B and F, and then hot filled into the final container, and next refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present;
    - Products dried to control the growth of *C. botulinum* type E and non-proteolytic 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. Control of refrigeration is covered in this chapter for *C. botulinum* and in Chapter 12 for other pathogenic bacteria.

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 non-proteolytic types B and F. In these products, you should also identify the formulation step as a CCP for the hazard. Guidance provided in "Control Strategy Example 4 - Pickling and Salting" may be useful in developing controls at this step.

Guidance for the *C. botulinum* control strategies listed above is contained in the following locations:

- Control of cooking and hot-filling is covered in Chapters 16 and 18;
- Control of pasteurization is covered in Chapters 16 and 18;
- Control of drying is covered in Chapter 14;
- Control of acidification is covered in the Acidified Foods regulation, 21 CFR 114;
- Control of retorting is covered in the LACF Regulation, 21 CFR 113.

Note: Acidification and retorting controls for *C. botulinum* required by 21 CFRs 113 and 114 need not be included in your HACCP plan.

b. If there is no acidification step (equilibrium pH of 4.6 or below), drying step, pasteurization step, cooking and hot-filling, or retorting (commercial sterility) step in the process, then decide which of the following categories best describes your product and refer to the guidance below:

- Smoked and smoke-flavored fish;
- Fishery products in which refrigeration is the sole barrier to prevent toxin formation;
- Fishery products in which freezing is the sole barrier to toxin formation;
- Pickled fish and similar products.

- **Smoked and smoke-flavored fish**

1. 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, and the brining, dry salting and, where applicable, drying steps should be identified as CCPs. 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 non-proteolytic 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 is partially achieved during drying. Control should be exercised over both operations.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1a - Brining, Dry Salting, and Drying)."

2. Is the temperature of the heating or smoking process important to the safety of the product?

   For both cold-smoked and hot-smoked fish products, the temperature of smoking is critical, and the smoking step should be identified as a CCP for this hazard. The smoking step for hot-smoked fish should be sufficient to damage the spores and make them more susceptible to inhibition by salt. The smoking step for cold-smoked fish should 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 produce acid, which will further inhibit *C. botulinum* growth and toxin formation.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1b - Cold Smoking and 1c - Hot Smoking)."

3. Is the storage temperature important to the safety of the product?

   Refrigerated (not frozen) finished product storage is critical to the safety of all products in this category and should be identified as a CCP. Toxin formation by *C. botulinum* type A and proteolytic types B and F is not inhibited by water phase salt levels below 10%, nor by the combination of inhibitors present in most smoked or smoke-flavored fish. *Bacillus cereus* can grow and form toxin at water phase salt concentrations as high as 18%.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1d - Refrigerated Finished Product Storage)."

   In some cases, salted, smoked, or smoke-flavored fish are received as ingredients for assembly into another product, such as a salmon paté. In other cases, they are received simply for storage and further distribution (e.g., by a warehouse). In either case, the refrigerated (not frozen) storage step is critical to the safety of the product and should be identified as a CCP. Control is the same as that provided under "Control Strategy Example 1 - Smoking (1d - Refrigerated

Finished Product Storage)." Additionally, receiving of these products should be identified as a CCP, where control can be exercised over the time and temperature during transit.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1e - Receipt of Products by Secondary Processor)."

- **Fishery products in which refrigeration is the sole barrier to prevent toxin formation**

1. Is the storage temperature important to the safety of the product?

Refrigerated finished product storage is critical to the safety of all products in this category and should be identified as a CCP. These products contain no barriers (other than refrigeration) to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution. These types of *C. botulinum* will grow at temperatures as low as 38°F (3.3°C), necessitating particularly stringent temperature control.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Refrigeration With TTI (2d - Refrigerated Finished Product Storage)."

In some cases, these products are received as ingredients for assembly into another product. In other cases, they are received simply for storage and further distribution (e.g., by a warehouse). In either case, the refrigerated storage step is critical to the safety of the product and should be identified as a CCP. Control is the same as that provided under "Control Strategy Example 2 - Refrigeration With a TTI (2d - Refrigerated Finished Product Storage)." Additionally, receiving of these products should be identified as a CCP, where control can be exercised over the time and temperature during transit.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Refrigeration With a TTI (2e - Receipt of Product by Secondary Processor)."

As previously noted, maintenance of temperatures below 38°F (3.3°C) after the product leaves your control and enters the distribution system cannot normally be ensured. The use of a TTI on the smallest unit of packaging (i.e., the unit of packaging that will not be distributed any further, usually consumer or end-user package) may be an appropriate means of overcoming these problems in the distribution system. When TTIs are used in this manner, their receipt, storage, and application and activation should be identified as CCPs.

This control approach is a control strategy referred to as "Control Strategy Example 2 - Refrigeration With TTI (2a - Unactivated TTI Receipt, 2b - Unactivated TTI Storage, and 2c - Application and Activation of TTI)."

- **Fishery products in which freezing is the sole barrier to toxin formation**

1. Is the storage temperature important to the safety of the product?

Frozen finished product storage is critical to the safety of all products in this category. These products contain no barriers (other than freezing) to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution. As previously noted, because these products may appear to the retailer, consumer, or end user to be intended to be refrigerated, rather than frozen, labeling to ensure that they are held frozen throughout distribution is critical to their safety and should be identified as a CCP.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 3 - Frozen With Labeling."

- **Pickled and salted fish and similar products**

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 are critical to the safety of the product because they are the principal inhibitors to growth and toxin formation by *C. botulinum* type E and non-proteolytic type B and F. The levels of these inhibitors needed to inhibit toxin formation are achieved during the pickling, brining, or formulation step. Control should be exercised over the relevant step.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Pickling and Salting (4a - Brining, Pickling, Salting, and Formulation)."

2. Is the 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 that 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 that this value is based on the minimum water activity for growth of *S. aureus*), refrigerated finished product storage is critical to ensure the safety of the product and should be identified as a CCP.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Pickling and Salting (4b - Refrigerated Finished Product Storage)."

   In some cases, pickled fish or similar products are received as ingredients for assembly into another product. In other cases, they are received simply for storage and further distribution (e.g., by a warehouse). In either case, the refrigerated storage step is critical to the safety of the product and should be identified as a CCP. Control is the same as that provided under "Control Strategy Example 4 - Pickling and Salting (4b - Refrigerated Finished Product Storage)." Additionally, receiving of these products should be identified as a CCP, where control can be exercised over time and temperature during transit.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Pickling and Salting (4c - Receipt of Product by Secondary Processor)."

DEVELOP A CONTROL STRATEGY.

The following guidance provides four control strategies for *C. botulinum* toxin formation. You may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations. Control strategies contain several elements that may need to be used in combination to result in an effective control program.

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

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Smoking	✓	✓
Refrigeration with TTI	✓	✓
Frozen with labeling	✓	✓
Pickling and salting	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - SMOKING**

This control strategy should include the following elements, as appropriate:

a. Brining, dry salting, and drying;

b. Cold smoking;

c. Hot smoking;

d. Refrigerated finished product storage;

e. Receipt of products by secondary processor.

1A. BRINING, DRY SALTING, AND DRYING

Set Critical Limits.

- 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 ensure that the finished product has not less than 3.5% wps or, where permitted, the combination of 3% wps 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; and drier loading.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The critical factors 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; and drier loading;

  OR

- The water phase salt and, where appropriate, nitrite level of the finished product.

» **How Will Monitoring Be Done?**

- For monitoring critical factors:
  - Monitor brine strength with a salinometer;

    AND

  - Monitor brine time with a clock;

    AND

  - Monitor brine temperature using:
    - A temperature-indicating device (e.g., a thermometer);

      OR

    - Monitor brine temperature at the start of the brining process with a temperature- indicating device (e.g., a thermometer), and then monitor ambient air temperature using a continuous temperature-recording device (e.g., a recording thermometer);

      AND

  - Monitor the drying time and the input/output air temperature (as specified by the study) using a continuous temperature-recording device (e.g., a recording thermometer);

    AND

  - Monitor all other critical factors specified by the study with equipment appropriate for the measurement;

  OR

- Collect a representative sample of the finished product and conduct water phase salt analysis and, when appropriate, nitrite analysis.

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

- For brine strength:
  - At least at the start of the brining process;

  AND

- For brine time:
  - Once per batch;

  AND

- For manual brine temperature monitoring:
  - At the start of the brining process and at least every 2 hours thereafter;

  AND

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

AND

- For brine to fish ratio:
  - At the start of the brining process;

AND

- For time requirements of the drying process:
  - Each batch;

AND

- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

OR

- For water phase salt and, when appropriate, nitrite:
  - Each lot or batch of finished product.

» **Who Will Do the Monitoring?**

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

OR

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Chill and hold the 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 an LACF, or a frozen product);

OR

- Destroy the product;

OR

- Divert the product to a non-food use.

AND

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

- Adjust the salt and/or nitrite concentration in the brine;

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

- Cool the brine;

OR

- Move some or all of the product to another drying chamber;

OR

- Make repairs or adjustments to the drying chamber as necessary.

Establish a Recordkeeping System.

- Printouts, charts, or readings from continuous temperature-recording devices;

AND

- Record of visual checks of recorded data;

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, and 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.

Establish Verification Procedures.

- Process validation study (except where water phase salt analysis and, where appropriate, nitrite analysis of the finished product are the monitoring procedure):
    - The adequacy of the brining, dry salting, and drying processes should be established by a scientific study. It should be designed to consistently achieve a water phase salt level of 3.5% or 3% with not less than 100 ppm nitrite. Expert knowledge of salting and/or drying processes may be required to establish such a process. Such knowledge can be obtained by education or experience, or both. Process validation study for establishment of brining, dry salting, and drying processes may require access to adequate facilities and the application of recognized methods. The drying equipment should 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 may be required to establish minimum processes. In other instances, existing literature, which establishes minimum processes or adequacy of equipment, is available. Characteristics of the process, product, and/or equipment that affect the ability of the established minimum salting, dry salting, and drying process to deliver the desired finished product water phase salt and, where applicable, nitrite levels should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

- Before a temperature-indicating device (e.g., a thermometer) or temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

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

      OR
    - Doing a combination of the above if the device will be used at or near room temperature;

      OR
    - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., air temperature, brine temperature, product internal temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-indicating device or temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended

by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

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

AND

- Perform other calibration procedures as necessary to ensure the accuracy of the monitoring instruments;

AND

- Do finished product sampling and analysis to determine water phase salt and, where appropriate, nitrite analysis at least once every 3 months (except where such testing is performed as part of monitoring);

AND

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

1B. COLD SMOKING

Set Critical Limits.

- The smoker temperature must not exceed 90°F (32.2°C).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The smoker temperature.

» **How Will Monitoring Be Done?**

- Measure ambient smoker chamber temperature using a continuous temperature-recording device (e.g., a recording thermometer).

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

- Continuous monitoring by the device itself, with a visual check of the recorded data at least once per batch.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Chill and 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 an LACF, or a frozen product);

OR

- Destroy the product;

  OR

- Divert the product to a non-food use.

AND

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

- Make repairs or adjustments to the smoking chamber;

  AND/OR

- Move some or all of the product to another smoking chamber.

Establish a Recordkeeping System.

- Printouts, charts, or readings from continuous temperature-recording devices;

  AND

- Record of visual checks of recorded data.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

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

    OR

  - Doing a combination of the above if the device will be used at or near room temperature;

    OR

  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND

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

  AND

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

  AND

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

1C. HOT SMOKING

Set Critical Limits.

- 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.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The internal temperature at the thickest portion of three of the largest fish in the smoking chamber.

» **How Will Monitoring Be Done?**

- Use a continuous temperature-recording device (e.g., a recording thermometer) equipped with three temperature-sensing probes.

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

- Continuous monitoring by the device itself, with visual check of the recorded data at least once per batch.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Chill and 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 a LACF, or a frozen product);

  OR

- Destroy the product;

  OR

- Divert the product to a non-food use.

AND

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

- Make repairs or adjustments to the heating chamber;

  OR

- Move some or all of the product to another heating chamber.

Establish a Recordkeeping System.

- Printouts, charts, or readings from continuous temperature-recording devices;

  AND

- Record of visual checks of recorded data.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

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

    OR

  - Doing a combination of the above if the device will be used at or near room temperature;

    OR

- Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

AND

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

AND

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

AND

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

1D. REFRIGERATED FINISHED PRODUCT STORAGE

Set Critical Limits.

- For refrigerated (not frozen) finished product storage:
  - The product is held at a cooler temperature of 40°F (4.4°C) or below. Note that allowance for routine refrigeration defrost cycles may be necessary. Also note that you may choose to set a critical limit that specifies a time and temperature of exposure to temperatures above 40°F (4.4°C);

OR

- For finished product stored under ice:
  - The product is completely and continuously surrounded by ice throughout the storage time.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For refrigerated finished product storage:
  - The temperature of the cooler;

OR

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

» **How Will Monitoring Be Done?**

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

OR

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

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

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

  OR
- For finished product storage under ice:
  - Sufficient frequency to ensure control.

» **Who Will Do the Monitoring?**

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

  OR
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

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

  OR
- Destroy the product;

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

AND

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

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

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

    OR
  - Freeze the product;

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

    OR
  - Make adjustments to the ice application operations.

Establish a Recordkeeping System.

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

    AND
  - Record of visual checks of recorded data;

  OR
- For finished product storage under ice:
  - Results of ice checks:
    - The number of containers examined and the sufficiency of ice for each;

      AND
    - The approximate number of containers in the cooler.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

- Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

AND

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

AND

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

AND

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

AND

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

1E. RECEIPT OF PRODUCTS BY SECONDARY PROCESSOR

Set Critical Limits.

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

OR

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

OR

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

AND

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

OR

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

- Time of transit does not exceed 4 hours;

  AND

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

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

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

    OR

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

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

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

    AND

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

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

    AND

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

» **How Will Monitoring Be Done?**

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

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

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

    AND

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

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

    AND

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

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

- Each lot received.

» **Who Will Do the Monitoring?**

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

  OR
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

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

  OR
- Reject the lot.

AND

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

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

Establish a Recordkeeping System.

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

      AND
    - Visual check of recorded data;

    OR
  - Results of ice checks, including:
    - The number of containers examined and the sufficiency of ice for each;

      AND
    - The number of containers in the lot;

    OR
  - Results of the chemical media checks, including:
    - The number of containers examined and the frozen status of the media for each;

      AND
    - The number of containers in the lot;

    AND/OR
  - Results of internal product temperature monitoring, including:
    - The number of containers examined and the internal temperatures observed for each;

      AND
    - The number of containers in the lot;

      AND
    - Date and time fish were initially removed from a controlled

temperature environment and date and time fish were delivered, when applicable.

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

      OR
    - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

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

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

  AND
- Check the accuracy of temperature-recording devices that are used for monitoring transit conditions, for all new suppliers and at least quarterly for each supplier thereafter. Additional checks may be warranted based on observations at receipt (e.g., refrigeration units appear to be in poor repair or readings appear to be erroneous). The accuracy of the device can be checked by comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

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

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

TABLE 13-1

CONTROL STRATEGY EXAMPLE 1 - SMOKING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Smoking." This example illustrates how a processor of vacuum-packaged hot-smoked salmon can control C. botulinum toxin formation. 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 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, survival of other pathogenic bacteria through the cook step, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Brining	C. botulinum toxin formation in the finished product	Minimum brining time: 6 hours Maximum brine temperature: 40°F	Start time and end time of the brining process Brine temperature	Clock Dial thermometer	Every batch Every 2 hours	Brine room employee	Extend the brining process Hold and evaluate the product Cool the brine	Production record	Establish a brining and drying process Check the dial thermometer for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Monthly calibration of the scale Quarterly water phase salt analysis of the finished product Review monitoring, corrective action, and verification records within 1 week of preparation
		Minimum salt concentration of brine at the start of brining: 60° salinometer	Salt concentration of brine	Salinometer	Start of each brining process	Brine room employee	Add salt	Production record	
		Minimum ratio of brine to fish: 2:1	Weight of brine (as determined by volume)	Visual, to mark on the tank	Start of each brining process	Brine room employee	Add brine	Production record	
			Weight of fish	Scale	Each batch		Remove some fish and reweigh		
		Maximum fish thickness 1½ in. Note: To produce a minimum water phase salt level in the loin muscle of 3.5%	Fish thickness	Caliper	Each batch (10 largest fish)	Brine room employee	Hold and evaluate based on finished product water phase salt analysis	Production record	

TABLE 13-1

CONTROL STRATEGY EXAMPLE 1 - SMOKING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Smoking." This example illustrates how a processor of vacuum-packaged hot-smoked salmon can control C. botulinum toxin formation. 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 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, survival of other pathogenic bacteria through the cook step, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Smoking and drying	C. botulinum toxin formation in finished product	Minimum time open vent: 2 hours	Time of open vent	Clock	Each batch	Smoker employee	Extend the drying process Hold and evaluate based on finished product water phase salt analysis	Production record	Establish a brining and drying process Quarterly water phase salt analysis of the finished product Review monitoring, corrective action, and verification records within 1 week of preparation
Heating	C. botulinum toxin formation in the finished product	Internal temperature of fish held at or above 145°F for at least 30 minutes	Internal temperature of fish and time at that temperature	Digital data logger with three probes in thickest fish in cold spot of smoking chamber	Continuous, with visual check of recorded data at the end of the batch	Smoker employee	Extend the heating process Make repairs or adjustments to the smoking chamber Hold and evaluate the product	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
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 check of recorded data once per day	Production employee	Adjust or repair the cooler Hold and evaluate the product based on time and temperature of exposure	Digital data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

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

- **CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI**

This control strategy should include the following elements, as appropriate:

a. Unactivated TTI receipt;

b. Unactivated TTI storage;

c. Application and activation of TTI;

d. Refrigerated finished product storage;

e. Receipt of product by secondary processor.

2A. UNACTIVATED TTI RECEIPT

Set Critical Limits.

- The TTI is suitable for use. It should be designed to perform properly under the conditions that it will be used. It should also be designed to produce an alert indicator (e.g., a color change of the device) at a combination of time and temperature exposures that will prevent the formation of non-proteolytic *C. botulinum* toxin formation (e.g., consistent with the "Skinner-Larkin curve");

  AND

- Where transportation conditions (e.g., temperature) could affect the functionality of the TTI, all lots of TTIs are accompanied by transportation records that show that they were held at conditions that do not result in loss of functionality throughout transit;

  AND

- The TTI functions (i.e., produces an alert indicator, such as a color change of the device, when exposed to time and temperature abuse) at time of receipt.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For suitability of use:
  - Performance data from the manufacturer;

  AND

- For transportation conditions:
  - The temperature within the truck or other carrier throughout transportation;

    OR
  - Other conditions that affect the functionality of the TTI, where applicable;

  AND

- For functionality at receipt:
  - The ability of the TTI to produce an alert indicator, such as a color change of the device, when exposed to time and temperature abuse at time of receipt.

» **How Will Monitoring Be Done?**

- For suitability of use:
  - Review performance data;

  AND

- For transportation conditions:
  - Use a continuous temperature-recording device (e.g., a recording thermometer) for ambient air temperature monitoring during transit;

  AND

- For functionality at receipt:
  - Activate and then expose a TTI from the lot to ambient air temperature for sufficient time to determine whether it is functional (i.e., produces an alert indicator, such as a color change of the device).

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

- For suitability of use:
  - The first shipment of a TTI model;

  AND

- For transportation conditions and functionality at receipt:
  - Every shipment.

» **Who Will Do the Monitoring?**

- For suitability of use:
  - Anyone with an understanding of TTI validation studies and of the intended conditions of use;

  AND
- For transportation conditions and functionality at receipt:
  - Anyone with an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Reject or return the shipment.

AND

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

- For suitability of use:
  - Discontinue use of the supplier until documentation of validation has been provided;

  AND
- For transportation conditions and functionality at receipt:
  - Discontinue use of the supplier or carrier until evidence is obtained that the identified production or transportation practices have been improved.

Establish a Recordkeeping System.

- For suitability of use:
  - Manufacturer's performance data;

  AND
- For transportation conditions:
  - Printouts, charts, or readings from continuous temperature-recording devices;

    AND
  - Records of visual checks of recorded data;

  AND
- For functionality at receipt:
  - Results of a TTI challenge test (i.e., whether the TTI produces an alert indicator, such as a color change of the device, when exposed to time and temperature abuse).

Establish Verification Procedures.

- Check the accuracy of temperature-recording devices that are used for monitoring transit conditions, for all new suppliers and at least quarterly for each supplier thereafter. Additional checks may be warranted based on observations at receipt (e.g., refrigeration units appear to be in poor repair or readings appear to be erroneous). The accuracy of the device can be checked by comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

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

2B. UNACTIVATED TTI STORAGE

Set Critical Limits.

- The combination of storage conditions (e.g., temperature) that prevent loss of functionality throughout storage (based on manufacturer's specifications).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Storage air temperature, where temperature affects functionality of the TTI;

  AND/OR

- Other storage conditions that affect functionality of the TTI.

» **How Will Monitoring Be Done?**

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

  AND/OR

- For other conditions:
  - Use instruments appropriate for the purpose.

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

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

  AND/OR

- For other conditions:
  - With sufficient frequency to ensure control.

» **Who Will Do the Monitoring?**

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

  AND

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Destroy the lot of TTIs.

AND

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

- Make repairs or adjustments to the malfunctioning cooler;

  AND/OR

- Make other repairs or adjustment appropriate for the condition.

Establish a Recordkeeping System.

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

    AND
  - Record of visual checks of recorded data;

  AND/OR

- Storage record showing the results of monitoring of other conditions.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

AND

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

AND

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

AND

- Perform other instrument calibration, as appropriate;

AND

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

2C. APPLICATION AND ACTIVATION OF TTI

Set Critical Limits.

- Each consumer package has an activated TTI.

Establish Monitoring Procedures.

» What Will Be Monitored?

- Packages for the presence of an activated TTI.

» How Will Monitoring Be Done?

- Visual examination.

» How Often Will Monitoring Be Done (Frequency)?

- Representative number of packages from each lot of product.

» Who Will Do the Monitoring?

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

Establish Corrective Action Procedures.

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

- Hold the lot below 38°F (3.3°C) until TTIs are applied and activated.

AND

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

- Identify and correct the cause of the TTI application or activation deficiency.

Establish a Recordkeeping System.

- Packaging control record that shows the results of the TTI checks.

Establish Verification Procedures.

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

2D. REFRIGERATED FINISHED PRODUCT STORAGE

Follow the guidance for "Control Strategy Example 1 - Smoking (1d - Refrigerated Finished Product Storage)," except that the where the critical limits list 40°F (4.4°C), they should list 38°F (3.3°C).

2E. RECEIPT OF PRODUCTS BY SECONDARY PROCESSOR

Follow the guidance for "Control Strategy Example 1 - Smoking (1e - Receipt of Products by Secondary Processor)," except that the where the critical limits list 40°F (4.4°C), they should list 38°F (3.3°C).

TABLE 13-2

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigeration With TTI." This example illustrates how a processor of refrigerated, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. 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 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receipt of TTI	C. botulinum toxin formation in the finished product	TTI is suitable for use	Performance data from the manufacturer	Review of performance data	First shipment of a TTI model	Quality assurance supervisor	Reject the shipment Discontinue use of the supplier until appropriate validation documentation is provided	Manufacturer's performance data	Review monitoring, corrective action records within 1 week of preparation
		All lots received are accompanied by truck records that show temperature was maintained at or below 40°F	Truck temperature	Digital time and temperature data logger	Continuous, with visual review and evaluation of temperature-monitoring records for each shipment	Receiving employee	Discontinue use of the supplier or carrier until evidence is obtained that the identified transportation- handling practices have been improved Reject the shipment	Receiving record	Check the data logger for all new suppliers and for all suppliers at least quarterly thereafter Review monitoring, corrective action records within 1 week of preparation
		The TTI functions at receipt	The ability of the TTI to change color when exposed to room air temperature	Expose a TTI from the lot to room air temperature for sufficient time to determine whether it changes color	Every shipment	Quality assurance staff	Discontinue use of the supplier or carrier until evidence is obtained that the identified production or transportation-handling practices have been improved	TTI challenge record	Review monitoring, corrective action records within 1 week of preparation

TABLE 13-2

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigeration With TTI." This example illustrates how a processor of refrigerated, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. 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 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
TTI storage	C. botulinum toxin formation in the finished product	Cooler maintained below 38°F	Cooler temperature	Digital time and temperature data logger	Continuous, with visual check of recorded data once per day	Quality assurance staff	Repair or adjust cooler Destroy the lot of TTIs	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
TTI attachment and activation	C. botulinum toxin formation in the finished product	Each package has an activated TTI	Packages for the presence of an activated TTI	Visual examination	Representative number of packages from each lot of product	Production employee	Hold lot below 38°F, and apply and activate TTIs Identify and correct the cause of TTI application deviation	Packaging control record	Review monitoring, and corrective action and verification records within 1 week of preparation

TABLE 13-2

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigeration With TTI." This example illustrates how a processor of refrigerated, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. 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 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Finished product storage	C. botulinum toxin formation during finished product storage	Maximum cooler temperature 38°F	Cooler air temperature	Digital data logger	Continuous, with visual check of recorded data once per day	Production employee	Adjust or repair cooler Hold and evaluate the product based on time and temperature of exposure	Digital logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

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

- **CONTROL STRATEGY EXAMPLE 3 - FROZEN WITH LABELING**

Set Critical Limits.

- All finished product labels must contain a "keep frozen" statement (e.g., "Important, keep frozen until used, thaw under refrigeration immediately before use").

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Finished product labels for the presence of a "keep frozen" statement.

» **How Will Monitoring Be Done?**

- Visual examination.

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

- Representative number of packages from each lot of product.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Segregate and relabel any improperly labeled product.

AND

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

- Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper statement;

  AND

- Determine and correct the cause of improper labels.

Establish a Recordkeeping System.

- Record of labeling checks.

Establish Verification Procedures.

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

TABLE 13-3

CONTROL STRATEGY EXAMPLE 3 - FROZEN WITH LABELING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3 - Frozen With Labeling." This example illustrates how a processor of frozen, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. 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 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receipt of labeling	C. botulinum toxin formation during finished product storage	All finished product labels must contain a "keep frozen" statement	Finished product labels for the presence of a "keep frozen" statement	Visual examination	Representative number of packages from each lot of product	Receiving employee	Segregate and relabel any improperly labeled product Segregate and destroy any label stock that does not contain the proper statement Determine and correct the cause of improper labels	Label receiving record	Review monitoring and correction action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 4 - PICKLING AND SALTING**

This control strategy should include the following elements, as appropriate:

a. Brining, pickling, salting, and formulation;

b. Refrigerated finished product storage;

c. Receipt of Product by secondary processor.

4A. BRINING, PICKLING, SALTING, AND FORMULATION

Set Critical Limits.

- The minimum or maximum values for the critical factors of the brining, pickling, or formulation process established by a scientific study. The critical factors are those that are necessary to ensure that the finished product has:

For refrigerated, reduced oxygen-packaged fishery products:

- A water phase salt level of at least 5%;

  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 2.4% in surimi-based products, when combined with a pasteurization process in the finished product container of 185°F (85°C) for 15 minutes (pasteurization controls are covered in Chapter 16);

  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 non-proteolytic types B and F.

For unrefrigerated (shelf-stable), reduced oxygen-packaged products:

- A water phase salt level of at least 20% (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*).

A heat treatment, addition of chemical additives, or other treatment may be necessary to inhibit or eliminate spoilage organisms (e.g., mold) in shelf-stable products.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The critical factors of the established pickling, brining, or formulation process. These may include: brine and acid strength; brine or acid to fish ratio; brining and pickling time; brine and 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.

» **How Will Monitoring Be Done?**

- For brine strength:
  - Use a salinometer;

  AND

- For acid strength:
  - Use a pH meter or titrate for acid concentration;

  AND

- For brine/acid temperature:
  - Use a temperature-indicating device (e.g., a thermometer);

  AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

  OR
- For water phase salt, pH, and/or water activity:
  - Collect a representative sample of the finished product, and conduct water phase salt, pH, and/or water activity analysis, as appropriate.

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

- For brine and acid strength:
  - At the start of each brining, pickling, and formulation process;

  AND
- For brine and acid temperature:
  - At the start of each brining, pickling, and formulation process and at least every 2 hours thereafter;

  AND
- For brine or acid to fish ratio:
  - At the start of each brining, pickling, and formulation process;

  AND
- For 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.

» **Who Will Do the Monitoring?**

- For water activity:
  - Any person with sufficient training to perform the analysis;

  OR
- For other checks:
  - Any person with an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Chill and hold the product until it can be evaluated based on its water phase salt, pH, and/or water activity level;

  OR
- Reprocess the product (if reprocessing does not jeopardize the safety of 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 a LACF, or a frozen product);

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

  OR
- Destroy the product.

AND

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

- Adjust the brine or acid strength or brine or acid to fish ratio;

  OR
- Extend the brining or pickling time to compensate for an improper brine or acid temperature.

Establish a Recordkeeping System.

- Records, as necessary, to document the monitoring of the critical factors of the brining or pickling process, as established by a study (e.g., a processing record showing the results of the brine or acid strength and temperature, brine or acid to fish ratio, size and species of fish, time of brining or pickling);

  OR
- Record of determinations of the finished product water phase salt, pH, or water activity.

Establish Verification Procedures.

- Process validation study (except where water phase salt, pH, or water activity analysis of the finished product is the monitoring procedure):
    - The adequacy of the pickling, brining, and formulation process steps 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%; a pH of 5.0 or below; a water activity of below 0.97; a water phase salt level of at least 2.4% 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 non-proteolytic types B and F (established by a 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 the 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 the growth of *S. aureus*). Expert knowledge of pickling, brining, and formulation processes may be required to establish such a process. Such knowledge can be obtained by education or experience, or both. Establishment of pickling, brining, and formulation processes may require access to adequate facilities and the application of recognized methods. In some instances, pickling, brining, and formulation studies may be required to establish minimum processes. In other instances, existing literature, which establishes minimum processes, is available. Characteristics of the process and/or product that affect the ability of the established minimum pickling, brining, and formulation process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

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

      OR
    - Doing a combination of the above if the device will be used at or near room temperature;

      OR
    - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., brine temperature) within the temperature range at which it will be used;

  AND
- Once in service, check the temperature-indicating device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your

facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational;

AND

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

AND

- Perform daily calibration of pH meters against standard buffers;

AND

- Perform other calibration procedures as necessary to ensure the accuracy of the monitoring instruments;

AND

- Do finished product sampling and analysis to determine water phase salt, pH, or water activity level, as appropriate, at least once every 3 months (except where such testing is performed as part of monitoring);

AND

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

4B. REFRIGERATED FINISHED PRODUCT STORAGE

Follow the guidance for "Control Strategy Example 1 - Smoking (1d - Refrigerated Finished Product Storage)."

4C. RECEIPT OF PRODUCT BY SECONDARY PROCESSOR

Follow the guidance for "Control Strategy Example 1 - Smoking (1e - Receipt of Product by Secondary Processor)."

TABLE 13-4

CONTROL STRATEGY EXAMPLE 4 - PICKLING AND SALTING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4 - Pickling and Salting." This example illustrates how a pickled herring processor can control C. botulinum toxin formation. 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 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., histamine, environmental and chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Pickling	C. botulinum toxin formation in the finished product	Maximum finished product pH in the loin muscle of 5.0	Finished product pH in the loin muscle	Collect a sample of the 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	Quality control personnel	Continue the pickling process until pH meets the critical limit	Pickling control record	Daily calibration of the pH meter Review monitoring, corrective action, and verification records within 1 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	Time and temperature data logger	Continuous, with visual check of recorded data once per day	Production employee	Adjust or repair cooler Hold and evaluate the product based on time and temperature of exposure	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

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

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NOTES:

CHAPTER 14: **Pathogenic Bacteria Growth and Toxin Formation as a Result of Inadequate Drying**

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

UNDERSTAND THE POTENTIAL HAZARD.

Pathogenic bacteria growth and toxin formation in the finished product as a result of inadequate drying of fishery products can cause consumer illness. The primary pathogens of concern are *Staphylococcus aureus* (*S. aureus*) and *Clostridium botulinum* (*C. botulinum*). See Appendix 7 for a description of the public health impacts of these pathogens.

- **Control by Drying**

Dried products are usually considered shelf stable and are, therefore, often stored and distributed unrefrigerated. Examples of shelf-stable dried fish products are salmon jerky, octopus chips, dried shrimp, stock fish, and shark cartilage. 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 pathogenic bacteria. A water activity of 0.85 or below will prevent the growth and toxin production of all pathogenic bacteria, including *S. aureus* and *C. botulinum*, and is critical for the safety of a shelf-stable dried product. *S. aureus* grows at a lower water activity than other pathogenic bacteria, and should, therefore, be considered the target pathogen for drying for shelf-stable products.

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. Chapter 18 provides guidance on control of container closures.

Some dried products that are reduced oxygen packaged (e.g., vacuum packaged, modified atmosphere packaged) are dried only enough to control growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F (i.e., types that will not form toxin with a water activity of below 0.97). These dried products are then refrigerated to control growth and toxin formation by *C. botulinum* type A and proteolytic types B and F and by other pathogenic bacteria that may be present in the product, including *S. aureus*. The products might have the appearance of a fully dried product. Therefore, their packaging should include "keep refrigerated" labeling to ensure that temperature controls are applied throughout distribution.

Distributing partially dried, reduced oxygen packaged products frozen also could be used to control these pathogens. However, labeling with "keep frozen" instructions would then be important to ensure food safety. More information on *C. botulinum* and reduced oxygen packaging is contained in Chapter 13.

This chapter does not cover the growth of pathogenic bacteria, including *S. aureus*, which may occur as a result of time and 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 that of other pathogenic bacteria 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, respectively.

Controlling pathogenic bacteria 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). Note that a heat treatment, addition of chemical additives, further drying, or other treatment may be necessary to inhibit or eliminate spoilage organisms, for example, mold;
- 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 a product receives at least the established minimum process;
- Packaging the finished product in a container that will prevent rehydration.

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. The controls for these products are described in Chapter 13.

Because spores of *C. botulinum* are known to be present in the viscera of fish, any product that will be preserved by salting, drying, pickling, or fermentation should be eviscerated prior to processing (see the "Compliance Policy Guide," Sec. 540.650). Without evisceration, toxin formation is possible during the process even with strict control of temperature. Evisceration should 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 eliminates preformed toxin and prevents toxin formation and that reach (1) a water phase salt content of 10%, a value based on the control of *C. botulinum* type A and proteolytic types B and F, in refrigerated products; or (2) a water activity of 0.85 or below (note that this is a value based on the minimum water activity for toxin production by *S. aureus*, in shelf-stable products); or (3) a pH (acidity) level of 4.6 or less in shelf-stable products are not subject to the evisceration recommendation.

- **Strategies for controlling pathogenic bacteria 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, contaminated water, and sewage. There are a number of strategies for the control of pathogenic bacteria in fish and fishery products. They include:

- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in Chapter 13);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the pH in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by Chapter 13 for refrigerated acidified products);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 12);

- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16) or by retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (called the Low-Acid Canned Foods Regulation in this guidance document));
- Killing pathogenic bacteria by processes that retain raw product characteristics (covered in Chapter 17).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether pathogenic bacteria growth and toxin formation as a result of inadequate drying is a significant hazard at a processing step:

1. For shelf-stable, dried 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 that is not distributed refrigerated or frozen and meets these conditions (i.e., in Table A-1) before drying, then drying will usually be important to the safety of the product, because it provides the barrier to *S. aureus* growth and toxin formation. 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. Note that drying to control toxin formation by *S. aureus* will also control toxin formation by *C. botulinum* in these products.

2. For shelf-stable, dried products, can *S. aureus* toxin formation that is reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Pathogenic bacteria 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 the hazard of *S. aureus* toxin formation (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measure that can be applied for pathogenic bacteria growth and toxin formation as a result of inadequate drying are:

   - Proper design and control of the drying process (covered in this chapter);

3. For refrigerated or frozen, partially dried (i.e., not shelf stable) 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 non-proteolytic types B and F will grow. Because of the need to prevent rehydration of dried products, these products generally will be contained in a reduced oxygen package. If your refrigerated (not frozen), reduced oxygen packaged food meets these conditions (i.e., Table A-1) 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 non-proteolytic types B and F. Note that refrigeration will control toxin formation by *S. aureus* and *C. botulinum* type A and non-proteolytic types B and F in these products. Under ordinary

circumstances, it would be reasonably likely that *C. botulinum* type E and non-proteolytic types B and F will grow and form toxin in such products during finished product storage and distribution if drying is not properly performed. In addition, controlling labeling (e.g., "keep refrigerated" labeling) to ensure that the product is held refrigerated throughout distribution may be important to the safety of the product, because the product may appear to retailers, consumers, and end users to be shelf stable.

However, if your dried, reduced oxygen packaged product is distributed frozen, then freezing may provide the barrier to growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F, rather than drying. In this case, labeling to ensure that the product is distributed frozen may be important to the safety of the product. Chapter 13 provides guidance on labeling controls to ensure that frozen product that supports the growth of non-proteolytic *C. botulinum* is distributed frozen.

4. For refrigerated or frozen, partially dried, reduced oxygen packaged dried products, can growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F that are reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Pathogenic bacteria 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 the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measures that can be applied for pathogenic bacteria growth and toxin formation as a result of inadequate drying for refrigerated or frozen, partially dried, reduced oxygen packaged products are:

   - Proper design and control of the drying process (covered in this chapter);
   - Refrigeration (covered in Chapter 12) and labeling to ensure that the product is held refrigerated throughout distribution (covered in this chapter);
   - Freezing (Chapter 13 provides guidance on labeling controls to ensure that a frozen product that otherwise supports the growth of non-proteolytic *C. botulinum* is distributed frozen).

- **Intended use**

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.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for pathogenic bacteria growth and toxin formation as a result of inadequate drying:

1. If you identified the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying as significant because drying (rather than, or in addition to, refrigeration) is important to the safety of the product, you should identify the drying step as a CCP for this hazard.

   Example:

   A salmon jerky processor that distributes the product unrefrigerated should set the CCP for controlling the hazard of pathogenic bacteria 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 CCPs for that hazard. However, these steps may be CCPs for the control of other hazards, such as the growth of pathogenic bacteria as a result of time and temperature abuse during processing, covered by Chapter 12.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Control by Drying."

2. If you identified the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying as significant because refrigeration (in addition to drying) is important to the safety of the product, you should identify the finished product storage step and the labeling step, where you will ensure that the "keep refrigerated" labeling is included on every package, as a CCP, for this hazard.

   Example:

   A partially dried catfish processor that distributes the product refrigerated and reduced oxygen packaged should set the CCPs for controlling the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying at the drying step, finished product labeling step, and finished product storage step. The processor would not need to identify the processing steps prior to drying as CCPs for that hazard. However, these steps may be CCPs for the control of other hazards, such as the growth of pathogenic bacteria as a result of time and temperature abuse during processing, covered by Chapter 12.

The control by drying is covered in "Control Strategy Example 1 - Control by Drying." Control of labeling is referred to in this chapter as "Control Strategy Example 2 - Control by Refrigeration With Labeling." It should be used along with "Control Strategy Example 1 - Control by Drying." Note that control of refrigerated finished product storage is covered in Chapter 12. Note also that Chapter 13 provides guidance on labeling controls to ensure that a frozen product that otherwise supports the growth of non-proteolytic *C. botulinum* is distributed frozen.

DEVELOP A CONTROL STRATEGY.

The following guidance provides examples of two control strategies for pathogenic bacteria growth and toxin formation that occurs as a result of inadequate drying. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation. It is important to note that you may select a control strategy that is different from those that are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

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

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Control by drying	✓	✓
Control by refrigeration with labeling	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING**

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

Set Critical Limits.

- The 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 below; 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, as well as 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, that which must be met in order to ensure that the finished product has a water activity of 0.85 or below; for refrigerated (not frozen), reduced oxygen packaged products, that 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 above;

OR

- For refrigerated (not frozen), reduced oxygen packaged products:
  - Maximum finished product water activity of less than 0.97.

Note: A heat treatment, addition of chemical additives, further drying, or other treatment may be necessary to inhibit or eliminate spoilage organisms (e.g., mold) in shelf-stable products.

Establish Monitoring Procedures.

» What Will Be Monitored?

- 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, as well as flesh thickness;

OR

- Percent weight loss;

OR

- Water activity of the finished product.

» How Will Monitoring Be Done?

For batch drying equipment:

- For drying time and input/output air temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

OR

- For percent weight loss:
  - Weigh all, or a portion, of the batch before and after drying;

OR

- For water activity analysis:
  - Collect a representative sample of the finished product and conduct water activity analysis.

For continuous drying equipment:

- For input/output air temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

AND

- For drying time:
  - Measure:
    - The revolutions per minute (RPM) of the belt drive wheel, using a stopwatch or tachometer;

    OR

    - The time necessary for a test unit or belt marking to pass through the equipment, using a stopwatch;

AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

OR

- For percent weight loss:
  - Weigh all, or a portion, of the batch before and after drying;

OR

- For water activity:
  - Collect a representative sample of the finished product and conduct water activity analysis.

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

For batch drying equipment:

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

  AND
- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

  OR
- For percent weight loss:
  - Each batch;

  OR
- For water activity:
  - Each batch.

For continuous drying equipment:

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

  AND
- For time:
  - At least once per day, and whenever any changes in belt speed are made;

  AND
- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

  OR
- For percent weight loss:
  - Each lot of finished product;

  OR
- For water activity:
  - Each lot of finished product.

» **Who Will Do the Monitoring?**

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

  AND
- For all other critical factors specified by the study:
  - Any person who has an understanding of the nature of the controls;

  OR
- For percent weight loss:
  - Any person who has an understanding of the nature of the controls;

  OR
- For water activity:
  - Any person with sufficient training to perform the analysis.

Establish Corrective Action Procedures.

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

- Redry the product (provided that redrying does not present an unacceptable opportunity for pathogenic bacteria growth);

  OR
- Chill and hold the product for an evaluation of the adequacy of the drying process. The evaluation may involve water activity determination 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 use in which

pathogenic bacteria growth in the finished product will be controlled by means other than drying, diverted to a non-food use, or redried;

OR

- Divert the product to a use in which the critical limit is not applicable because pathogenic bacteria 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;

OR

- Destroy the product.

AND

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

Establish a Recordkeeping System.

For batch drying equipment:

- Record of continuous temperature monitoring;

AND

- Record of visual checks of recorded data;

AND

- Record of notation of the start time and end time of the drying periods;

AND

- Records that are appropriate for the other critical factors (e.g., a drying log that indicates input/output air humidity and/or velocity);

OR

- Record of weight before and after drying;

OR

- Record of water activity analysis.

For continuous drying equipment:

- Record of continuous temperature monitoring;

AND

- Record of visual checks of recorded data;

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., a drying log that indicates input/output air humidity and/or velocity);

OR

- Record of weight before and after drying;

OR

- Record of water activity analysis.

Establish Verification Procedures.

- Process validation study (except where a water activity analysis of the finished product is the monitoring procedure):
    - The adequacy of the drying process should be established by a scientific study. For shelf-stable products, the drying process 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 product water activity of less than 0.97. Expert knowledge of drying process calculations and the dynamics of mass transfer in processing equipment may be required

to establish such a drying process. Such knowledge can be obtained by education or experience or both. Establishment of drying processes may require access to adequate facilities and the application of recognized methods. The drying equipment should be designed, operated, and maintained to deliver the established drying process to every unit of a product. In some instances, drying studies may be required to establish the minimum process. In other instances, existing literature that establishes minimum processes or adequacy of equipment is available. Characteristics of the process, product, and/or equipment that affect the ability to achive 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 3 months (except where such testing is performed as part of monitoring);

  AND

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

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

    OR
  - Doing a combination of the above if the device will be used at or near room temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND

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

  AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable

device). For example, devices subjected to high temperatures for extended periods of time may require more frequent calibration. Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Calibrate other instruments as necessary to ensure their accuracy;

AND

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

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Maximum product thickness: ¼ inch	Product thickness	Preset slicer to just less than ¼ inch	Once per day before operations	Slicer operator	Re-adjust slicer	Processing log	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Minimum drying time: 5 hours	Drying time	Digital time and temperature data logger	Continuous, with visual check of recorded data each batch	Oven operator	Continue drying	Data logger printout	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Minimum oven temperature: 140°F To achieve a final water activity of 0.85 or less	Oven air input temperature	Digital time and temperature data logger	Continuous, with visual check of recorded data each batch	Oven operator	Extend drying process Segregate the product and hold under refrigeration for evaluation Evaluate by performing water activity analysis on finished product Redry if less than 0.85	Data logger printout	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - CONTROL BY REFRIGERATION WITH LABELING**

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

Set Critical Limits.

- All finished product labels must contain a "keep refrigerated" statement (e.g., "Important, keep refrigerated until used").

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Finished product labels for presence of "keep refrigerated" statement.

» **How Will Monitoring Be Done?**

- Visual examination.

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

- Representative number of packages from each lot of a finished product.

» **Who Will Do the Monitoring?**

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

Establish Corrective Action Procedures.

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

- Segregate and relabel any improperly labeled product.

AND

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

- Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper statement;

AND

- Determine and correct the cause of improper labels.

Establish a Recordkeeping System.

- Record of labeling checks.

Establish Verification Procedures.

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

TABLE 14-2

CONTROL STRATEGY EXAMPLE 2 - CONTROL BY REFRIGERATION WITH LABELING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Control by Refrigeration With Labeling." This example illustrates how a processor of refrigerated, partially dried catfish can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receipt of labeling	C. botulinum toxin formation during finished product storage	All finished product labels must contain a "keep refrigerated" statement	Finished product labels for the presence of the "keep refrigerated" statement	Visual examination	One label from each case of labels at receipt	Receiving employee	Segregate and re-label any improperly labeled product Segregate and return or destroy any label stock that does not contain the proper statement Determine and correct the cause of improper labels	Label receiving record	Review monitoring and correction action records within 1 week of preparation

*Note: Chapter 12 covers control of pathogenic bacteria growth at the CCP of finished product storage.

BIBLIOGRAPHY.

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

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CHAPTER 15: Staphylococcus aureus Toxin Formation in Hydrated Batter Mixes

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

UNDERSTAND THE POTENTIAL HAZARD.

Staphylococcus aureus (*S. aureus*) toxin formation in hydrated batter mixes can cause consumer illness. *S. aureus* is the bacterium responsible for Staphylococcal Food Poisoning (SFP). Ten to thirty outbreaks of SFP occur annually in the United States, from all sources. Symptoms include: vomiting, diarrhea, abdominal pain, nausea, and weakness. Symptoms usually start within 4 hours of consumption. Everyone is susceptible to intoxication by *S. aureus* toxin, with more severe symptoms, including occasionally death, occurring in infants, the elderly, and debilitated persons. Generally, it is a self-limiting illness.

This chapter covers control of *S. aureus* toxin formation that occurs as a result of time and temperature abuse at the hydrated batter mix storage or recirculation step. This toxin in particular is a concern at this step because it is not likely to be destroyed by subsequent heating steps that the processor or the consumer may perform. Pathogenic bacteria other than *S. aureus*, such as those described in Chapter 12, are less likely to grow in hydrated batter mixes and/or are likely to be killed by subsequent heating.

- **Control of *S. 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 500,000 to 1,000,000 per gram. *S. aureus* will grow at temperatures as low as 44.6°F (7°C) and at a water activity as low as 0.83 (additional information on conditions favorable to *S. aureus* growth is provided in Table A-1 (Appendix 4)). However, toxin formation is not likely at temperatures lower than 50°F (10°C) or at water activities below 0.85. 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 at temperatures between 50°F (10°C) and 70°F (21.1°C) could result in toxin formation. Exposure times greater than 3 hours at 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 *Clostridium botulinum*; and Chapter 12 for other pathogenic bacteria and conditions);
- Killing pathogenic bacteria by cooking or pasteurizing (covered in Chapter 16), or retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (called the Low-Acid Canned Foods Regulation in this guidance document));

- Killing pathogenic bacteria by processes that retain the raw product characteristics (covered in Chapter 17);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in Chapter 13);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the level of acidity (pH) in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by Chapter 13 for refrigerated acidified products);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 4);
- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether *S. aureus* toxin formation in hydrated batter mixes is a significant hazard at a processing step:

1. Is it reasonably likely that *S. aureus* will grow and form toxin in the hydrated batter mix at the hydrated batter mix storage or recirculation step?

   The previous section, "Understand the Potential Hazard," provides information to help you decide whether the time and temperature conditions of your hydrated batter mix storage or recirculation step are favorable for *S. aureus* growth and toxin formation.

2. Can the hazard of *S. aureus* growth and toxin formation that was introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?

   S. aureus toxin formation in hydrated batter mixes should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measure that can be applied for *S. aureus* toxin formation in hydrated batter mixes is controlling the amount of time that hydrated batter mixes are exposed to temperatures above 50°F (10°C).

- **Intended use**

Because of the highly heat-stable nature of *S. aureus* toxin, it is unlikely that the intended use will affect the significance of the hazard.

IDENTIFY CRITICAL CONTROL POINTS.

If the hazard of *S. aureus* toxin formation in hydrated batter mixes is significant, you should identify the hydrated batter mix storage or recirculation step as the critical control point (CCP) for this hazard. For hand-battering operations, where hydrated batter mix is stored at each hand-battering station, the hand-battering stations also should be identified as a CCP.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example - Hydrated Batter Mix Control."

Example:

A mechanized breaded fish processor should set the CCP for controlling the hazard of S. aureus growth and toxin formation in hydrated batter mixes at the hydrated batter mix storage or recirculation step. The processor would not need to identify other processing steps as CCPs for that hazard.

DEVELOP A CONTROL STRATEGY.

The following guidance provides an example of a control strategy for *S. aureus* toxin formation in hydrated batter mixes. It is important to note that you may select a control strategy that is different from that which is suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

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

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Hydrated batter mix control	✓	✓

- **CONTROL STRATEGY EXAMPLE - HYDRATED BATTER MIX CONTROL**

Set Critical Limits.

- Hydrated batter mix should not be held for more than 12 hours, cumulatively, at temperatures between 50°F (10°C) and 70°F (21.1°C);

  AND

- Hydrated batter mix should not be held for more than 3 hours, cumulatively, at temperatures above 70°F (21.1°C).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The temperature of the hydrated batter mix and the time of exposure at temperatures above 50°F (10°C) and above 70°F (21.1°C).

» **How Will Monitoring Be Done?**

- Use a continuous temperature-recording device (e.g., a recording thermometer);

  OR

- Use a temperature-indicating device (e.g., a thermometer) and observe the time of exposure.

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

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

  OR

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

» **Who Will Do the Monitoring?**

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

  OR

- For temperature-indicating devices:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Destroy the product and remaining hydrated batter mix;

  OR

- Divert the product and 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 and 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.

AND

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

- Add ice to the hydrated batter mix storage and recirculation tank;

  AND/OR

- Make repairs or adjustments to the hydrated batter mix refrigeration equipment.

Establish a Recordkeeping System.

- For continuous temperature-recording devices:
  - Recorder thermometer charts or digital time and temperature data logger printouts;

    AND

  - Record of visual checks of recorded data;

  OR

- For temperature-indicating devices:
  - Record of visual checks of devices (time and temperature).

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) or temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

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

    OR

  - Doing a combination of the above if the device will be used at or near room temperature;

    OR

  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., batter temperature) within the temperature range at which it will be used;

  AND

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

  AND

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

  AND

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

TABLE 15-1

CONTROL STRATEGY EXAMPLE - HYDRATED BATTER MIX CONTROL

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example - Hydrated Batter Mix Control." This example illustrates how a breaded fish processor can control S. aureus toxin formation in hydrated batter mixes. It is provided for illustrative purposes only.

S. aureus toxin formation in hydrated batter mixes may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Batter mix recirculation tank	S. aureus growth and toxin formation	Hydrated batter mix temperature not to exceed 50°F for more than 12 hours, cumulatively, nor 70°F for more than 3 hours, cumulatively	The temperature of the hydrated batter mix and the time of exposure at temperatures above 50°F (10°C) and above 70°F (21.1°C)	Recorder thermometer	Continuous, with visual check once per day	Production employee	Destroy hydrated batter mix and any product produced during the period of the deviation Adjust hydrated batter mix refrigeration equipment	Recorder thermometer chart	Check the recorder thermometer for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

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

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CHAPTER 16: **Pathogenic Bacteria Survival Through Cooking or Pasteurization**

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

UNDERSTAND THE POTENTIAL HAZARD.

The survival of pathogenic bacteria through cooking or pasteurization can cause consumer illness. The primary pathogens of concern are *Clostridium botulinum* (*C. botulinum*), *Listeria monocytogenes* (*L. monocytogenes*), *Campylobacter jejuni* (*C. jejuni*), pathogenic strains of *Escherichia coli* (*E. coli*), *Salmonella spp.*, *Shigella spp.*, *Yersinia enterocolitica* (*Y. enterocolitica), Staphylococcus aureus* (*S. aureus*), *Vibrio cholera* (*V. cholera*), *Vibrio vulnificus* (*V. vulnificus*), and *Vibrio parahaemolyticus* (*V. parahaemolyticus*). See Appendix 7 for a description of the public health impacts of these pathogens.

It is not practical to target viral pathogens in cooking or pasteurization processes because of their extreme heat resistance. Viral pathogens should be controlled through a rigorous sanitation regime as part of a prerequisite program or as part of Hazard Analysis Critical Control Point (HACCP) itself. The Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products regulation, 21 CFR 123 (called the Seafood HACCP Regulation in this guidance document) requires such a regime.

- **Types of heat processing**

Cooking is a heat treatment, usually performed before the product is placed in the finished product container. It is applied to fishery products that are distributed either refrigerated or frozen. Generally, after cooking, fishery products are referred to as cooked, ready to eat. Examples of cooked, ready-to-eat fishery products are crabmeat, lobster meat, crayfish meat, cooked shrimp, surimi-based analog products, seafood salads, seafood soups and sauces, and hot-smoked fish.

Pasteurization is a treatment (usually, but not always, the application of heat) applied to eliminate the most resistant pathogenic bacteria of public health concern that is reasonably likely to be present in the food for as long as the shelf-life of the product, when stored under normal and moderate abuse conditions. With fishery products, pasteurization is usually performed after the product is placed in the hermetically sealed finished product container. It is applied to fishery products that are distributed either refrigerated or frozen. Examples of pasteurized fishery products are pasteurized crabmeat, pasteurized surimi-based analog products, and pasteurized lobster meat.

In addition to eliminating bacterial pathogens, cooking and pasteurization also greatly reduce the number of spoilage bacteria present in the fishery product. These bacteria normally restrict the growth of pathogens through competition. Elimination of spoilage bacteria allows rapid growth of newly introduced pathogenic bacteria. Pathogenic bacteria that may be introduced after cooking or pasteurization are, therefore, a concern. This is especially true for pasteurization, because that process can significantly extend the shelf-life of the fishery product, providing more time for pathogenic bacteria growth and toxin formation.

Retorting is a heat treatment that eliminates all food-borne pathogens and produces a product that is shelf stable. Mandatory controls for retorting are provided in the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (hereinafter, the Low Acid Canned Foods (LACF) Regulation), but are not covered in this chapter.

- **Goal of pasteurization**

Selection of the target pathogen is critical to the effectiveness of pasteurization. You should consider the potential that *C. botulinum* type E or non-proteolytic types B and F will survive the pasteurization process and grow under normal storage conditions or moderate abuse conditions. This is of particular concern if the product is reduced oxygen packaged (e.g., vacuum packaged or modified atmosphere packaged), does not contain a barrier that is sufficient to prevent growth and toxin formation by this pathogen, is not equipped with a time and temperature integrator, and is stored or distributed refrigerated (not frozen). In such products, you should ordinarily select *C. botulinum* type E and non-proteolytic types B and F as the target pathogen. For example, vacuum-packaged lobster meat that is pasteurized to kill *L. monocytogenes*, but not *C. botulinum* type E or non-proteolytic types B and F, and is not equipped with a Time-Temperature Indicator should be frozen to prevent growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F, and should be 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").

If the product is not reduced oxygen packaged, or contains a barrier that is sufficient to prevent the growth and toxin formation by *C. botulinum* type E or non-proteolytic types B and F, or is equipped with a time and temperature integrator, or is distributed frozen, then selection of another target pathogen may be appropriate. *L. monocytogenes* may be selected as the target pathogen for pasteurization of this type of product because it is the most resistant bacterial pathogen of public health concern that is reasonably likely to be present.

Surveys of retail display cases and home refrigerators indicate that temperatures above the minimum growth temperature of *C. botulinum* type E and non-proteolytic types B and F (38°F (3.3°C)) are not uncommon. Therefore, refrigeration alone cannot be relied upon for control of the *C. botulinum* hazard. When freezing is relied upon to control the growth of *C. botulinum* type E and non-proteolytic types B and F, controls should be in place to ensure that the product is labeled with instructions that it be kept frozen throughout distribution.

For pasteurization processes that target *C. botulinum* type E and non-proteolytic types B and F, 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 levels in the food before pasteurization. It is also possible that higher levels of destruction may be necessary in some foods, if especially high initial levels of the target pathogen are anticipated. Table A-4 (Appendix 4) provides 6D process times for a range of pasteurization temperatures, with *C. botulinum* type B (the most heat resistant form of non-proteolytic *C. botulinum*) as the target pathogen. The lethal rates and process times provided in the table may not be sufficient for the destruction of *C. botulinum* type E and non-proteolytic types B and F in dungeness crabmeat, because of the potential that naturally occurring substances, such as lysozyme, may enable the pathogen to more easily recover after heat damage.

Examples of properly pasteurized products are fish and fishery products generally (e.g., surimi-based products, soups, or sauces) pasteurized to a minimum cumulative total lethality of $F_{194°F}$ ($F_{90°C}$) = 10 minutes, where z = 12.6°F (7°C) for temperatures less than 194°F (90°C) and z = 18°F (10°C) for temperatures above 194°F (90°C); blue crabmeat pasteurized to a minimum cumulative total lethality of $F_{185°F}$ ($F_{85°C}$) = 31 minutes, where z = 16°F (9°C); and dungeness crabmeat pasteurized to a minimum cumulative total lethality of $F_{194°F}$ ($F_{90°C}$) = 57 minutes, where z = 15.5°F (8.6°C). Equivalent processes at different temperatures can be calculated using the z values provided.

EXAMPLES OF PROPERLY PASTEURIZED PRODUCTS		
PRODUCT	MINIMUM CUMULATIVE TOTAL LETHALITY	Z VALUE
Fish and fishery products generally (e.g., surimi-based products, soups, or sauces)	$F_{194°F}$ ($F_{90°C}$) = 10 minutes	12.6°F (7°C), for temperatures less than 194°F (90°C) 18°F (10°C) for temperatures above 194°F (90°C)
Blue crabmeat	$F_{185°F}$ ($F_{85°C}$) = 31 minutes	16°F (9°C)
Dungeness crabmeat	$F_{194°F}$ ($F_{90°C}$) = 57 minutes	15.5°F (8.6°C)

In some pasteurized surimi-based products, salt, in combination with a milder heat pasteurization process in the finished product container, works to prevent growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F. An example of a properly pasteurized surimi-based product in which 2.4% water phase 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 *C. botulinum* type E and non-proteolytic types B and F, but not *C. botulinum* type A and proteolytic types B and F, and that do not contain barriers to its growth should be refrigerated or frozen to control *C. botulinum* type A and proteolytic types B and F. 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.

In cases where *L. monocytogenes* is selected as the target pathogen, a 6D process is also generally suitable. FDA and U.S. Department of Agriculture's *L. monocytogenes* risk assessment indicates that approximately 8% of raw seafood are contaminated with from 1 to 10^3 colony forming unit (CFU)/g and that approximately 91% are contaminated at less than 1 CFU/g. Less than 1% of raw seafood are contaminated at levels greater than 10^3 CFU/g and none at levels greater than 10^6 CFU/g. FDA's limit for *L. monocytogenes* in ready-to-eat products, nondetectable, corresponds to a level of less than 1 CFU/25g.

Table A-3 (Appendix 4) 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 levels in the food before pasteurization. It is also possible that higher degrees of destruction may be necessary in some foods if especially high initial levels are anticipated.

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 contaminated cooling water, are critical to the safety of these products and are covered in Chapter 18.

- **Goal of cooking for most products**

One reason for cooking products that will not be reduced oxygen packaged is to eliminate vegetative cells of pathogenic bacteria (or reduce them to an acceptable level) that may have been introduced to the process by raw materials or by processing that occurs before the cooking step. Selection of the target pathogen is critical to the effectiveness of cooking. Generally, *L. monocytogenes* is selected as the target pathogen because it is regarded as the most heat-tolerant, foodborne bacterial pathogen that does not form spores. Cooking processes are not usually designed to eliminate spores of bacterial pathogens. Determining the degree of destruction of the target pathogen is also critical. 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.

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 levels in the food before pasteurization. It is also possible that higher degrees of destruction may be necessary in some foods if especially high initial levels are anticipated.

- **Goal of cooking refrigerated, reduced oxygen-packaged products**

Cooking is sometimes performed on products immediately before placement in reduced oxygen packaging (e.g., vacuum packaging or modified atmosphere packaging). These products include cooked, hot-filled soups, chowders, or sauces that are filled directly from the cook kettle using sanitary, automated, continuous filling systems designed to minimize risk of recontamination. They are often marketed under refrigeration, which is important for the control of *C. botulinum* type A and proteolytic types B and F.

The cooking process for these products should be sufficient to eliminate the spores of *C. botulinum* type E and non-proteolytic 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. Generally, a 6D process (six logarithms, e.g., from 10^{3} to 10^{-3}) is suitable. However, lower degrees of destruction may be acceptable if supported by a scientific study of the normal levels in the food before pasteurization. It is also possible that higher degrees of destruction may be necessary in some foods if especially high initial levels are anticipated.

Table A-4 provides 6D process times for a range of cooking temperatures, with *C. botulinum* type B (the most heat-resistant form of non-proteolytic *C. botulinum*) as the target pathogen. The lethal rates and process times provided in the table may not be sufficient for the destruction of *C. botulinum* type E and non-proteolytic types B and F in soups or sauces containing dungeness crabmeat because of the potential that naturally occurring substances, such as lysozyme, may enable the pathogen to more easily recover after damage. An example of a product that is properly cooked to eliminate *C. botulinum* type E and non-proteolytic types B and F is a soup or sauce that is cooked to a minimum cumulative total lethality of $F_{194°F}$ ($F_{90°C}$) = 10 minutes, where z = 12.6°F (7°C) for temperatures less than 194°F (90°C) and z = 18°F (10°C) for temperatures above 194°F (90°C).

Reduced oxygen-packaged soups or sauces that are cooked immediately before packaging to control *C. botulinum* type E and non-proteolytic types B and F, but not *C. botulinum* type A and proteolytic types B and F, and that do not contain barriers to its growth should be refrigerated or frozen to control *C. botulinum* type A and proteolytic types B and F. 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 *C. botulinum* type E and non-proteolytic types B and F have much in common with pasteurization processes. 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 contaminated cooling water, are critical to the safety of these products and are covered in Chapter 18.

Additionally, because these products are cooked before they are packaged, they are at risk of recontamination between cooking and packaging. The risk of recontamination may be minimized by filling the container in a sanitary, automated, continuous filling system while the product is still hot (i.e., hot filling). This is 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 that are handled between cooking and filling. Hot filling is also covered in Chapter 18.

- **Control by cooking or pasteurization**

Controlling pathogenic bacteria survival through cooking or pasteurization is accomplished by:

- Scientifically establishing a cooking or pasteurization process that will eliminate pathogenic bacteria of public health concern or reduce their numbers to acceptable levels;
- Designing and operating the cooking or pasteurization equipment so that every unit of product receives at least the established minimum process;
- Continuously monitoring the critical process parameters to verify achievement of a scientifically established process (e.g., time and temperature).

You may monitor End-Point Internal Product Temperature (EPIPT), a measurement of the temperature of the product as it exits the heat process, instead of performing continuous time and temperature monitoring. This approach is suitable if you have conducted a scientific study to validate that the EPIPT that you have selected will provide an appropriate reduction in the numbers of the target pathogen (e.g., 6D) in the slowest heating unit or portion of product under the worst set of heating conditions covered by the scientific study. You should (1) conduct a temperature distribution study within the heating system to identify any cold spots; (2) conduct a heat penetration study that accounts for the slowest heating product under the worst case heating conditions covered by the scientific study; and identify other critical factors of processing and/or packaging that affect the rate of product heating when scientifically establishing a cooking or pasteurization process (i.e., process validation). The EPIPT should be used as a monitoring technique only under those conditions that were evaluated by the scientific study. Those conditions may need to be identified as critical limits and monitored as part of the HACCP plan.

EPIPT monitoring may not be an option when the objective is control of *C. botulinum* type E and non-proteolytic types B and F spores. These spores are far more heat resistant than vegetative cells of *L. monocytogenes* and destroying them requires an EPIPT that could be achieved only in a pressurized steam environment, making measurement impractical. Additional guidance on EPIPT monitoring can be found in Food Processors Association guidance document "FPA Guidance Document: Establishing or Verifying a Heat Process for Cooked, Ready-to-Eat Seafood Products, and Heat Process Monitoring Considerations under HACCP," 2nd Edition, February 2005 and purchased at the Grocery Manufacturers Association, Washington DC 20005.

- **Strategies for controlling pathogenic bacteria growth**

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

- Killing pathogenic bacteria by cooking or pasteurizing (covered in this chapter) or retorting (covered by the LACF Regulation, 21 CFR 113);
- Killing pathogenic bacteria by processes that retain the raw characteristics of the products (covered in Chapter 17);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in Chapter 13);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the level of acidity (pH) in the product (covered by the Acidified Foods

regulation, 21 CFR 114, for shelf-stable acidified products, and by Chapter 13 for refrigerated acidified products);

- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 4);
- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether pathogenic bacteria survival through cooking and pasteurization is a significant hazard at a processing step.

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

   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 be present only at low levels or only occasionally, but even such occurrences warrant consideration because of the potential for growth and toxin production.

   Pathogenic bacteria 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 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 bacterial pathogens. For this reason, you should consider it reasonably likely that low numbers of pathogenic bacteria will be present in the product.

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

   Pathogenic bacteria survival through cooking or pasteurization should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measure that can be applied for pathogenic bacteria survival through cooking and pasteurization is proper design and control of the cooking or pasteurization process.

- **Intended use**

Because cooked or pasteurized products are ready to eat, it is unlikely that the intended use will affect the significance of the hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for the survival of pathogenic bacteria through cooking or pasteurization:

Will the finished product be pasteurized in the final container?

1. If the finished product will be pasteurized in the final container, you should identify the pasteurization step as the CCP. In this case, you would not need to identify the cooking step as a CCP for the hazard of pathogenic bacteria survival through cooking.

   Example:

   A crabmeat processor cooks, picks, packs, and pasteurizes the crabmeat.

The processor sets the CCP for pathogenic bacteria survival through cooking and pasteurization at the pasteurization step and does not identify the cooking step as a CCP for this hazard.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example - Cooking and Pasteurization."

2. If the product will not be pasteurized, you should identify the cooking step as the CCP.

   This control approach is the same as the one above and is a control strategy also referred to in this chapter as "Control Strategy Example - Cooking and Pasteurization." For products in reduced oxygen packaging for which the cooking process does not target *C. botulinum* type E and non-proteolytic types B and F, see Chapter 13 for additional guidance.

DEVELOP A CONTROL STRATEGY.

The following guidance provides a control strategy for survival of pathogenic bacteria through cooking or pasteurization. You may select a control strategy that is different from that which is suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

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

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Cooking and pasteurization	✓	✓

- **CONTROL STRATEGY EXAMPLE - COOKING AND PASTEURIZATION**

Set Critical Limits.

- The minimum or maximum values for the critical factors established by a scientific study. These may include length of the cook or pasteurization cycle (speed of the belt for a continuous cooker or pasteurizer), temperature of the steam or water used for cooking or pasteurization (or visual observation of minutes at a boil for cooking), initial temperature of the product, container size (e.g., can dimensions, pouch thickness), and product formulation. Other critical factors that affect the rate of heating of the product may also be established by the study;

  OR

- The EPIPT, established by a scientific study. Other critical factors that affect the rate of heating of the product may also be established by the study.

Note: EPIPT monitoring may not be an option when the objective is control of C. botulinum type E and non-proteolytic types B and F spores.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The critical factors established by a scientific study. These may include length of the cook or pasteurization cycle (speed of the belt for a continuous cooker or pasteurizer) and temperature of the steam or water used for cooking or pasteurization (or visual observation of minutes at a boil for cooking), initial temperature of the product, container size (e.g., can dimensions, pouch thickness), and product formulation;

  OR

- The EPIPT.

» **How Will Monitoring Be Done?**

For batch cooking or pasteurization equipment:

- For cooking or pasteurization temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer). The device should be installed where it measures the coldest temperature of the cooking equipment (cold spot to be determined by a study). Where cooking

is performed at the boiling point, visual observation of minutes at a boil may be an acceptable alternative;

AND

- For the start and end of each cooking or pasteurization cycle:
  - Visual observation;

AND

- For other critical factors:
  - Use equipment appropriate to the critical factor (e.g., initial temperature with a temperature-indicating device, (e.g., a thermometer);

OR

- For the EPIPT:
  - Use a temperature-indicating device (e.g., a thermometer).

For continuous cooking or pasteurization equipment:

- For cooking or pasteurization temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer). The device should be installed where it measures the coldest temperature of the cooking equipment (cold spot to be determined by a study). Because of 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

- For cooking or pasteurization time, use:
  - A stopwatch or tachometer to monitor the speed of the belt drive wheel;

OR

  - A stopwatch to monitor the time necessary for a test unit or belt marking to pass through the equipment;

AND

- For other critical factors:
  - Use equipment appropriate to the critical factor (e.g., initial temperature with a temperature-indicating device, (e.g., a thermometer);

OR

- For the EPIPT:
  - Use a temperature-indicating device (e.g., a thermometer).

» How Often Will Monitoring Be Done (Frequency)?

For batch cooking or pasteurization equipment:

- For cooking or pasteurization temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once per batch;

AND

- For the start and end of each cooking or pasteurization cycle:
  - Each batch;

AND

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

OR

- For the EPIPT:
  - Each batch.

For continuous cooking or pasteurization equipment:

- For cooking or pasteurization temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once per day;

AND

- For cooking or pasteurization time:
  - At least once per day, and whenever any changes in belt speed are made;

AND

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

OR

- For the EPIPT:
  - At least every 30 minutes, and whenever any changes in product-heating critical factors occur.

» **Who Will Perform the Monitoring?**

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

AND

- For other monitoring:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Recook or repasteurize the product;

OR

- Chill and hold the product for an evaluation of the adequacy of the cooking or pasteurization process. If the product has not received an adequate process, it should be destroyed, diverted to a non-food use, or recooked or repasteurized;

OR

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

OR

- Destroy the product;

OR

- Divert the product to a non-food use.

AND

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

- Adjust the steam supply to increase the processing temperature;

OR

- Extend the length of the cooking or pasteurization cycle to compensate for a temperature drop, using a process developed by a process authority;

OR

- Process at a higher temperature to compensate for a low initial temperature, using a process developed by a process authority;

OR

- Adjust the belt speed.

Establish a Recordkeeping System.

For batch cooking or pasteurization equipment:

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

    AND
  - Record of visual checks of recorded data;

OR

- Cooking log that indicates visual observation of boiling, where cooking is performed at the boiling point;

AND

- Record of notation of the start time and end time of the cooking or pasteurization periods;

AND

- Records that are appropriate for the other critical factors (e.g., a cooking or pasteurization log that indicates the initial temperature);

OR

- Record of EPIPT results.

For continuous cooking or pasteurization equipment:

- Record of continuous temperature monitoring;

  AND

- Record of visual checks of devices;

  AND

- Cooking or 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., a cooking or pasteurization log that indicates the initial temperature);

  OR

- Record of EPIPT results.

Establish Verification Procedures.

For cooking, process validation study (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 number of pathogenic bacteria of public health concern. Selecting the target organism is critical. In most cases, it will be a relatively heat-tolerant vegetative pathogen, such as *L. 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 step (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 or modified atmosphere packaging), for a product that will be marketed under refrigeration, it may be necessary for the cooking process to be sufficient to eliminate the spores of *C. botulinum* type E and non-proteolytic 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 bacterial pathogen. However, lower degrees of destruction may be acceptable if supported by a scientific study of the normal levels 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 non-proteolytic *C. botulinum*) as the target pathogens. The values provided in Table A-4 may not be sufficient for the destruction of *C. botulinum* type E and non-proteolytic types B and F in products containing dungeness crabmeat because of the potential protective effect of naturally occurring substances, such as lysozyme.

  Expert knowledge of thermal process calculations and the dynamics of heat transfer in processing equipment may be required to establish such a cooking process. Such knowledge can be obtained by education or experience, or both. Conducting a validation study for cooking processes may require 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 the product. In some cases, thermal death time, heat penetration, temperature distribution, and inoculated pack studies may be necessary to validate 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 ensure the inactivation of all vegetative bacterial 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 that 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 validation of the process. A record of the process validation study should be maintained;

OR

For pasteurization, process validation study (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 number of target bacterial pathogens. Selecting the target organism is critical. In most cases, it will be the spores of *C. botulinum* type E and non-proteolytic types B and F. In some cases (e.g., products that are distributed frozen or contain other barriers to prevent growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F), the process will target another pathogen, such as *L. monocytogenes*. 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 levels 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 non-proteolytic *C. botulinum*) as the target pathogens. The values provided in Table A-4 may not be sufficient for the destruction of *C. botulinum* type E and non-proteolytic types B and F in products containing dungeness crabmeat because of the potential protective effect of naturally occurring substances, such as lysozyme.

  Expert knowledge of thermal process calculations and the dynamics of heat transfer in processing equipment may be required to determine the target bacterial pathogen and to establish a pasteurization process. Such knowledge can be obtained by education or experience, or both. Conducting a validation study for pasteurization processes may require 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 the product. In some cases, thermal death time, heat penetration, temperature distribution, and inoculated pack studies may be necessary to validate the minimum process. In other instances, existing literature or federal, state, or local regulations that establish minimum processes or adequacy of equipment 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 validation of the process. A record of the validation study should be maintained;

  AND

- Before a temperature-indicating device (e.g., a thermometer) or temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

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

    OR
  - A combination of the above if the

device will be used at or near room temperature;

OR

- Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., steam temperature, water temperature, product internal temperature) within the temperature range at which it will be used;

AND

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

AND

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

AND

- Calibrate other instruments as necessary to ensure their accuracy;

AND

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

TABLE 16-1

CONTROL STRATEGY EXAMPLE - COOKING AND PASTEURIZATION (COOKING MODEL)

This table is an example of a portion of a HACCP plan using "Control Strategy Example - Cooking and Pasteurization (Cooking Model)." This example illustrates how a processor of wild-caught cooked shrimp can control cooking using a continuous steam cooker. It is provided for illustrative purposes only.

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

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Cooking	Pathogenic bacteria survival	Minimum cook time: 2.5 minutes	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 critical limit, based on alternate processes provided by the process authority Chill and hold for evaluation	Cooking record	Scientific study establishing the thermal process (process validation) Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Calibrate the scale monthly Review monitoring, corrective action and verification, records within 1 week of preparation
		Minimum cook temperature: 210°F Note: To achieve a 6D reduction of L. monocytogenes	Temperature of steam in the cooker	Digital time and temperature data logger	Continuous, with visual check of recorded data once per day	Cooker operator		Data logger printout	
		Maximum shrimp size: 40 count/pound	Shrimp size	Scale	Hourly and after every raw material lot change or grader adjustment	Grader operator		Grading record	

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

TABLE 16-2

CONTROL STRATEGY EXAMPLE - COOKING AND PASTEURIZATION (PASTEURIZATION MODEL)

This table is an example of a portion of a HACCP plan using "Control Strategy Example - Cooking and Pasteurization (Pasteurization Model)." This example illustrates how a processor of pasteurized, refrigerated blue crabmeat can control pasteurization. It is provided for illustrative purposes only.

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

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Batch pasteurization	Pathogenic bacteria survival	Minimum initial product temperature: 37°F	Initial temperature	Dial thermometer	Coldest can entering each batch	Pasteurizer operator	Extend the process or elevate the temperature to compensate for deviation from the critical limit Segregate and hold for evaluation	Pasteurization log	Process establishment Check the temperature-recording device and dial thermometer for accuracy and damage and to ensure that they are operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, verification, and corrective action records within 1 week of preparation
		Minimum length of pasteurization cycle: 120 minutes	Time up to 189°F and time cycle ends	Temperature-recording device	Each batch	Pasteurizer operator		Pasteurization log	
		Minimum water bath temperature: 189°F	Temperature of water bath	Temperature-recording device	Continuously, with visual check at end of batch	Recorder thermometer, with visual check by pasteurizer operator		Recorder thermometer chart	

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

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

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

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

UNDERSTAND THE POTENTIAL HAZARD.

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

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

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

Examples of processes designed to retain raw product characteristics include:

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

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

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

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

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

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

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

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

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

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

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

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

- **Mild heat processing**

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

- **Irradiation**

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

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

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

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

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

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

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

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

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

- **Strategies for control of pathogens**

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

- Killing pathogenic bacteria by processes that retain the raw product characteristics (covered in this chapter);
- Killing pathogenic bacteria by cooking or pasteurizing (covered in Chapter 16) or by retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113, called the Low-Acid Canned Foods Regulation in this guidance document);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in Chapter 13; and for *Staphylococcus aureus* in hydrated batter mixes, in Chapter 15);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in Chapter 13);

- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the level of pH in the product (covered by the Acidified Foods regulation, 21 CFR 114 for shelf-stable acidified products, and by Chapter 13 for refrigerated acidified products);
- Controlling the source of molluscan shellfish and time from exposure to air (e.g., by harvest or receding tide) to refrigeration in order to control pathogens from the harvest area (covered in Chapter 4);
- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

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

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

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

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

   - The shellfish control authority has conducted a risk evaluation and determined that the risk of *V. parahaemolyticus* illness from the consumption of oysters harvested from that growing area is reasonably likely to occur. Specific guidance for determining risk can be found in the "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision";
   - The shellfish control authority has determined that harvesting occurs in the growing area at a time when average monthly daytime water temperatures exceed 60°F for waters bordering the Pacific Ocean and 81°F for waters bordering the Gulf of Mexico and the Atlantic Ocean (New Jersey and south), except where a more rigorous risk evaluation has led the shellfish control authority to conclude that the risk of *V. parahaemolyticus* illness from the consumption of oysters harvested from that growing area is not reasonably likely to occur;
   - The waters of the state have been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past 3 years.

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

   Pathogenic bacteria survival through processes designed to retain raw product characteristics should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measure that can be applied for pathogenic

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

- **Intended use**

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

IDENTIFY CRITICAL CONTROL POINTS.

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

1. If the finished product is raw oyster shellstock intended for raw consumption, will it be subjected to a process in your facility that is designed to retain raw product characteristics (e.g., mild heat processed, IQF with extended frozen storage, high hydrostatic pressure processed, or irradiated) and is sufficient to reduce *V. vulnificus* or *V. parahaemolyticus* to acceptable levels (i.e., reduced to a non-detectable level, less than 30 MPN/gram)?

    a. If the finished product will be subjected to a process designed to retain raw product characteristics, you should identify that processing step as the CCP for the target pathogen. In this case, you would not need to identify the receiving step as a CCP for the control of the target pathogen. However, you may need to identify the receiving step as a CCP for control of other non-target pathogens (e.g., *Salmonella spp.* and norovirus), as described in Chapter 4.

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

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

DEVELOP A CONTROL STRATEGY.

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

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

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

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

Set Critical Limits.

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Pressure;

  AND

- Hold time at pressure;

  AND

- Initial temperature of the product;

  AND

- Other critical factors that affect the effectiveness of the process, as specified by the study (e.g., pressurization time (step-up time), decompression time (step-down time), and treatment temperature).

» **How Will Monitoring Be Done?**

- For time and pressure:
  - Use a continuous pressure-recording device (e.g., a pressure recorder);

  AND

- For initial temperature of the product:
  - Use a temperature-indicating device (e.g., a thermometer);

  AND

- For other critical limits:
  - Use equipment appropriate to the critical limit.

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

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

  AND

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

  AND

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

» **Who Will Do the Monitoring?**

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

  AND

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

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

- Reprocess the product;

  OR

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

  OR

- Divert the product to a use in which the

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

OR

- Destroy the product;

OR

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

AND

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

- Adjust or repair the processing equipment;

AND/OR

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

Establish a Recordkeeping System.

- Record of continuous pressure monitoring;

AND

- Record of visual checks of recorded data;

AND

- Record of visual observations of initial temperature of product;

AND

- Records that are appropriate for other critical limit monitoring.

Establish Verification Procedures.

- Process validation study:
  - The adequacy of the high hydrostatic pressure treatment should be validated by conducting a scientific study. It should be designed to ensure an appropriate reduction in the number of the target pathogen(s). In the case of *V. vulnificus* or *V. parahaemolyticus*, it should be designed to reduce the presence of these pathogens to non-detectable levels. Non-detectable for these pathogens is defined under the NSSP as less than 30 MPN/gram. If "added safety" labeling is to be used on the product or if the process is used as a substitute for the time from exposure to air (e.g., by harvest or receding tide) to refrigeration limitations described in Chapter 4, the ability of a post-harvest process to reliably achieve the appropriate reduction of the target pathogen should be validated by a study approved by the shellfish control authority with concurrence from FDA. A study is used to initially validate the efficacy of the process and to revalidate it when there has been a change in the process. Additional guidance on conducting a validation study can be found in the "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision" (*http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm046353.htm*).

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

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

AND

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

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

    OR
  - Doing a combination of the above if the device will be used at or near room temperature;

    OR
  - Comparing the temperature indicated by the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

  AND
- Once in service, check the temperature-indicating device daily before the beginning of operations. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational;

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

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

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

TABLE 17-1

CONTROL STRATEGY EXAMPLE 1 - HIGH HYDROSTATIC PRESSURE PROCESSING

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

Pathogen survival through processes designed to retain raw product characteristics may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., pathogens from the harvest area, environmental chemical contaminants, natural toxins, pathogenic bacteria growth and toxin formation during processing, food and color additives, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIG-NIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
High hydrostatic pressure processing	V. vulnificus survival	Minimum hold time: 250 seconds	Hold time at pressure	Pressure-recording device	Continuous, with visual check of the recorded data once per batch	Pressure equipment operator	Chill and hold for evaluation Adjust or repair equipment as needed	Pressure-recording device printout	Process validation Check the dial thermometer for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
		Minimum pressure: 350 MPa	Pressure during the holding period	Pressure-recording device	Continuous, with visual check of the recorded data once per batch	Pressure equipment operator		Pressure-recording device printout	
		Minimum initial temperature of product: 60°F	Initial temperature of product	Dial thermometer	Each batch	Pressure equipment operator		Initial temperature log	

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

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

Set Critical Limits.

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

Establish Monitoring Procedures.

» **What Will Be Monitored?**

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

  AND

- Frozen storage temperature;

  AND

- Length of frozen storage.

» **How Will Monitoring Be Done?**

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

  AND

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

  AND

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

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

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

  AND

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

  AND

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

» **Who Will Do the Monitoring?**

- For temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have consistently been met, may be performed by any person who has an understanding of the nature of the controls;

  AND

- For other monitoring:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Refreeze the product;

  OR

- Hold the product for an evaluation of the adequacy of the freezing process. If the product has not received an adequate process, it should be destroyed, diverted to a non-food use or other appropriate use, or refrozen;

  OR

- Divert the product to a use in which the critical limit is not applicable (e.g., divert an improperly frozen product to a cooking or canning operation);

  OR

- Destroy the product;

  OR

- Divert the product to a non-food use or a use without the "added safety" labeling.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Make repairs or adjustments to the IQF freezing equipment;

  OR

- Make repairs or adjustments to the frozen storage freezer;

  OR

- Move some or all of the product in the frozen storage freezer to a properly functioning freezer.

  AND/OR

- Extend the freezing cycle or frozen storage time period to compensate for a rise in temperature, using a process developed by a process authority;

Establish a Recordkeeping System.

- For the IQF freezer:
  - Records that are appropriate to the monitoring;

  AND

- For frozen storage temperature:
  - Record of continuous temperature monitoring;

  AND

- For length of frozen storage:
  - Freezing log with notation of the start and end of frozen storage periods.

Establish Verification Procedures.

- Process validation study:
  - The adequacy of the IQF with extended frozen storage process should be validated by conducting a scientific study. It should be designed to ensure an appropriate reduction in the number of the target pathogen(s). In the case of *V. vulnificus* or *V. parahaemolyticus*, it should be designed to reduce the presence of these pathogens to non-detectable levels. Non-detectable for these pathogens is defined under the NSSP as less than 30 MPN/gram. If "added safety" labeling is to be used on the product or if the process is used as a substitute for the time from harvest to refrigeration limitations described in Chapter 4, the ability of a post-harvest process to reliably achieve the appropriate reduction of the target pathogen should be validated by a study approved by the shellfish control authority with concurrence from FDA. A study is performed to initially validate the efficacy of the process and to revalidate it when there has been a change in the process. Process verification may also be required at predetermined intervals. Additional guidance on conducting a validation study can be found in the "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007 Revision."

    Validating an IQF with extended frozen storage process may require access to suitable facilities and the application of recognized methods. The equipment should be designed, operated, and maintained to deliver the established process to every unit of the product. In some instances, inoculated pack studies may be necessary to establish the minimum process. In other instances, existing literature or federal, state, or local regulations that establish minimum processes or adequacy of equipment

may be available. Characteristics of the process, product, and/or equipment that affect the adequacy of the established minimum IQF with extended frozen storage process should be taken into consideration in the validation of the process. A record of the process validation studies should be maintained;

AND

- Before a temperature-indicating device (e.g., a thermometer) or temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR
  - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point (note that the temperature should be adjusted to compensate for altitude, when necessary);

    OR
  - Doing a combination of the above if the device will be used at or near room temperature;

    OR
  - Comparing the temperature indicated by the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature, product internal temperature) within the temperature range at which it will be used;

  AND
- Once in service, check the temperature-indicating device or temperature-recording device daily before the beginning of operations. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and has, where applicable, sufficient ink and paper;

  AND
- Calibrate the temperature-indicating device or temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Devices used to determine the core temperature of frozen fish or fishery products may require more frequent calibration. Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

  AND
- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 17-2

CONTROL STRATEGY EXAMPLE 2 - IQF WITH EXTENDED STORAGE

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 2 - IQF With Extended Storage." This example illustrates how a raw oyster processor using a continuous cryogenic freezer can control pathogen survival through processes designed to retain raw product characteristics. It is provided for illustrative purposes only.

Pathogen survival through processes designed to retain raw product characteristics may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., pathogens from the harvest area, environmental chemical contaminants and pesticides, natural toxins, pathogenic bacteria growth and toxin formation during processing, food and color additives, and metal fragments)

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
IQF freezer	V. vulnificus survival	The minimum or maximum values for the critical factors established by a scientific validation study*	Critical factors that affect the effectiveness of the process, as specified by the study*	Use equipment appropriate to the critical limit*	With sufficient frequency to achieve control*	IQF equipment operator	Segregate and hold the product for evaluation Adjust or repair equipment as needed	IQF record	Process validation Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
		The minimum length of frozen storage established by a scientific validation study*	Length of frozen storage	Clock	Beginning and end of each lot	Frozen storage operator		Frozen storage record	
		The maximum temperature of frozen storage established by a scientific validation study*	Temperature of frozen storage	Digital time/ temperature data logger	Continuous, with visual check of recorded data once per lot	Frozen storage operator		Data logger printout	

* Note: This plan is for illustrative purposes only. An actual plan should specify the actual critical limits for the IQF freezer, actual minimum frozen storage temperature, and actual minimum length of frozen storage. Additionally, an actual plan should specify the actual critical factors that will be monitored, the way in which they will be monitored, and the frequency of monitoring.

BIBLIOGRAPHY.

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CHAPTER 18: Introduction of Pathogenic Bacteria After Pasteurization and Specialized Cooking Processes

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

UNDERSTAND THE POTENTIAL HAZARD.

The introduction of pathogenic bacteria after pasteurization and certain specialized cooking processes can cause consumer illness. The primary pathogens of concern are *Clostridium botulinum* (*C. botulinum*), *Listeria monocytogenes*, *Campylobacter jejuni*, pathogenic strains of *Escherichia coli*, *Salmonella spp.*, *Shigella spp.*, *Yersinia enterocolitica*, *Staphylococcus aureus* (*S. aureus*), *Vibrio cholerae*, *Vibrio vulnificus*, and *Vibrio parahaemolyticus*. See Appendix 7 for a description of the public health impacts of these pathogens.

- **Goal of pasteurization and specialized cooking processes**

Pasteurization is a heat treatment applied to eliminate the most resistant pathogenic bacteria of public health concern that is reasonably likely to be present in the food. With fishery products, pasteurization is usually performed after the product is placed in the hermetically sealed finished product container. It is applied to fishery products that are distributed either refrigerated or frozen. Examples of pasteurized fishery products follow: pasteurized crabmeat, pasteurized surimi-based analog products, and pasteurized lobster meat.

In addition to eliminating pathogenic bacteria, the pasteurization process also greatly reduces the number of spoilage bacteria present in the fishery product. Spoilage bacteria normally restrict the growth of pathogenic bacteria through competition. Rapid growth of pathogenic bacteria that may be introduced after pasteurization is, therefore, a concern. This chapter covers control of recontamination after pasteurization.

For some products that are marketed refrigerated, cooking is performed immediately before reduced oxygen packaging (e.g., vacuum packaging, modified atmosphere packaging). For these products, the cooking process is targeted to eliminate the spores of *C. botulinum* type E and non-proteolytic types B and F, particularly when the product does not contain other barriers that are sufficient to prevent growth and toxin formation by this pathogen (e.g., many refrigerated, vacuum packaged hot-filled soups, chowders, and sauces).

These specialized cooking processes, which are discussed in Chapter 16, have much in common with pasteurization processes, which are also discussed in Chapter 16. For example, control of recontamination after the product is placed in the finished product container is critical to the safety of these products. Additionally, because these products are cooked before they are packaged, they are at risk for recontamination between cooking and packaging. The risk of this recontamination may be minimized by filling directly from the cook kettle using a sanitary, automated, continuous-filling system (designed to minimize the risk of recontamination) while the product is still hot (i.e., hot filling). This control strategy may not be suitable for products such as crabmeat, lobster meat, or crayfish meat that are

handled between cooking and filling. Hot filling is covered in this chapter.

- **Control of pathogenic bacteria introduction after pasteurization and after specialized cooking processes**

There are three primary causes of recontamination after pasteurization and after cooking that is performed immediately before reduced oxygen packaging:

- Defective container closures;
- Contaminated container cooling water;
- Recontamination between cooking and reduced oxygen packaging.

Poorly formed or defective container closures can increase the risk of pathogens entering the container through container handling that occurs after pasteurization or after the cooked product is filled into the reduced oxygen package. This risk is a particular concern during container cooling performed in a water bath. Contaminated cooling water can enter through the container closure, especially when the closure is defective. Container closure can be controlled by adherence to seal guidelines that are provided by the container or sealing machine manufacturer. Control is accomplished through periodic seal inspection.

Contamination of cooling water can be controlled either by ensuring that a measurable residual of chlorine, or other approved water treatment chemical, is present in the cooling water or by ensuring that ultraviolet (UV) treatment systems for the cooling water are operating properly, particularly for systems in which the water is reused or recirculated.

Recontamination between cooking and reduced oxygen packaging in continuous filling systems, where the product is packaged directly from the kettle, can be controlled by hot filling at temperatures at or above 185°F (85°C). FDA is interested in information on the value of adding a time component (e.g., 3 minutes) to this hot filling temperature recommendation to provide limited lethality for any non-proteolytic *C. botulinum* spores present on the packaging material.

It may also be prudent to use packaging that has been manufactured or treated to inactivate spores of *C. botulinum* type E and non-proteolytic types B and F (e.g., gamma irradiation and hot extrusion). FDA is also interested in comment on the utility of such measures.

- **Strategies for controlling pathogenic bacteria growth**

There are a number of strategies for the control of pathogenic bacteria in fish and fishery products. They include:

- Controlling the introduction of pathogenic bacteria after the pasteurization process and after the cooking process performed immediately before reduced oxygen packaging (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in Chapter 13);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the level of acidity (pH) in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by Chapter 13 for refrigerated acidified products);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 4);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16) or by retorting (covered by the Thermally

Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113, called the Low Acid Canned Foods regulation in this guidance document);

- Killing pathogens by processes that retain the raw product characteristics (covered in Chapter 17);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether introduction of pathogenic bacteria after pasteurization is a significant hazard at a processing step:

1. Is it reasonably likely that pathogenic bacteria will be introduced at this processing step (consider post-pasteurization and post-cooking processing steps only)?

   It is reasonable to assume that in the absence of controls, pathogens of various types may enter the finished product container after pasteurization or after filling the cooked product into the reduced oxygen package. This is a particular concern for products that are cooled in a water bath.

2. Can the introduction of pathogenic bacteria after pasteurization be eliminated or reduced to an acceptable level here?

   Introduction of pathogenic bacteria after pasteurization should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. Preventive measures for introduction of pathogenic bacteria after pasteurization can include:

   - Controlling container sealing;
   - Controlling the residual of chlorine, or other approved water treatment chemical, in container cooling water;
   - Controlling UV light intensity of bulbs used for treating container cooling water and the flow rate of the cooling water moving through the UV treatment system;
   - Hot filling the product into the final container in a continuous filling system.

- **Intended use**

It is unlikely that the intended use will affect the significance of this hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for introduction of pathogenic bacteria after pasteurization.

If you identified the hazard as significant, you should identify the container sealing step, the water bath container cooling step, and the hot filling step (where applicable) as the CCPs for this hazard.

Example:

A crabmeat processor that pasteurizes the finished product cans after filling and cools them in a water bath should set the CCPs for introduction of pathogenic bacteria after pasteurization at the can seaming and water bath can cooling steps.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example - Control of Recontamination."

DEVELOP A CONTROL STRATEGY.

The following guidance provides a strategy to control the introduction of pathogenic bacteria into the product after pasteurization. You may select a control strategy that is different from that which is suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following is an example of a control strategy included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Control of recontamination	✓	✓

- **CONTROL STRATEGY EXAMPLE - CONTROL OF RECONTAMINATION**

Set Critical Limits.

For container sealing:

- Container or sealing machine manufacturer's seal guidelines.

For container cooling:

- Measurable residual of chlorine, or other approved water treatment chemical, at the discharge point of the container cooling tank;

  OR

- Equipment manufacturer's UV light intensity and flow rate guidelines.

For hot filling:

- Product temperature of 185°F (85°C) or higher as the product enters the final container.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

For container sealing:

- Container integrity.

For container cooling:

- For chemical treatment:
  - Residual chlorine, or other approved water treatment chemical, in the cooling water;

  OR

- For UV treatment:
  - Intensity of UV light;

    AND
  - Cooling water flow rate.

For hot filling:

- Product temperature as the product enters the final container.

» **How Will Monitoring Be Done?**

For container sealing:

Visual examination of containers (non-destructive):

- Recommendations for visual examinations that ensure a reliable hermetic seal should be obtained from the container or sealing machine manufacturer. They should include:
  - For double-seamed metal and plastic cans:
    - The external features of the double seam should be examined for gross closure defects, including: cutovers, seam sharpness, false seams, deadheading, droop, damage to the countersink wall indicating a broken chuck, cable cuts, and product overlapping the flange. In addition, visual examination should include examination of the entire container for product leakage or other obvious defects;

    OR
  - For pouches:
    - Visual examination should be sufficient to detect gross closure defects, including: cuts, fractures,

non-bonding, malformation, puncture, abrasion, blister, contaminated seal, delamination, seal creep, wrinkle, flex cracks, crushed package, or other obvious defects;

OR

- For glass containers:
  - Visual examination should be sufficient to detect gross closure and glass defects, including: cap tilt, cocked cap, crushed lug, stripped cap, cut through, and chipped and cracked glass finish;

AND

Detailed examination of containers (destructive):

- Recommendations for seal evaluation measurements that ensure a reliable hermetic seal should be obtained from the container or sealing machine manufacturer. They should include:
  - For double-seamed metal and plastic cans:
    - The examination should include a teardown examination of the can. If the micrometer method is used, three measurements, approximately 120° apart around the double seam, should be made. Measurements should include: cover hook, body hook, width, tightness, and thickness. If the optical method (seamscope or projector) is used, cuts should be made at at least two different locations, excluding the side seam juncture. Measurements should include body hook, overlap, tightness, and thickness;

    OR

  - For pouches:
    - The examination should include burst, vacuum or bubble testing. It may also include: drop testing, peel testing (tensile strength), residual gas testing, electroconductivity testing, and dye testing;

    OR

  - For glass containers:
    - The examination should include cold water vacuum testing. Additional examinations may include: for lug-type caps, security values (lug-tension) and for lug-type, twist caps, pull-up (lug position).

For container cooling:

- For chemical treatment:
  - Measure residual of chlorine, or other approved water treatment chemical, at the discharge point of the container cooling tank;

  OR

- For UV treatment:
  - Use a UV light meter;

    AND

  - Use a flow rate meter.

For hot filling:

- Use a continuous temperature-measuring instrument (e.g., a recorder thermometer).

» How Often Will Monitoring Be Done (Frequency)?

For container sealing:

Visual examination of containers:

- At least one container from each sealing head at least every 30 minutes of sealing machine operation. At a minimum, visual examinations should include those made at the beginning of the production day, and immediately after a jam in the sealing machine, or after machine adjustment, repair, or prolonged shutdown;

AND

Detailed examination of containers:

- At least one container from each sealing head at least every 4 hours of sealing machine operation. At a minimum, visual examinations should include those made at the beginning of the production day, and immediately after a jam in the sealing machine, or after machine adjustment, repair, or prolonged shutdown.

For container cooling:

- For chemical treatment:
  - At least once every 4 hours of use;

  OR
- For UV treatment:
  - At least daily.

For hot filling:

- Continuous monitoring, with a visual check of the instrument at least once per batch of cooked product.

» Who Will Do the Monitoring?

For container sealing:

- Monitoring may be performed by any person who is trained and qualified to conduct container examinations.

For container cooling:

- Monitoring may be performed by any person who has an understanding of the nature of the controls.

For hot filling:

- For continuous temperature-measuring instruments:
  - Monitoring is performed by the equipment itself. The visual check of the data generated by the equipment, to ensure that the critical limits have consistently been met, may be performed by any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

For container sealing:

- Repack and recook or repasteurize the affected product;

  OR
- Segregate and hold the product to evaluate the seriousness of the defects, which may include, but is not limited to, 100% visual inspection of all affected containers to remove the defective containers. Any containers that are found to be unsafe should be destroyed, diverted to a non-food use, or repacked and recooked;

  OR
- Divert the product to a use in which the critical limit is not applicable (e.g., divert to a canning operation);

  OR
- Destroy the product;

  OR
- Divert the product to a non-food use.

For hot filling:

- Recook the product;

  OR
- Segregate and hold the product for a safety evaluation. If the product is found to be unsafe, it should be destroyed, diverted to a non-food use, or recooked;

  OR
- Divert the product to a use in which the critical limit is not applicable (e.g., divert to a canning operation);

  OR
- Destroy the product;

  OR
- Divert the product to a non-food use.

AND

Take one or more of the following corrective actions to regain control over the operation after a critical limit deviation:

For container sealing:

- Identify and correct the source of the defect.

For container cooling:

- If no measurable residual chlorine, or other approved water treatment chemical, is detected, add chlorine or adjust the chlorine-metering system and recheck for chlorine residual;

  OR

- If UV intensity is inadequate, replace or clean the bulbs or shields;

  OR

- If flow exceeds the critical limit, adjust or replace the pump.

For hot filling:

- Adjust the cooking equipment to increase the processing temperature;

  OR

- Adjust the post-cook process to minimize time delays.

Establish a Recordkeeping System.

For container sealing:

- Record of visual examination of containers;

  AND

- Record of detailed examination of containers.

For container cooling:

- For chemical treatment:
  - Record of residual chlorine, or other approved water treatment chemical;

  OR

- For UV treatment:
  - Record of UV intensity testing;

    AND
  - Record of flow rate testing.

For hot filling:

- Record of continuous temperature monitoring;

  AND

- Record of visual checks of recorded data.

Establish Verification Procedures.

For container sealing:

- Obtain container seal guidelines from container or sealing machine manufacturer;

  AND

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

For container cooling:

- Obtain UV light intensity and flow rate guidelines from the UV light manufacturer;

  AND

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

For hot filling:

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point (note that the temperature should be adjusted to compensate for altitude, when necessary);

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National

Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Devices subjected to high temperatures for extended periods of time may require more frequent calibration. Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 18-1

CONTROL STRATEGY EXAMPLE - CONTROL OF RECONTAMINATION

This table is an example of a portion of a Hazard Analysis Critical Control Point plan using "Control Strategy Example - Control of Recontamination." This example illustrates how a processor of pasteurized blue crabmeat, packed in steel cans, can control introduction of pathogenic bacteria after pasteurization. It is provided for illustrative purposes only.

Pathogenic bacteria recontamination after pasteurization may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides, pathogenic bacteria growth and toxin formation during processing, pathogenic bacteria survival through cooking and pasteurization, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Container sealing	Pathogenic bacteria introduction	No visible cutovers, seam sharpness, false seams, deadheading, droop, damage to the countersink wall indicating a broken chuck, cable cuts, product overlapping the flange, product leakage, or other obvious defects	Container integrity	Visual seam examination	One can per seaming head every 30 minutes; at startup; and after jams, adjustments, repairs, and prolonged shutdowns	Seamer operator	Identify and correct the source of the defect Evaluate the seriousness of the defect, and hold for further evaluation if necessary	Visual seam examination record	Obtain can seam guidelines from the can manufacturer Review monitoring and corrective action records within 1 week of preparation
		Cover hook: .070 inch minimum; body hook: .072-.088 inch; width: .125 inch maximum; thickness .052-.058 inch; tightness 80%	Container integrity	Double seam teardown examination, using a micrometer at 3 points on the seam, 120° apart	One can per seaming head every 4 hours; at startup; and after jams, adjustments, repairs, and prolonged shutdowns	Seamer operator	Identify and correct the source of the defect Evaluate the seriousness of the defect, and hold for further evaluation if necessary	Double seam teardown record	
Water bath container cooling	Pathogenic bacteria introduction	Measurable residual chlorine	Residual chlorine in water bath	Rapid test	Every batch	Pasteurizer operator	Add chlorine and recheck for residual	Residual chlorine record	

* Note: The critical limits in this example are for illustrative purposes only and are not related to any recommended process

BIBLIOGRAPHY.

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CHAPTER 19: UNDECLARED MAJOR FOOD ALLERGENS AND FOOD INTOLERANCE SUBSTANCES

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UNDERSTAND THE POTENTIAL HAZARD

- **Food Allergens**

Food allergies are a significant public health concern. Allergic reactions vary in severity from gastrointestinal disturbances and skin irritation, to anaphylaxis, shock and death. Consumers with allergies must avoid food containing allergenic materials to avoid these reactions. Because of this, consumers rely on food labels to disclose the presence of allergenic ingredients. Successful avoidance requires that food manufacturers develop, implement, and maintain the necessary controls to ensure allergens that are intended to be present in a food are declared on the label and that the presence of unintended allergens is prevented.

Advisory statements such as "may contain [allergen]" or "manufactured on equipment that also processes [allergen]" cannot be used as a substitute for current good manufacturing practices (cGMPs) intended to prevent allergen cross-contact.

Control of allergens will be accomplished through both the implementation of prerequisite programs and through HACCP plan controls that ensure accurate product labeling. Product labeling, label control, and allergen cross-contact controls are important components of a processor's HACCP program. Product development, product formulation, receipt of pre-printed labels, printing of in-house labels, and storage of allergenic ingredients are examples of things to consider during the development of an allergen control strategy.

Domestic and imported food product labels, packaging materials and other finished product containers must accurately reflect U.S. regulations regarding the declaration of major food allergens ingredients.

No minimum threshold has been established for allergenic ingredients, for either intentionally or unintentionally added allergens. However, there are emerging data on levels of major food allergens that may be tolerated by a large majority of individuals in the allergic population and that can be used in manufacturer's risk assessment of allergen cross-contact hazards.

- **Labeling:**

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) has identified a "Major food allergen" (allergen) as one of the following eight foods or food groups:

- Crustacean shellfish (e.g., crab, lobster, or shrimp);
- Eggs;
- Fish (e.g., finfish);
- Milk;
- Peanuts;
- Soybeans;
- Tree nuts (e.g., almonds, pecans, or walnuts); and
- Wheat.

Foods that contain a major food allergen as an ingredient, must (with a few exceptions such as highly refined soybean oil) declare the presence of that allergen in plain English terms using the common or usual name of the major food allergen either as part of the ingredient declaration or in a "contains" statement that is located immediately after or adjacent to the ingredient declaration

on labels. A "contains" statement differs from a "may contain" statement in that the "contains" statement identifies allergenic ingredients added to the commodity based on product formulation; whereby, the "may contain" statement describes the potential presence of an allergenic ingredient which is not part of the product formulation.

The definition of "fish" differs between the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and 21 CFR Part 123 Fish and Fishery Products. For more information regarding FALCPA and the Seafood regulation go their respective websites: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm and https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=123. "Fish", within the context of FALCPA and the identification of allergenic ingredients, refers to finfish such as flounder, tilapia, grouper, and other vertebrate fish with fins. This differs from the definition in 21 CFR Part 123 which includes all aquatic animal life intended for human consumption, excluding mammals and birds. Allergen label declarations must be in compliance with FALCPA as well as other labeling requirements.

FDA considers the "common or usual name" synonymous with the "market" name for the seafood industry. Therefore, the "market" name of fish species and crustacean shellfish should be used to identify the food source for these two major food allergen groups. The "market" names can be found on "The Seafood List". For more information regarding the seafood list, go to its website: https://www.accessdata.fda.gov/scripts/fdcc/?set=seafoodlist. In addition, the term "fish" may be added to the market name on the label if the market name is not otherwise recognized as a fish by the consumer for example, gar fish.

Refer to the following websites for more information regarding allergen labeling requirements:

- https://www.fda.gov/food/ingredientspackaginglabeling/foodallergens/default.htm and
- https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/default.htm.

Raw agricultural commodities (whole raw fish or crustaceans in their natural state), fish other than finfish and crustacean shellfish (i.e., molluscan shellfish), and highly refined oils are exempt from allergen labeling requirements; however, they are still subject to other FDA labeling requirements.

- **Allergen Cross-Contact:**

Processors are required to implement cGMP controls that prevent allergen cross-contact. Allergen cross-contact is defined as the unintentional incorporation of a food allergen into a food. Allergen cross-contact can occur either between foods that contain different food allergens or between foods with and without food allergens. There can be multiple opportunities for cross-contact within a processing facility such as incoming ingredients with unintentional allergens, during processing or storage of ingredients, through inadequate cleaning of equipment and/or utensils [e.g. spoons, spatulas, scoops, employee apparel (aprons and gloves)], lack of process scheduling, and through poor facility design (e.g. air flow movement and filtration). Controls are normally implemented and monitored as part of the cGMP, prerequisite program, and/or sanitation monitoring procedures to prevent cross-contact in these areas.

For facilities that manufacture or process multiple food allergens, FDA recommends the facility take measures to prevent allergen cross-contact and subsequently the hazard of undeclared food allergens with product that do not contain or contain different allergens. Allergen cross-contact controls are needed when ingredients, in-process materials, and finished products are received, handled, transported, and stored.

At this time FDA does not require cross-contact controls between specific finfish species; however, we do require cross-contact controls between crustacean species and finfish species.

Allergen cross-contact controls are intended to provide separation in time and space between the products with different allergenic ingredients. The appropriate allergen control measures are facility and product dependent. Factors to consider include the properties of the allergenic ingredients being used, the manufacturing process, facility structure and design, and the finished product. Areas where controls may be implemented include:

- Review/assessment of incoming or supplier ingredients for allergen cross-contact risk;
- Equipment and process design (look at traffic patterns, air flow, equipment design

to prevent accumulation of food residue, provide shields/catch pans/partitions for equipment);

- Dedication of processing systems (dedicated processing and packaging lines and equipment, dedicated utensils and employees' apparel, color code system for allergens, dedicate and/or restrict movement of employees);
- Product containments and equipment barriers (physically separating the system through the use of walls/closed off rooms);
- Production scheduling (separate by time of manufacture through sequencing whereby the food with the fewest allergen or no allergen is produced first and the food with the most allergens is produced last in combination with effective allergen cleaning and sanitation procedures between changeover of production);
- Management of the movement of materials and personnel (movement of ingredients, equipment, employees, utensils, tools, employees apparel, work-in-progress (WIP), rework, finished products and waste materials during operation needs to be managed to minimize allergen cross-contact); and
- Rework of finished or partially finished products that are reincorporated into the manufacturing process and WIP of partially finished products moving between different productions states/steps. Rework can increase the risk of introducing allergens, either by erroneous addition of allergen-containing rework/WIP into a product that does not contain the specific allergen(s) as ingredients, or by cross-contact of allergen-containing materials with non-allergen-containing materials during holding or storage.
- Control of oil in fryers. Using dedicated fryers would minimize the risk of allergen cross-contact.

Measures should be taken to control allergen cross-contact within the facility; however, the measures do not necessarily have to be incorporated into the HACCP plan itself. The measures can be incorporated into the firm's prerequisite programs or other programs as appropriate.

FDA has been conducting research to determine whether allergenic proteins (shrimp protein) can be transferred through fryer oils. The following conclusions were identified as a result of our first series of tests:

- Shrimp protein was observed being transferred into the fryer oil through the frying process.
- Shrimp protein was transferred to French fries when fried in the same oil used to fry the shrimp; however, limitations were observed to only the first batch of oils and fries tested.

Refer to Appendix 10 of this Guide for further assistance with identification of potential cross-contact areas and establishing controls for allergen cross-contact.

- **Allergen Sanitation Control Procedures:**

Cleaning and sanitation controls are crucial for the prevention of allergen cross-contact within a facility. Establishing written SSOPs or prerequisite programs help to define the controls and ensure cleaning sufficient to prevent cross-contact. Many manufacturing facilities have already established and implemented effective cleaning and sanitation controls for microbial cross contamination; however, procedures targeting microbial hazards may not be adequate for allergen removal. Therefore, it is important to evaluate the sanitation controls to ensure they adequately remove allergen residues from all surfaces.

FDA has identified considerations for establishing and implemented effective cleaning and sanitation controls for allergen removal. Refer to Appendix 9 of this Guide for further assistance with establishing allergen sanitation controls or to assist with verifying and validation of the current controls to ensure they are adequate to prevent allergen cross-contact.

- **Food Intolerance Substances**

Certain food and color additives can cause hypersensitivity reactions, or food intolerances, in some consumers. Symptoms may be similar to those caused by food allergens and can include a tingling sensation in the mouth, swelling of the tongue and

throat, difficulty in breathing (e.g. asthma), hives, vomiting, abdominal cramps, and diarrhea. Food intolerance substances including sulfiting agents and FD&C Yellow No. 5 (Yellow No. 5) are commonly used in fish and fishery products. People sensitive to sulfiting agents can experience symptoms that range from mild to life-threatening reactions. People sensitive to Yellow No. 5 can experience symptoms that can range from mild to moderate severity.

Common uses of Yellow No. 5 include its addition to certain species of smoked fish, such as sable, to impart color. When Yellow No. 5 is used, it must be declared on the label as an ingredient per 21 CFR 74.705. No minimum threshold has been established.

Sulfiting agents are commonly used as a preservative to prevent melanosis or "black spot" on shrimp and spiny lobster shells. In addition, they can be used to retain the red color of the octopus' skin in cooked octopus' processes, to prevent darkening of conch meat, and may be included as an ingredient in breading. FDA requires that processors declare the presence of sulfites when the concentration meets or exceeds 10 ppm. The usage and/or concentration of the sulfiting agent found in the food will determine whether it will be declared on the label as an ingredient (to be discussed later in the chapter.)

Currently, there are six sulfiting agents allowed in processed food. They should be listed on food labels as follows per 21 CFR 101.100(a)(4):

- potassium bisulfite;
- potassium metabisulfite;
- sodium bisulfite;
- sodium metabisulfite;
- sodium sulfite; and
- sulfur dioxide.

Advisory statements such as "may contain sulfites" cannot be used as a substitute for accurate labeling in the ingredient panel through the implementation of HACCP plan controls.

Table 19-1, "When to Declare Sulfiting Agents on Finished Product Label," provides several examples of raw materials treated with sulfiting agents and the rationale for deciding whether or not the finished product requires a sulfiting agent declaration.

TABLE 19-1

Declaring Sulfiting Agents on Finished Product Label

Examples of Sulfiting Agent Use.	Examples of Finished Food.	Label Finished Food when levels are < 10 ppm.	Label Finished Food when Levels are ≥ 10 ppm.
• Raw, shell-on shrimp or lobster treated with sulfiting agents to prevent black spot. • Sulfiting agents added to cooked octopus as an antioxidant to retain the red skin color of the octopus. • Sulfiting agents added to conch meat to prevent discoloration.	• Raw or cooked shell-on shrimp or lobster. • Cooked octopus. • Conch meat.	YES [1] (Labels required.)	YES [1] (Labels required.)
• Raw, shell-on shrimp or lobster treated with sulfiting agents to prevent black spot. • Raw, shell-on shrimp or lobster treated with sulfiting agents to prevent black spot.	• Raw or cooked, peeled shrimp or lobster meat. • Food containing raw or cooked, peeled shrimp or lobster meat as an ingredient (e.g., seafood casserole).	NO [2] (Labels not required)	YES [2] (Labels required)

FOOTNOTE:

1. The sulfiting agents have an ongoing technical or functional effect on/in the finished food and must be declared regardless of the level in the finished food.

2. The sulfiting agents have no technical or functional effect in the finished food and do not have to be declared unless the level in the finished food is either ≥ 10 ppm or the sulfiting agents were added to the finished food at any level. In addition, when a sulfiting agent or a combination of sulfiting agents is added to finished food such that their collective concentration in/on the finished food is ≥ 10 ppm, then each must be declared by its approved label name (listed above).

Example:

A processor receives frozen, raw, headless, shell-on shrimp that are labeled with a sulfiting agent declaration. The shrimp had been treated with sulfiting agents to prevent the formation of black spot during on-board handling. The processor thaws, peels, and deveins the shrimp, and then adds it to a gumbo in which the processor has determined that the final sulfiting agent concentration is less than 10 ppm. Because the sulfiting agent no longer has a functional effect in the finished food, and because the concentration of the sulfiting agent is less than 10 ppm in the finished product, the processor is not required to have a sulfiting agent declaration on the label of the shrimp gumbo.

Example:

A processor receives frozen, raw, headless, shell-on shrimp that are labeled with a sulfiting agent declaration. The processor uses the shrimp to prepare a shell-on, deveined, easy-peel shrimp, which is packaged and refrozen. Because the sulfiting agent continues to have an ongoing technical effect in the finished product, the processor is required to have a sulfiting agent declaration on the finished product label, regardless of the concentration of sulfiting agent in the finished product.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT

The following guidance will assist in determining whether undeclared food allergens and food intolerance substances (e.g., sulfiting agents or Yellow No. 5) are a significant hazard at a processing step:

1. **Is it reasonably likely that a major food allergen, and/or food intolerance substance, 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, consider whether food allergens and food intolerance substances are a significant hazard at the:

   - Receiving step:
     - When the raw ingredients contain or are reasonably likely to contain major food allergens and/or food intolerance substances, for example, a historic occurrence of food intolerance substances in that ingredient or containing an allergenic sub-ingredient.
   - Product formulation step:
     - When a raw material is, or contains one or more of the major food allergens (including non-fishery allergens), or a food intolerance substance is used as an ingredient in the formulation of any of the products; AND/OR
     - When sulfiting agent(s) are used or declared in products containing shrimp, lobster or conch meat. A study that tests the range of concentration of sulfiting agents in the raw material and possible variation in formulation should be conducted to establish whether sulfiting agents will not be present at 10 ppm or greater in the finished product;

2. **Can the hazard of undeclared major food allergens, and food intolerance substances that were introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?**

   Allergens and food intolerance substances may be introduced during processing (e.g., through product formulation). The hazard occurs when the end products are not accurately labeled to declare their presence. The controls are either to ensure an allergen or food intolerance substance is not present or to ensure that its presence is accurately declared on the finished product label. Measures to prevent undeclared major food allergens and food intolerance substances include:

   - Review of raw material labels (e.g., ingredient panel and/or "contains" statement) or accompanying documents in the case of unlabeled products for allergen and/or food intolerance substance declaration;
   - Review of finished product labels to ensure that the presence of allergens and/or food intolerance substances are declared. For example, compare product specifications, raw material labels, and end-product labels for allergen or food intolerance substance declarations;
   - Review of a supplier's certification or accompanying documentation (i.e., certificate of analysis) for lack of sulfiting agent use;
   - Test incoming shrimp, lobster or conch meat for residues of sulfiting agents;
   - Review of the label at the point of application to the finished product to ensure that the appropriate label is placed on the product.

- **Intended use**

In the case of undeclared major food allergens and food intolerance substances the hazard will have no impact on the intended use of the product.

IDENTIFY CRITICAL CONTROL POINTS

Receiving and finished product labeling steps are likely CCPs. A receiving critical control point can be used to monitor the content of pre-printed labels and to identify raw materials containing allergenic or food intolerance ingredients. Monitoring the list of ingredients and "contains" statement declarations also applies to labels generated in-house. The finished product labeling step may be used to monitor the accuracy of the finished product labels

affixed to the packaging. Some operations may only require a single CCP while others may require both critical control points.

The following guidance will assist you in determining whether the receiving or product labeling step is a critical control point (CCP) for undeclared major food allergens and food intolerance substances:

1. In the case of products that are known to contain allergenic or food intolerance ingredients, how will you ensure the finished product labels accurately declare the presence of the hazard?

a. If the finished product is known to contain an allergenic ingredient or a food intolerance substance you should identify the product labeling step as a CCP.

Example:

A smoked sablefish processor treats the fish with Yellow No. 5 before smoking. The sablefish is an allergen and Yellow No. 5 is a food intolerance substance. The finished product labeling step should be identified as the CCP to ensure:

i. The labels declare sablefish and Yellow #5 in the ingredient panel; AND

ii. The correct label is applied to the finished product.

The control approach is referred to in this chapter as: Control Strategy Example 1 – Finished Product Label Examinations.

b. If you receive pre-printed labels and process products that contain identical allergenic or food intolerance substance ingredients, you may identify receipt of preprinted labels step as the CCP.

Example:

A breaded fish processor makes breaded fish fillets and breaded fish fingers using breading and batter that contains the allergens of wheat, eggs, soy, and pollock. The processor may identify receiving of the preprinted packaging materials as their CCP and monitor the packaging ingredients statements for declaration to control the hazards of undeclared allergens (pollock, wheat, eggs, soy).

The control approach is referred to in this chapter as: Control Strategy Example 2 – Receiving Controls for Pre-printed Labels

2. In the case of shrimp, lobster, or conch meat for which sulfiting agents have been identified as a significant hazard, how will you prevent the presence of sulfiting agents?

The receiving step of raw material for the shrimp, lobster, or conch meat should be identified as a CCP when the finished product label does not declare the presence of sulfiting agents. The incoming lots of raw materials should be assessed for the presence of sulfiting agents. Preventive measures that can be applied here include:

a. Testing incoming shrimp, lobster, or conch meat for residues of sulfiting agents at or above 10 ppm.

Example:

A frozen shrimp processor receives shrimp directly from the harvest vessel and does not label the finished product with a sulfiting agent declaration. The processor should set the CCP for sulfiting agents 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 CCP for this hazard at finished product labeling.

This control approach is a control strategy referred to in this chapter as: Control Strategy Example 3 - Raw Material Testing.

b. Receiving a supplier's certification identifying whether or not sulfiting agents were used on incoming lots of shrimp, lobster, or conch meat (with appropriate verification).

Example:

A frozen shrimp processor receives shrimp directly from the harvest vessel and does not label the finished product with a sulfiting agent declaration. The processor should set the CCP for sulfiting agents

at the raw material receiving step and obtain certificates from the harvest vessels that sulfiting agents were not used on the shrimp. The processor would not need to have a CCP for this hazard at finished product labeling since sulfiting agents are not utilized.

This approach is the control strategy referred to as: Control Strategy Example 4 - Review of Supplier Declarations or Labeling.

DEVELOP A CONTROL STRATEGY

The following guidance provides four (4) control strategies to prevent undeclared major food allergens, certain food intolerance causing substances, and prohibited food and color additives. You may select a control strategy that is different from those that are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following are examples of control strategies included in this chapter:

Control Strategy	May apply to primary processor	May apply to secondary processor
Finished product label examinations	✓	✓
Receiving controls for pre-printed labels	✓	✓
Raw material testing	✓	
Review of supplier declarations or labeling	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 – FINISHED PRODUCT LABEL EXAMINATIONS**

NOTE: Assuring the accuracy of finished product labels may be accomplished through: a single CCP whereby monitoring both the ingredient declaration and application of the label to the appropriate product are conducted in one CCP, usually at the labeling step; **OR** two separate CCPs whereby the label ingredient declarations are monitored at another processing step such as receiving (e.g., Control Strategy Example 2) and the label application to the finished product is monitored at the labeling step. This is an example of implementing a single CCP at the finished product labeling step.

All label declarations must meet FALPCA requirements.

Set Critical Limits.

- All allergen and food intolerance substance ingredients are declared on the labels.

Establish Monitoring Procedures.

➢ What Will Be Monitored?

- The ingredients listing on finished product labels.

➢ How Will Monitoring Be Done?

- Visual comparison of the label against the product specification for accuracy;

  OR

- Visual comparison of the label against a list of allergenic ingredients and/or food intolerance substances incorporated in the finished product.

➢ How Often Will Monitoring Be Done (Frequency)?

- At the start of the production lot;

  AND

- At least every 2 hours.

  OR

- When new containers of labels are opened or rolls of labels are changed.

➢ Who Will Do the Monitoring?

- Any person with an understanding of the nature of the controls such as trained production employees or quality control personnel.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Hold and isolate labeled product since the last acceptable inspection of labels;

AND

- Inspect 100% of affected product and relabel mislabeled products;

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Inspect remaining labels staged for use and remove inaccurate labels from processing area;

AND

- Review a representative sample of labels in storage, and hold and isolate inaccurate labels, if appropriate;

AND

- Discontinue use of label supplier;

OR

- Work with label supplier to ensure corrections are made to prevent recurrence;

AND

- Modify label procedures, as appropriate.

Establish a Recordkeeping System.

- Record of labeling checks of finished product packages.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed;

AND

- Verify the product specification against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur;

OR

- Verify the list of allergenic or food intolerance substance ingredients against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur, if appropriate.

TABLE 19-2

Control Strategy Example 1 – FINISHED PRODUCT LABEL EXAMINATIONS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1." This example illustrates how a smoked fish processor can control undeclared major food allergens and food intolerance substances in the production of hot smoked sablefish. It is provided for illustrative purposes only.

Major food allergens and food intolerance causing substances may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards.

Example Only - See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limit**	**What**	**How**	**Frequency**	**Who**	**Corrective Actions(s)**	**Records**	**Verification**
Finished product labeling	Undeclared major food allergens and food intolerance substances	Finished product labels must declare the presence of sablefish and Yellow No. 5	The ingredients listing on finished product labels	Visual confirmation listing sablefish and Yellow No. 5 on the label	One label at the beginning of the production of each lot and one label every hour thereafter	Quality control staff	Hold and isolate product labeled since last inspection; Inspect affected product labeling and relabel mislabeled products; Inspect remaining labels staged for use and remove inaccurate labels from processing area; Review a representative sample of labels in storage, and hold and isolate inaccurate labels; Work with label supplier to ensure corrections are made to prevent recurrence; and Modify label procedures	Record of review of finished product labels	Review monitoring and corrective action records within 1 week of preparation; Verify product specification against raw materials ingredient's label declaration at least annually and when changes to supplier or formulation occurs

- **CONTROL STRATEGY EXAMPLE 2 – RECEIVING CONTROLS FOR PRE-PRINTED LABELS**

NOTE: Assuring the accuracy of finished product labels may be accomplished through: a single CCP whereby monitoring both the ingredient declaration and application to the appropriate product are conducted in one CCP usually at the labeling step; **OR** two separate CCPs whereby the label ingredients declarations are monitored at another processing step such as receiving and the label application to the finished product (e.g., Control Strategy Example 1) is monitored at the labeling step. This is an example of implementing a single CCP at the receiving step.

All label declarations must meet FALPCA requirements.

Set Critical Limits.

- Pre-printed labels list all food allergen and food intolerance substance ingredients.

Establish Monitoring Procedures.

➢ **What Will Be Monitored?**

- The ingredients listing on pre-printed labeled packaging material.

➢ **How Will Monitoring Be Done?**

- Comparison of pre-printed labels against product specification;

OR

- Comparison of pre-printed labels against list of allergenic ingredients.

➢ **How Often Will Monitoring Be Done (Frequency)?**

- A representative number of containers from each lot received.

➢ **Who Will Do the Monitoring?**

- Any person with an understanding of the nature of the controls such as trained production employees or quality control personnel.

Establish Corrective Action Procedures.

Take the following corrective action to pre-printed labels involved in a critical limit deviation:

- Refuse labels.

AND

Take the following corrective action to regain control of the operation after a critical limit deviation:

- Discontinue use of supplier;

OR

- Work with supplier to ensure corrections are made to prevent recurrence.

Establish a Recordkeeping System.

- Record of reviewing of pre-printed product labels.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

AND

- Verify the product specification against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur, if appropriate;

OR

- Verify the list of allergenic or food intolerance substance ingredients against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur, if appropriate.

TABLE 19-3

Control Strategy Example 2 – RECEIVING CONTROLS FOR PRE-PRINTED LABELS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2." This example illustrates how a breaded fish processor can control undeclared major food allergens in the production of raw breaded fish fillets and fingers. It is provided for illustrative purposes only.

Major food allergens and food intolerance causing substances may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only - See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5) Monitoring		(6)	(7)	(8)	(9)	(10)
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**		**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving of pre-printed finished product labels	Undeclared major food allergens	Allergens (pollock, eggs, wheat, soy) accurately declared on labels	The ingredients are listed on pre-printed labels	Visual comparison of label against product specification		A representative number of pre-printed finished product label rolls from each lot received	Quality control staff	Refuse labels; and Work with supplier to ensure corrections are made to prevent recurrence	Record of review of product labels	Review monitoring and corrective action records within 1 week of preparation; Verify the product specification against raw materials ingredients' label declarations at least annually and when changes to suppliers or formulation occur.

- **CONTROL STRATEGY EXAMPLE 3 – RAW MATERIAL TESTING**

Set Critical Limits.

- Less than 10 ppm sulfiting agents detected

NOTE: < 10 ppm sulfiting agents may be present in finished product shell-off shrimp and lobster without a sulfiting agent declaration on the label if the sulfiting agents have no functional (ongoing technical) effect in the finished food. However, if the sulfiting agents have a functional (ongoing technical) effect in finished shell-on or shell-off shrimp or lobster product regardless of level, then they must be declared as ingredients on the product label).

Establish Monitoring Procedures.

➢ **What Will Be Monitored?**

- The presence of sulfiting agents as an ingredient or sub-ingredient.

➢ **How Will Monitoring Be Done?**

- Screening test for sulfiting agents.

➢ **How Often Will Monitoring Be Done (Frequency)?**

- Representative sample from each incoming lot.

➢ **Who Will Do the Monitoring?**

- Any person who is qualified by training or experience to perform the screening test procedure.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Reject the lot.

AND

Take the following corrective action to regain control of the operation after a critical limit deviation:

- Discontinue use of the supplier until evidence is obtained that control of sulfiting agent content has improved.

Establish a Recordkeeping System.

- Test results for sulfiting agents.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 19-4

Control Strategy Example 3 – RAW MATERIAL TESTING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3." This example illustrates how a processor of shell-on shrimp can control sulfiting agents that are used on the harvest vessel. It is provided for illustrative purposes only.

Major food allergens and certain food intolerance causing substances may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-3 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only: See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification
Shrimp receiving	Undeclared sulfiting agents	Less than 10 ppm sulfites in shrimp	Each lot of raw material shrimp for sulfiting agent residual	Malachite green test	Representative sample from multiple locations in each lot received	Quality control staff	Reject any incoming lot of shrimp that contains ≥ 10ppm of sulfiting agent; and Discontinue use of the supplier until evidence is obtained that control of sulfiting agents has improved	Test results for sulfiting agents	Review monitoring and corrective action records within 1 week of preparation; and Annually conduct proficiency testing of QC personnel conducting malachite green testing

- **CONTROL STRATEGY EXAMPLE 4 – REVIEW OF SUPPLIER DECLARATIONS OR LABELING**

Set Critical Limits.

- Supplier's certificate or declaration stating that sulfites have not been used;

  OR

- Product labels do not declare the presence of sulfiting agents.

Establish Monitoring Procedures.

➢ **What Will Be Monitored?**

- Supplier's certificate or declaration;

  OR

- Raw material labels.

➢ **How Will Monitoring Be Done?**

- Review of supplier's certificate or declaration;

  OR

- Visual examination of raw material labels for sulfite declaration.

➢ **How Often Will Monitoring Be Done (Frequency)?**

- Each incoming lot.

  OR

- A representative sample of containers/ packages from each incoming lot.

➢ **Who Will Do the Monitoring?**

- Any person who understands the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Reject the lot;

  OR

- Hold the lot until a certificate or declaration can be provided by supplier;

  OR

- Label finished product with appropriate sulfite declaration.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Discontinue use of the supplier until evidence is obtained that certificates will accompany future shipments.

Establish a Recordkeeping System.

- Suppliers' declarations;

AND

- Record of label review or review of supplier declaration.

Establish Verification Procedures.

- Collect at least one representative sample per quarter, randomly selected from each supplier, and analyze for sulfiting agents. Additionally, collect at least one representative sample from each new supplier, and analyze for sulfiting agents;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 19-5

Control Strategy Example 4 - Review of Supplier Declarations or Labeling

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4." This example illustrates how a processor of shell-on shrimp can control sulfiting agents that are used on the harvest vessel. It is provided for illustrative purposes only.

Major food allergens and certain food intolerance causing substances may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants, pesticides, and metal fragments).

Example Only: See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification
Shrimp receiving	Undeclared sulfiting agents	Declaration or certificate stating sulfites were not used on the product	Suppliers' certificate or declaration	Review of certificate or declaration	Every lot received	Receiving employee	Hold lot until certificate or declaration is received; Discontinue use of the supplier until evidence is obtained that certificates will accompany future shipments	Certificates or declarations; Receiving records documenting review of certificates or declarations	Collect at least one representative sample per quarter and test for sulfiting agents; in addition, test at least one lot from each new supplier and analyze for sulfiting agents; Review monitoring, corrective action, and verification records within 1 week of preparation

- **BIBLIOGRAPHY**

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of July 2018, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after July 2018.

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NOTES:

CHAPTER 20: **Metal Inclusion**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

UNDERSTAND THE POTENTIAL HAZARD.

Ingesting metal fragments can cause injury to the consumer. These injuries may include dental damage, laceration of the mouth or throat, or laceration or perforation of the intestine. FDA's Health Hazard Evaluation Board has supported regulatory action against products with metal fragments 0.3 inch (7 mm) to 1 inch (25 mm) in length. The Federal Food, Drug, and Cosmetic Act (the FFD&C Act) prohibits interstate commerce of adulterated foods (21 U.S.C. 331). Under the FFD&C Act, a food containing foreign objects is considered adulterated (21 U.S.C 342). See FDA's "Compliance Policy Guide," Sec. 555.425. In addition, foreign objects that are less than 0.3 inch (7 mm) may cause trauma or serious injury to persons in special risk groups, such as infants, surgery patients, and the elderly.

Metal-to-metal contact (e.g., mechanical cutting or blending operations and can openers) and equipment with metal parts that can break loose (e.g., moving wire mesh belts, injection needles, screens and portion control equipment, and metal ties) are likely sources of metal that may enter food during processing.

- **Control of metal inclusion**

Once introduced into a product, metal fragments may be removed from the product by passing it through a screen, magnet, or flotation tank. The effectiveness of these measures depends on the nature of the product. These measures are more likely to be effective in liquids, powders, and similar products in which the metal fragment will not become imbedded.

Alternatively, metal fragments may be detected in the finished food by an electronic metal detector. The use of electronic metal detectors is complex, especially with regard to stainless steel, which is difficult to detect. The orientation of the metal object in the food affects the ability of the equipment to detect it. For example, if a detector is not properly calibrated and is set to detect a sphere 0.08 inch (2 mm) in diameter, it may fail to detect a stainless steel wire that is smaller in diameter but up to 0.9 inch (24 mm) long, depending on the orientation of the wire as it travels through the detector. Processing factors, such as ambient humidity or product acidity, may affect the conductivity of the product and create an interference signal that may mask metal inclusion unless the detector is properly calibrated. You should consider these factors when calibrating and using this equipment.

Finally, the hazard of metal inclusion may also be controlled by periodically examining the processing equipment for damage that can contribute metal fragments to the product. This measure will not necessarily prevent metal fragments from being incorporated into the product, but it will enable you to separate products that may have been exposed to metal fragments. Visually inspecting equipment for damaged or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire mesh belts. More complex equipment that contains many parts, some of which may not be readily visible, may not be suitable for visual inspection and may require controls such as metal detection or separation.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether metal inclusion is a significant hazard at a processing step:

1. Is it reasonably likely that metal fragments will be introduced at this processing step (e.g., do they come in with the raw material or will the process introduce them)?

   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 products;
   - Saw blades used to cut portions or steaks;
   - Wire from mechanical mixer blades;
   - Blades on mechanical chopping, filleting, or blending equipment;
   - Rings, washers, nuts, or bolts from breading, batter, sauce cooling, liquid dispensing, and portioning equipment;
   - Injection needles;
   - Metal ties used to attach tags or close bags;
   - Can slivers from opening cans.

   Under ordinary circumstances, it would not be reasonably likely to expect that metal fragments could enter the food from the following sources:

   - Utensils used for manual blending, cutting, shucking, or gutting;
   - Metal processing tables or storage tanks.

2. Can the hazard of metal inclusion that was introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?

   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 hazard (or is adequate to reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. Preventive measures for metal inclusion can include:

   - Periodically checking equipment for damaged or missing parts;
   - Passing the product through metal detection or separation equipment.

- **Control of metal inclusion**

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. 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 would not need to identify metal 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.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will also assist you in determining whether a processing step is a critical control point (CCP) for metal inclusion:

1. Will the product be run through a metal detector or a separation device, such as a screen, magnet, or flotation tank, on or after the last step where metal inclusion is identified as a significant hazard?

    a. If it will be, you should identify final metal detection or separation as the CCP. Then processing steps prior to metal detection or separation would not require controls and would not need to be identified as CCPs for the hazard of metal fragments.

    Example:

    A breaded fish processor uses saws, breading and batter machines, and wire conveyor belts. The processor should choose to use a metal detector on the finished product containers and should set the CCP for metal inclusion at the metal detection step for packaged products. The processor would not need to have CCPs for this hazard at each of the previous processing steps at which there was a reasonable likelihood that metal fragments could be introduced.

    This control approach is a control strategy referred to in this chapter as "Control Strategy *Example 1 - Metal Detection or Separation.*"

    You should recognize that by setting the CCP 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.

    b. 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.

    Example:

    A processor that cuts tuna steaks from frozen loins has identified the band saw cutting step as the only step that is reasonably likely to introduce metal fragments into the product. The processor should identify the band saw cutting step as the CCP for this hazard and should check the condition of the band saw blade every 4 hours to ensure that it has not been damaged.

    This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Equipment Checks." Visually inspecting equipment for damaged or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire mesh belts. More complex equipment that contains many parts, some of which may not be readily visible, may not be suitable for visual inspection and may require controls such as metal detection or separation.

DEVELOP A CONTROL STRATEGY.

The following guidance provides two examples of control strategies for metal inclusion. It is important to note that you may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following are examples of control strategies included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Metal detection or separation	✓	✓
Equipment checks	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION**

Set Critical Limits.

- All of the product passes through an operating metal detection or separation device;

  AND

- No detectable metal fragments are in the product that passes through the metal detection or separation device.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The presence of an operating metal detection or separation device;

  AND

- The product for the presence of metal fragments.

» **How Will Monitoring Be Done?**

- Visual examination for the presence of an operating electronic metal detector, magnet, intact screen, or flotation tank;

  AND

- Product monitoring is performed by the metal detection or separation device itself.

» **How Often Will Monitoring Be Done (Frequency)?**

- Check that the metal detection or separation device is in place and operating at the start of each production day;

  AND

- Continuous monitoring by the metal detection or separation device itself.

» **Who Will Do the Monitoring?**

- Monitoring is performed by the metal detection or separation device itself. Visual checks to ensure that the device is in place and operating may be performed by any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- When processing occurred without an operating metal detector or intact or operating separation device:
  - Hold all of the product produced since controls were last confirmed as functioning properly until it can be run through a metal detection or separation device;

    OR

  - Hold all of the 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 (may be suitable only for relatively simple equipment);

    OR

  - Divert all of the product produced since controls were last confirmed as functioning properly to a use in which it will be run through a properly calibrated metal detector (e.g., divert fish fillets to a breading operation that is equipped with a metal detector);

    OR

  - Destroy all of the product produced since controls were last confirmed as functioning properly;

OR

- Divert all of the product produced since controls were last confirmed as functioning properly to a non-food use.

AND

- When product is rejected by a metal detector:
  - Hold and evaluate the rejected product;

    OR
  - Rework the rejected product to eliminate metal fragments;

    OR
  - Destroy the rejected product;

    OR
  - Divert the rejected product to a non-food use.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Correct operating procedures to ensure that the product is not processed without an operating metal separation or detection device;

  OR
- Attempt to locate and correct the source of the fragments found in the product by the metal detector or separated from the product stream by the magnets, screens, or other devices;

  OR
- Repair or replace the metal separation device.

Establish a Recordkeeping System.

- Record documenting that the metal detection or separation device is in place and operating.

Establish Verification Procedures.

For metal detectors:

- Develop sensitivity standards that are based on whether the potential hazard is ferrous, non-ferrous, or stainless steel, or obtain such standards from the equipment manufacturer. The standards should be designed to ensure that metal fragments will be detected in the product. Conduct a validation study to identify the range of values for each of the processing factors over which the equipment will detect the standards that affect its operation in your product (e.g., ambient humidity and product acidity), or obtain such a study from the equipment manufacturer. The study should identify the appropriate equipment settings over the range of each of the processing factors. The study also should consider the range of orientations in which the metal fragments may be present;

  AND
- Challenge the metal detector using validated sensitivity standards daily, at the start of production, every 4 hours during operation, when processing factors (e.g., ambient humidity and product acidity) change, and at the end of processing;

AND

For all metal detection and separation devices:

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 20-1

CONTROL STRATEGY EXAMPLE 1 - METAL DETECTION OR SEPARATION

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Metal Detection or Separation." This example illustrates how a frozen fish sticks processor can control metal fragment inclusion. It is provided for illustrative purposes only.

Metal inclusion may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and Staphylococcus aureus toxin formation in the hydrated batter mix).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Metal detection	Metal inclusion	All of the product passes through an operating metal detector	Metal detector present and operating	Visual examination	Daily, at start of operations	Production employee	If the product is processed without metal detection, hold it for metal detection Correct operating procedures to ensure that the product is not processed without metal detection Rework to remove metal fragments from any product rejected by the metal detector Identify the source of the metal found in the product and fix the damaged equipment	Metal detector operation log	Conduct a validation study to determine appropriate settings for the metal detector Develop metal detector sensitivity standards Challenge the metal detector with sensitivity standards daily, before start-up, every 4 hours during production, whenever processing factors change, and at the end of processing Review monitoring, corrective action and verification records within 1 week of preparation
		No detectable metal fragments are in the product passing the through the metal detector	The product for the presence of metal fragments	Electronic metal detector	Continuous	Equipment itself			

- **CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS**

Set Critical Limits.

- No broken or missing metal parts from equipment.

Establish Monitoring Procedures.

» **What Will be Monitored?**

- The presence of broken or missing metal parts from equipment.

» **How Will Monitoring Be Done?**

- Visually check the equipment for broken or missing parts.

  Examples:
  - Check saw blades for missing teeth or sections;
  - Check that all parts are present and secure on blending equipment;
  - Check for missing links or broken wires on metal belts.

» **How Often Will Monitoring Be Done?**

- Check before starting operations each day;

  AND

- Check every 4 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 Do the Monitoring?**

- Any person who has a thorough understanding of the proper condition of the equipment.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Hold all of the product produced since the previous satisfactory equipment check until it can be run through a metal detector;

  OR

- Divert all of the product produced since the previous satisfactory equipment check to a use in which it will be run through a properly calibrated metal detector (e.g., divert fish fillets to a breading operation that is equipped with a metal detector);

  OR

- Destroy all of the product produced since the previous satisfactory equipment check;

  OR

- Divert all of the product produced since the previous satisfactory equipment check to a non-food use.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Stop production;

  AND

- If necessary, adjust or modify the equipment to reduce the risk of recurrence.

Establish a Recordkeeping System.

- Records of equipment inspections.

Establish Verification Procedures.

Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 20-2

CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Equipment Checks." This example illustrates how a frozen tuna steak processor can control metal fragment inclusion. It is provided for illustrative purposes only.

Metal inclusion may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., scombrotoxin (histamine) and parasites).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Fish cutting	Metal inclusion	No damage or missing parts to the saw blade	Check the saw blade	Visual check	Before start-up, every 4 hours during operation, at the end of day, and after an equipment jam	Saw operator	Stop production Adjust equipment Hold all of the product since the last visual check until it can be run through a metal detector Destroy rejected product	Equipment maintenance log	Review monitoring and corrective action records within 1 week of preparation

BIBLIOGRAPHY.

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

- Olsen, A. R. 1998. Regulatory action criteria for filth and other extraneous materials. I. Review of hard or sharp foreign objects as physical hazards in food. Regul. Toxicol. Pharmacol. 28:181-189.
- U.S. Food and Drug Administration. 1999. Foods - Adulteration involving hard or sharp foreign objects. *In* Compliance Policy Guides, Sec. 555.425. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD.

NOTES:

CHAPTER 21: **Glass Inclusion**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

UNDERSTAND THE POTENTIAL HAZARD.

Ingesting glass fragments can cause injury to the consumer. These injuries may include damage to teeth, laceration of the mouth and throat, or perforation of the intestine. FDA's Health Hazard Evaluation Board has supported regulatory action against products with glass 0.3 inch (7 mm) to 1 inch (25 mm) in length. The Federal Food, Drug, and Cosmetic Act (the FFD&C Act) prohibits interstate commerce of adulterated foods (21 U.S.C. 331). Under the FFD&C Act, a food containing foreign objects is considered adulterated (21 U.S.C 342). See FDA's "Compliance Policy Guide," Sec. 555.425. Foreign objects that are less than 0.3 inch (7 mm) may cause trauma or serious injury to persons in special risk groups, such as infants, surgery patients, and the elderly.

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 eaten with minimal handling on the part of the consumer providing little opportunity to detect glass inclusion.

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 sources such as overhead light fixtures must be addressed where applicable in a prerequisite sanitation program. The Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products regulation, 21 CFR 123 (called the Seafood HACCP Regulation in this guidance document), requires such a program.

- **Control of glass inclusion**

Once introduced into a product container, the hazard of glass fragments may be controlled by (1) removing the fragments by cleaning the containers before filling or (2) detecting the fragments by visual inspection before or after filling. Glass containers may be cleaned using water or compressed air and inverted during or after cleaning to help with glass removal. This measure may be suited only to processes that do not use automated filling systems which include filled container conveyors or capping equipment, because this equipment can result in glass breakage after glass container cleaning.

The effectiveness of visual inspection depends on the nature of the product and the process. For most fishery products, this measure also may be suited only to processes that do not use automated filled container conveyors or capping equipment, because visual inspection after the glass containers are filled is not practical. However, for clear liquids (e.g., some fish sauces), candling may be used to visually inspect all filled containers. Candling is a visual inspection process in which the container is illuminated from behind.

Alternatively, the hazard of glass inclusion may be controlled by periodically checking the processing areas and equipment for glass breakage. This measure will not necessarily prevent glass fragments from being incorporated into the product, but it will enable you to separate products that may have been exposed to glass fragments.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether glass inclusion is a significant hazard at a processing step:

1. Is it reasonably likely that glass fragments will be introduced at this processing step (e.g., do they come in with the raw material or will the process introduce them)?

   For example, under ordinary circumstances, it would be reasonably likely to expect that glass fragments could enter the process during the processing of any product that is packed in a glass container. These are likely areas of concern for glass containers:

   - Glass container receiving;
   - Glass container storage, when cases are moved mechanically;
   - Mechanized glass container cleaning;
   - Glass container conveyor lines;
   - Glass container filling;
   - Mechanized capping of glass containers;
   - Pasteurizing product in glass containers.

2. Can glass fragments that were introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?

   Glass inclusion should be considered a significant hazard at any processing step where a preventive measure is or can be used to prevent or eliminate the hazard (or is adequate to reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. Preventive measures for glass inclusion can include:

   - Visually examining the empty glass containers;
   - Cleaning (water or compressed air) and inverting the empty glass containers;
   - Periodically monitoring processing lines for evidence of glass breakage;
   - Visually examining glass containers containing transparent liquid fishery products.

- **Intended use**

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.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will also assist you in determining whether a processing step is a critical control point (CCP) for glass inclusion:

1. Will the containers be visually inspected 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?

   a. If they will be, you should identify the final visual inspection or cleaning as the CCP. For example, you should visually inspect the containers for broken glass or clean and invert the containers after the processing steps where breakage is reasonably likely to occur.

      For most fishery products, this method may be suited only to processes that do not use automated filling systems which include filled container conveyors or capping equipment. However, if your product is a clear liquid, you should visually inspect all filled containers by candling. In this case, the candling step would be designated as the CCP.

      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 should visually inspect each jar prior to the filling process. The processor should also collect a representative sample of inspected glass jars at the start of processing, every 4 hours during processing, at the end of processing and after any jams. The processor should identify the container inspection step as the CCP for this hazard.

Example:

Another processor that manually packs caviar has identified the glass container receiving and storage steps as the only steps that are reasonably likely to introduce glass fragments into the process. Just before filling, the empty glass jars are inverted and cleaned using filtered, compressed air. The processor should also collect a representative sample of cleaned glass jars at the start of processing, every 4 hours during processing, at the end of processing and after any jams. The processor should identify the container cleaning and inverting step as the CCP for this hazard.

Example:

A processor that bottles a transparent fish sauce has identified glass container receiving and storage, mechanical conveyor lines, mechanical filling, and mechanical capping as processing steps that are reasonably likely to introduce glass fragments into the process. The processor should visually inspect each filled and capped bottle for visible glass fragments by candling. The processor should also collect a representative sample of inspected glass jars at the start of processing, every 4 hours during processing, at the end of processing and after any jams. The processor should identify the finished product candling step as the CCP for this hazard.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Cleaning or Visual Inspection of Containers."

You should recognize that by setting the CCP 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.

b. If the containers will not be visually inspected or cleaned and inverted on or after the last step, you should 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, those processing steps should be CCPs. It would not ordinarily be necessary to identify these steps as CCPs in addition to identifying a final inspection or cleaning step as a CCP.

Example:

A processor bottles clam juice and has identified glass container receiving and storage, mechanical conveyor lines, mechanical filling, and mechanical capping as processing steps reasonably likely to introduce glass fragments into the process. The processor should visually inspect all processing areas for broken glass at start-up and once every 4 hours during processing. If broken glass is observed, the line should be stopped, the glass removed and the product that has moved through that area since the last inspection

placed on hold to be filtered or destroyed. The processor should identify glass container receiving and storage, mechanical conveyor lines, mechanical filling, and mechanical capping as the CCPs for this hazard.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Equipment Checks."

DEVELOP A CONTROL STRATEGY.

The following guidance provides examples of two control strategies for glass inclusion. You may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations. The following are examples of control strategies included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Cleaning or visual inspection of containers	✓	✓
Equipment checks	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - CLEANING OR VISUAL INSPECTION OF CONTAINERS**

Set Critical Limits.

- All containers pass through an operating glass container inspection or cleaning process;

  AND

- No detectable glass fragments are in glass containers that pass through the glass container inspection or cleaning process.

Establish Monitor Procedures.

» **What Will Be Monitored?**

- The presence of an operating glass container cleaning or inspection process;

  AND

- Cleaned or inspected containers for the presence of glass fragments.

» **How Will Monitoring Be Done?**

- Visual examination for the presence of equipment and employees for cleaning or inspecting glass containers;

  AND

- Visual examination of a representative sample of glass containers after cleaning or inspecting.

» **How Often Will Monitoring Be Done?**

- Check that the glass container cleaning or inspection process is in place and operating at the start of each production day and after each shift change;

  AND

- Examine a representative sample of glass containers after cleaning or inspection daily, at the start of processing, every 4 hours during processing, at the end of processing, and after any breakdowns.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Hold and evaluate all of the product processed since controls were last confirmed as functioning properly;

  OR

- Destroy all of the product produced since controls were last confirmed as functioning properly;

OR

- Divert all of the product produced since controls were last confirmed as functioning properly to a non-food use;

OR

- Rework all of the product produced since controls were last confirmed as functioning properly to eliminate glass fragments by visually examining for the presence of glass or by running the product through a filter or screen.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Correct operating procedures to ensure that the product is not processed without an operating glass container visual inspection or cleaning process;

AND/OR

- Stop operations and locate and correct the source of the glass fragments.

Establish a Recordkeeping System.

- Record documenting that the glass container cleaning or inspection process is in place and operating;

AND

- Record documenting the visual examination of glass containers after cleaning or inspection.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 21-1

CONTROL STRATEGY EXAMPLE 1 - CLEANING OR VISUAL INSPECTION OF CONTAINERS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Cleaning or Visual Inspection of Containers." This example illustrates how a processor of pickled herring in glass jars can control glass inclusion. It is provided for illustrative purposes only.

Glass inclusion may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., parasites, scombrotoxin (histamine), environmental chemical contaminants and pesticides, unapproved food and color additives, metal fragments, *Clostridium botulinum* toxin formation, and pathogen growth as a result of temperature abuse).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Jar cleaning and inversion	Glass inclusion	All containers pass through an operating glass cleaning process No glass fragments are in glass containers passing through the glass container cleaning process	The presence of the glass cleaning process The presence of glass fragments in cleaned containers	Visual check Visual examination of a representative sample of glass containers after cleaning	At the start of the production and shift changes One dozen jars after cleaning daily, at the start of processing, every 4 hours during processing, at the end of processing, and after any breakdowns	Quality control staff	Hold all of the product for an evaluation Correct operating procedures to ensure that the product is not processed without jar cleaning Stop operations and locate and correct the source of the glass fragments	Glass inspection record	Review monitoring and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS**

Set Critical Limits.

- No broken glass on or near equipment.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The presence of broken glass on or near equipment.

» **How Will Monitoring Be Done?**

- Visually check the glass handling areas for broken glass.

  Examples:

  - *Check pallets and packing cases for damage, broken jars, and glass fragments;*
  - *Check mechanical glass cleaning area for broken glass;*
  - *Check floors around conveyors for broken glass;*
  - *Check filling and capping equipment and surrounding floors for broken glass;*
  - *Check glass containers for breakage after exposure to heat (e.g., after heated product is added or after pasteurization).*

» **How Often Will Monitoring Be Done (Frequency)?**

- Check before starting operations each day;

  AND

- Check at least every 4 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 glass containers could be damaged.

» **Who Will Do the Monitoring?**

- Any person who has a thorough understanding of the proper condition of the equipment and surrounding area.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Hold and evaluate all of the product produced since the previous satisfactory equipment check;

  OR

- Destroy all of the product produced since the previous satisfactory equipment check;

  OR

- Divert all of the product produced since the previous satisfactory equipment check to a non-food use;

  OR

- Rework the product packaged since the previous satisfactory equipment check by visually examining for the presence of glass or by running the product through a filter or screen.

AND

Take one of the following corrective actions to regain control over the operation after a critical limit 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.

Establish a Recordkeeping System.

- Records of equipment and processing area inspections.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 21-2

CONTROL STRATEGY EXAMPLE 2 - EQUIPMENT CHECKS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Equipment Checks." This example illustrates how a processor of clam juice in glass jars can control glass inclusion. It is provided for illustrative purposes only.

Glass inclusion may be only one of several significant hazards for this product. Refer to Tables 3-3 and3-4 (Chapter 3) for other potential hazards (e.g., pathogens from the harvest area, environmental chemical contaminants and pesticides, natural toxins, unapproved food and color additives, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Glass bottle receiving, mechanical bottle conveyors, mechanical filling, and mechanical capping	Glass inclusion	No broken glass on or around processing equipment	Broken glass on or around equipment	Visual check	Before start-up, every 4 hours during operations, after equipment jams, and end of day	Filler Operator	Stop production Determine the source of the broken glass Adjust equipment that caused the breakage, if necessary Remove broken glass from the area Hold and evaluate the product since the last satisfactory check	Glass inspection record	Review monitoring and corrective action records within 1 week of preparation

BIBLIOGRAPHY.

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- Olsen, A. R. 1998. Regulatory action criteria for filth and other extraneous materials. I. Review of hard or sharp foreign objects as physical hazards in food. Regul. Toxicol. Pharmacol. 28:181-189.
- U.S. Food and Drug Administration. 1999. Foods – Adulteration involving hard or sharp foreign objects. *In* Compliance Policy Guide, Sect. 555.425. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD.

NOTES:

APPENDIX 1: **FORMS**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains the following templates:

- Hazard Analysis Worksheet;

And

- Hazard Analysis Critical Control Point (HACCP) Plan Form.

HAZARD ANALYSIS WORKSHEET

Product Name

Firm Name:	Product Description:
Firm Address:	Method of Distribution and Storage:
	Intended Use and Consumer:

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/Processing Step	**Identify Potential Biological, Chemical, and Physical Hazards Associated with this Product and Process**	**Are Any Potential Food Safety Hazards Significant at this Step? (Yes/No)**	**Justify Your Decision for Column 3**	**What Preventive Measure(s) can be Applied for the Significant Hazards?**	**Is this Step a Critical Control Point? (Yes/No)**

HAZARD ANALYSIS WORKSHEET

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/Processing Step	**Identify Potential Biological, Chemical, and Physical Hazards Associated with this Product and Process**	**Are Any Potential Food Safety Hazards Significant at this Step? (Yes/No)**	**Justify Your Decision for Column 3**	**What Preventive Measure(s) can be Applied for the Significant Hazards?**	**Is this Step a Critical Control Point? (Yes/No)**

HACCP PLAN FORM

HACCP PLAN NAME

Firm Name:	Product Description:
Firm Address:	Method of Distribution and Storage:
	Intended Use and Consumer:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification

Signature of Company Official: _____ Date: _____

HACCP PLAN FORM

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification

Signature of Company Official: _____ Date: _____

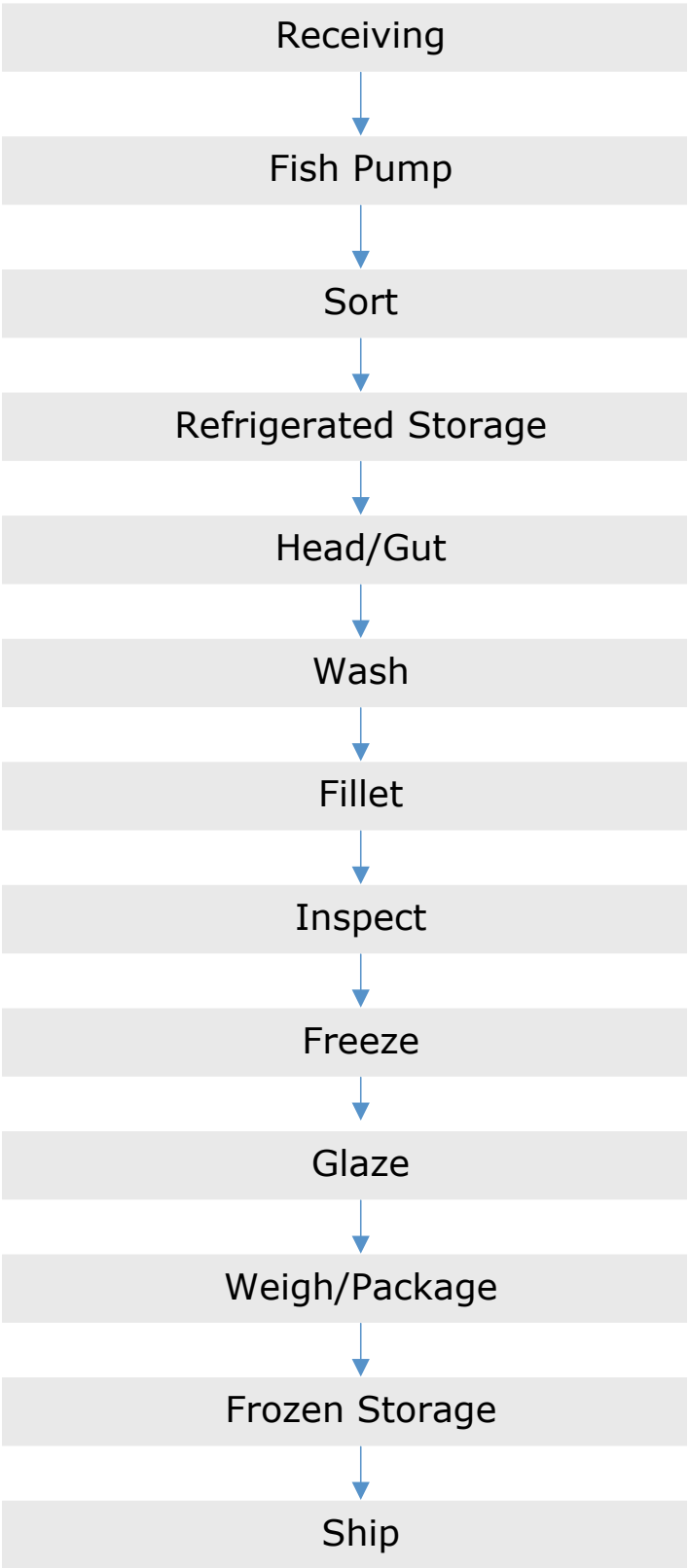
NOTES:

APPENDIX 2: **PRODUCT FLOW DIAGRAM - EXAMPLE**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains a product flow diagram that can be used as an example when you develop your own flow diagram.

FIGURE A-1:
PRODUCT FLOW DIAGRAM EXAMPLE:
FROZEN SALMON FILLETS



NOTES:

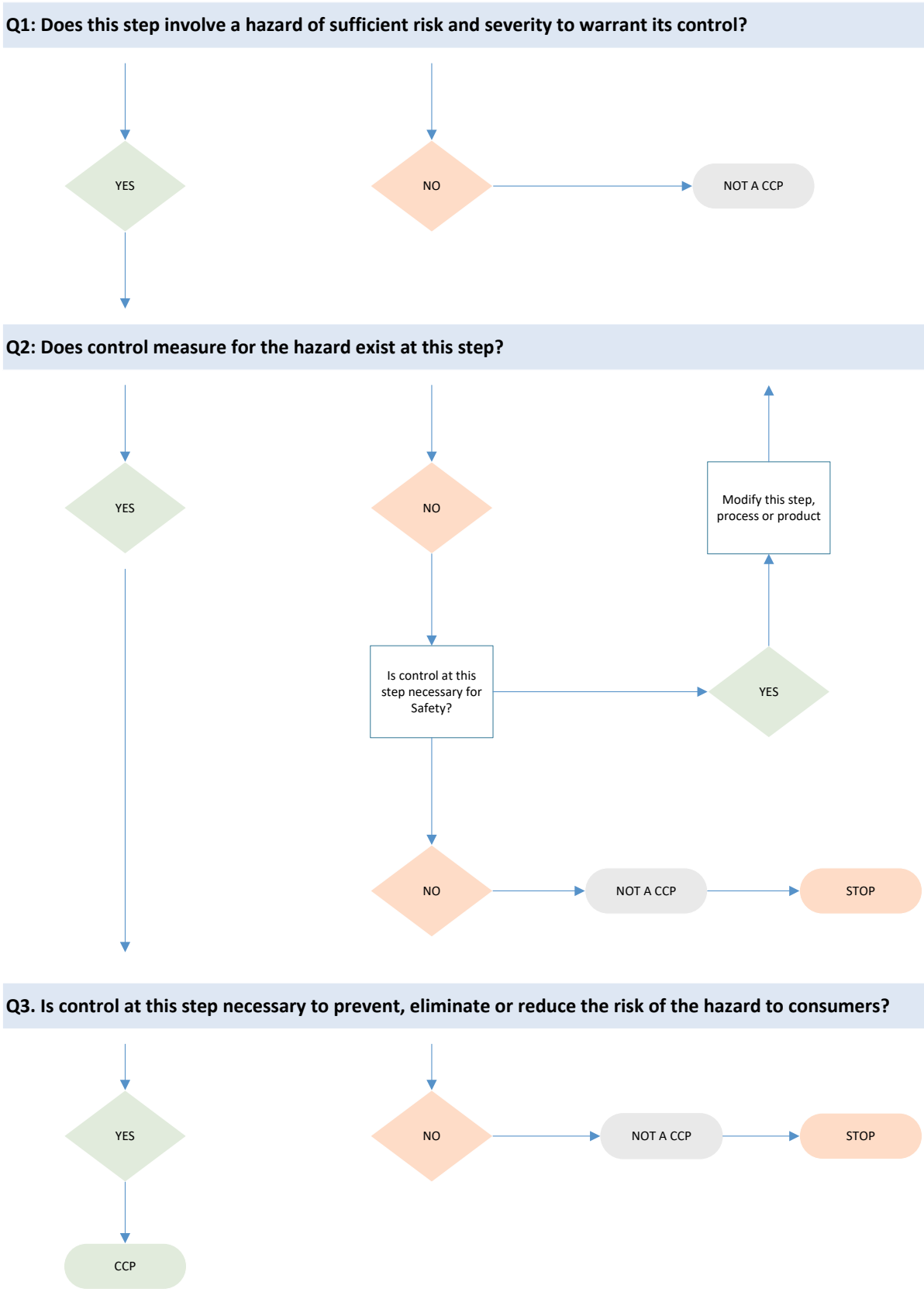
APPENDIX 3: **CRITICAL CONTROL POINT DECISION TREE**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains a decision tree that may be used to assist you with the identification of critical control points (CCPs). You should not rely exclusively on the decision tree, because error may result.

The following decision tree is derived from one that was developed by the National Advisory Committee on Microbiological Criteria for Foods.

FIGURE A-2: CCP DECISION TREE



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- National Advisory Committee on Microbiological Criteria for Foods. 1992. *Hazard Analysis and Critical Control Point System.* Intl. J. Food Microbiol. 16:1-23.

NOTES:

APPENDIX 4: **Bacterial Pathogen Growth and Inactivation**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

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 and 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 and temperature guidance may not be appropriate. Furthermore, the food matrix effects bacterial growth (e.g., presence of competing microorganisms, available nutrients, growth restrictive agents). Consideration of such attributes is needed when using the information in Tables A-1 and A-2.

In summary, Table A-2 indicates that:

For raw, ready-to-eat products:

- If at any time the product is held at internal temperatures above 70°F (21.1°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 2 hours (3 hours if *Staphylococcus aureus* (*S. aureus*) is the only pathogen of concern),

  OR

  Alternatively, exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 4 hours, as long as no more than 2 of those hours are between 70°F (21.1°C) and 135ºF (57.2ºC);

OR

- If at any time the product is held at internal temperatures above 50°F (10°C) but never above 70°F (21.1°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 5 hours (12 hours if *S. aureus* is the only pathogen of concern);

OR

- The product is held at internal temperatures below 50°F (10°C) throughout processing,

  OR

  Alternatively, the product is held at ambient air temperatures below 50°F (10°C) throughout processing.

For cooked, ready-to-eat products:

- If at any time the product is held at internal temperatures above 80°F (26.7°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 1 hour (3 hours if *S. aureus* is the only pathogen of concern),

  OR

Alternatively, if at any time the product is held at internal temperatures above 80°F (26.7°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135°F (57.2°C)) should be limited to 4 hours, as long as no more than 1 of those hours is above 70°F (21.1°C);

OR

- If at any time the product is held at internal temperatures above 70°F (21.1°C) but never above 80°F (26.7°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 2 hours (3 hours if *S. aureus* is the only pathogen of concern),

  OR

  Alternatively, if the product is never held at internal temperatures above 80°F (26.7°C), exposure times at internal temperatures above 50°F (10°C) should be limited to 4 hours, as long as no more than 2 of those hours are above 70°F (21.1°C);

OR

- If at any time the product is held at internal temperatures above 50°F (10°C) but never above 70°F (21.1°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 5 hours (12 hours if *S. aureus* is the only pathogen of concern);

OR

- The product is held at internal temperatures below 50°F (10°C) throughout processing,

  OR

  Alternatively, the product is held at ambient air temperatures below 50°F (10°C) throughout processing.

Note that the preceding recommended critical limits do not address internal product temperatures between 40°F (4.4°C), the recommended maximum storage temperature for refrigerated fish and fishery products, and 50°F (10°C). That is because growth of foodborne pathogenic bacteria is very slow at these temperatures and the time necessary for significant growth is longer than would be reasonably likely to occur in most fish and fishery product processing steps. However, if you have processing steps that occur at these temperatures that approach the maximum cumulative exposure times listed in Table A-2 below for the pathogenic bacteria of concern in your product, you should consider development of a critical limit for control at these temperatures.

It is not possible to furnish recommendations for each pathogenic bacteria, process, type of fish and fishery product, 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's (Pathogen Modeling Program (PMP)) and the United Kingdom's (Food MicroModel (FMM) program). 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, and generation time). FDA does not endorse or require the use of such modeling 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 and temperature limits derived from such predictive models.

Table A-3 contains information on the destruction of *Listeria monocytogenes* (*L. monocytogenes*). Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference internal product temperature of 158°F (70°C) (i.e., z = 13.5°F (7.5°C)). For example, 1

minute at 145°F (63°C) is 0.117 times as lethal as 1 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 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 initial levels in the food. It is also possible that higher levels of destruction may be necessary in some foods, if especially high initial levels are anticipated.

Table A-4 contains information on the destruction of *Clostridium botulinum* (*C. botulinum*) type B (the most heat- resistant form of non-proteolytic *C. botulinum*). Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 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, these values may not be sufficient for the destruction of non-proteolytic *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	0.92	4.3	9.3	10	39.2°F 4°C	131°F[1] 55°C	facultative anaerobe[4]
CAMPYLOBACTER JEJUNI	0.987	4.9	9.5	1.7	86°F 30°C	113°F 45°C	micro-aerophile[2]
CLOSTRIDIUM BOTULINUM, TYPE A, AND PROTEOLYTIC TYPES B AND F	0.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe[3]
CLOSTRIDIUM BOTULINUM, TYPE E, AND NON-PROTEOLYTIC TYPES B AND F	0.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe[3]
CLOSTRIDIUM PERFRINGENS	0.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe[3]
PATHOGENIC STRAINS OF ESCHERICHIA COLI	0.95	4	10	6.5	43.7°F 6.5°C	120.9°F 49.4°C	facultative anaerobe[4]
LISTERIA MONOCYTOGENES	0.92	4.4	9.4	10	31.3°F -0.4°C	113°F 45°C	facultative anaerobe[4]
SALMONELLA SPP.	0.94	3.7	9.5	8	41.4°F 5.2°C	115.2°F 46.2°C	facultative anaerobe[4]
SHIGELLA SPP.	0.96	4.8	9.3	5.2	43°F 6.1°C	116.8°F 47.1°C	facultative anaerobe[4]
STAPHYLOCOCCUS AUREUS GROWTH	0.83	4	10	20	44.6°F 7°C	122°F 50°C	facultative anaerobe[4]
STAPHYLOCOCCUS AUREUS TOXIN FORMATION	0.85	4	9.8	10	50°F 10°C	118°F 48°C	facultative anaerobe[4]
VIBRIO CHOLERAE	0.97	5	10	6	50°F 10°C	109.4°F 43°C	facultative anaerobe[4]
VIBRIO PARAHAEMOLYTICUS	0.94	4.8	11	10	41°F 5°C	113.5°F 45.3°C	facultative anaerobe[4]
VIBRIO VULNIFICUS	0.96	5	10	5	46.4°F 8°C	109.4°F 43°C	facultative anaerobe[4]
YERSINIA ENTEROCOLITICA	0.945	4.2	10	7	29.7°F -1.3°C	107.6°F 42°C	facultative anaerobe[4]

1. Has significantly delayed growth (>24 hours) at 131°F (55°C).
2. Requires limited levels of oxygen.
3. Requires the absence of oxygen.
4. Grows either with or without oxygen.

TABLE A-2 TIME AND TEMPERATURE GUIDANCE FOR CONTROLLING PATHOGEN GROWTH AND TOXIN FORMATION IN FISH AND FISHERY PRODUCTS		
POTENTIALLY HAZARDOUS CONDITION	PRODUCT TEMPERATURE	MAXIMUM CUMULATIVE EXPOSURE TIME
GROWTH AND TOXIN FORMATION BY ***BACILLUS CEREUS***	39.2-43°F (4-6°C) 44-59°F (7-15°C) 60-70°F (16-21°C) Above 70°F (21°C)	5 days 1 day 6 hours 3 hours
GROWTH OF ***CAMPYLOBACTER JEJUNI***	86-93°F (30-34°C) Above 93°F (34°C)	48 hours 12 hours
GERMINATION, GROWTH, AND TOXIN FORMATION BY ***CLOSTRIDIUM BOTULINUM*** TYPE A, AND PROTEOLYTIC TYPES B AND F	50-70°F (10-21°C) Above 70°F (21°C)	11 hours 2 hours
GERMINATION, GROWTH, AND TOXIN FORMATION BY ***CLOSTRIDIUM BOTULINUM*** TYPE E, AND NON-PROTEOLYTIC TYPES 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 (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 (21°C)	21 days 1 day 6 hours[1] 2 hours
GROWTH OF PATHOGENIC STRAINS OF ***ESCHERICHIA COLI***	43.7-50°F (6.6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH OF ***LISTERIA MONOCYTOGENES***	31.3-41°F (-0.4-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) 71-86°F (22-30°C) Above 86°F (30°C)	7 days 1 day 7 hours 3 hours 1 hour
GROWTH OF ***SALMONELLA*** SPECIES	41.4-50°F (5.2-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH OF ***SHIGELLA*** SPECIES	43-50°F (6.1-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH AND TOXIN FORMATION BY ***STAPHYLOCOCCUS AUREUS***	50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	14 days 12 hours[1] 3 hours
GROWTH OF ***VIBRIO CHOLERAE***	50°F (10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
GROWTH OF ***VIBRIO PARAHAEMOLYTICUS***	41-50°F (5-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
GROWTH OF ***VIBRIO VULNIFICUS***	46.4-50°F (8-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
GROWTH OF ***YERSINIA ENTEROCOLITICA***	29.7-50°F (-1.3-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	1 day 6 hours 2.5 hours

1. Additional data needed.
2. Applies to cooked, ready-to-eat foods only.

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 NON-PROTEOLYTIC CLOSTRIDIUM 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 non-proteolytic 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.

BIBLIOGRAPHY.

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NOTES:

APPENDIX 5: **FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix lists FDA and EPA levels relating to safety attributes of fish and fishery products. In many cases, these levels represent the point at which the agency could take legal action to include removing product from market. Consequently, the levels contained in this table may not always be suitable for critical limits.

Regardless of an established level or not, FDA may take legal action against food deemed to be adulterated as defined by the Federal Food, Drug and Cosmetic Act (FD&C Act) [21 U.S.C. 342]. A food is adulterated if the food bears or contains any poisonous or deleterious substance which may render it injurious to health under section 402 (a)(1) of the FD&C Act. Additionally, a food is adulterated if the food has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health under section 402 (a)(4) of the FD&C Act.

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

ANIMAL DRUGS

Products	Levels	References
All fish [10]	Drugs prohibited for extra-label use in animals: No residue permitted for the following: • Chloramphenicol; • Clenbuterol; • Diethylstilbestrol (DES); • Dimetridazole, Ipronidazole, and other Nitroimidazoles; • Furazolidone, Nitrofurazone, and other nitrofurans; • Fluoroquinilones; • Glycopeptides.	21 CFR 530.41
Finfish and lobster	Sum of tetracycline residues, including oxytetracycline, chlortetracycline, and tetracycline [1]: • ≥ 2.0 ppm (muscle tissue)	21 CFR 556.500
Salmonids	Azamethiphos [9]: • ≥ 0.02 ppm (muscle/adhering skin)	Import Tolerance (https://www.fda.gov/animalveterinary/products/importexports/ucm315830.htm)
Atlantic salmon and Rainbow trout	Benzocaine [9]: • ≥ 0.05 ppm (muscle with adhering skin)	Import Tolerance (https://www.fda.gov/animalveterinary/products/importexports/ucm315830.htm)
Salmonids and Walleye	Chloramine-T [1] (para-toluenesulfonamide-marker residue): • ≥ 0.90 ppm (muscle/skin)	21 CFR 556.118

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

Products	Levels	References
Freshwater-reared finfish (other than catfish) and salmonids, and catfish	Florfenicol (florfenicol amine-the marker residue): • Freshwater-reared finfish (other than catfish) and salmonids: ≥ 1.0 ppm (muscle/skin); • Catfish: ≥ 1.0 ppm (muscle)	21 CFR 556.283
Salmonids	Lufenuron [9]: • ≥ 1.35 ppm (muscle/adhering skin)	Import Tolerance (https://www.fda.gov/animalveterinary/products/importexports/ucm315830.htm)
Salmonids and catfish	Sulfadimethoxine/ormetoprim combination [1]: • ≥ 0.1 ppm for each drug (edible tissue)	21 CFR 556.640
Trout	Sulfamerazine [1]: • No residue permitted	21 CFR 556.660
Atlantic salmon	Telflubenzuron [9]: • ≥ 0.5 ppm (muscle/adhering skin)	Import Tolerance (https://www.fda.gov/animalveterinary/products/importexports/ucm315830.htm)

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

BIOLOGICAL

Products	Levels	References
All fish [10]	*Clostridium botulinum:* • Presence of viable spores or vegetative cells in products that will support their growth; OR • Presence of toxin [12]	International Commission on Microbiology Specifications for Food (ICMSF). 1996. Microorganisms in Food 5. Microbiological specification of food pathogens. London: Blackie Academic and Professional
All fish [10]. that is Ready-to-eat (RTE) as defined in 21 CFR 117.3 (including raw and cooked)	*Listeria monocytogenes:* • Presence of organism [12]	Shank F.R., E. L. Elliot, I. K. Wachsmuth, and M. E. Losikoff. 1996. US position on *Listeria monocytogenes* in foods. Food Control. 7: 229-234
All fish [10]	*Salmonella* spp.: • Presence of organism [12]	Sec. 555.300 Compliance Policy Guide
All fish [10]	*Staphylococcus aureus:* • Positive for staphylococcal enterotoxin; OR • ≥ 10^4/g (MPN); OR • Levels indicative of insanitary conditions [12]	Compliance Program 7303.842
All fish [10] that has been previously cooked	*Vibrio* spp.: • Presence of organism [12]	International Commission on Microbiology Specifications for Food (ICMSF. 1996. Microorganisms in Food 5. Microbiological specification of food pathogens. London: Blackie Academic and Professional

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

Products	Levels	References
Raw bivalve shellfish [11]	*Vibrio cholerae:* • Presence of toxigenic organism	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish
Raw fish [10] other than raw bivalve shellfish that is ready-to-eat (RTE) as defined in 21 CR 117.3	*Vibrio cholerae:* • Presence of organism [12]	International Commission on Microbiology Specifications for Food (ICMSF. 1996. Microorganisms in Food 5. Microbiological specification of food pathogens. London: Blackie Academic and Professional
Post-harvest processed clams, mussels, oysters, and whole and roe-on scallops, fresh or frozen, that make a label claim of "processed to reduce *Vibrio parahaemolyticus* to non-detectable levels."	*Vibrio parahaemolyticus:* • ≥ 30 MPN/g	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish
Raw bivalve shellfish [11]	*Vibrio parahaemolyticus:* • ≥ 1×10^4/g	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish
Post-harvest processed clams, mussels, oysters, and whole and roe-on scallops, fresh or frozen, that make a label claim of "processed to reduce *Vibrio vulnificus* to non-detectable levels."	*Vibrio vulnificus:* • ≥ 30 MPN/g	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

CHEMICAL

Products	Levels	References
Fish and shellfish [13]	2,4-Dichlorophenoxyacetic acid (2,4-D) [1]: • Fish: > 0.1 ppm; • Shellfish: > 1.0 ppm	40 CFR 180.142
All fish [10]	Aldrin and dieldrin: • ≥ 0.3 ppm (edible portion).	Sec. 575.100 Compliance Policy Guide
Crayfish	Bensulfuron methyl • >0.05 ppm	40 CFR 180.445
Frog legs	Benzene Hexachloride (BHC): • ≥ 0.3 ppm (edible portion)	Sec. 575.100 Compliance Policy Guide
Fish freshwater [13]	Bispyribac-sodium [1]: • > 0.01 ppm	40 CFR 180.577
Oysters [13]	Carbaryl [1]: • > 0.25 ppm	40 CFR 180.169
Fish and shellfish [13]	Carfentrazone-ethyl [1]: • > 0.3 ppm	40 CFR 180.515
Crayfish	Chlorantraniliprole • >8.0 ppm	40 CFR 180.628
All fish [10]	Chlordane: • ≥ 0.3 ppm (edible portion)	Sec. 575.100 Compliance Policy Guide

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

Products	Levels	References
All fish [10]	Chlordecone: • Crabmeat: ≥ 0.4 ppm; • Other fish: ≥ 0.3 ppm (edible portion)	Sec. 575.100 Compliance Policy Guide
All fish [10]	DDT, TDE, and DDE: • ≥ 5.0 ppm (edible portion)	Sec. 575.100 Compliance Policy Guide
Fish – • freshwater finfish • freshwater finfish, farm raised • saltwater finfish, tuna, other	Deltamethrin: • >0.1 ppm	40 CFR 180.435
Fish and shellfish [13]	Diquat [1]: • Fish: > 2.0 ppm; • Shellfish: > 20.0 ppm	40 CFR 180.226
Fish – freshwater finfish, farm raised [13]	Diuron and its metabolites [1]: • > 2.0 ppm	40 CFR 180.106
Fish [13]	Endothall and its monomethyl ester [1]: • > 0.1 ppm	40 CFR 180.293
All fish [10]	Ethoxyquin: • > 0.5 ppm (edible muscle)	21 CFR 172.140
Fish, freshwater [13]	Flumioxazin [1]: • > 1.5 ppm	40 CFR 180.568

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

Products	Levels	References
Crayfish, and Fish [13]	Fluridone [1]: • > 0.5 ppm	40 CFR 180.420
Fish – • Freshwater finfish, • Shellfish, crustacean, and • Shellfish, mollusc [13]	Florpyrauxifen-benzyl [1]: • Freshwater Finfish: > 2.0 ppm; • Shellfish, crustacean: > 0.5 ppm; • Shellfish, mollusc: > 20.0 ppm	40 CFR 180.695
Fish, and shellfish [13]	Glyphosate [1]: • Fish: > 0.25 ppm; • Shellfish: > 3.0 ppm	40 CFR 180.364
All fish [10]	Heptachlor and heptachlor epoxide: • ≥ 0.3 ppm (edible portion)	Sec. 575.100 Compliance Policy Guide
Scombrotoxin-forming fish, e.g., Tuna, mahi-mahi, and related fish	Histamine: • ≥ 500 ppm - toxic; • ≥ 50 ppm - decomposed	Sec. 540.525 Compliance Policy Guide
Fish and shellfish [13]	Imazapyr [1]: • Fish: > 1.0 ppm; • Shellfish: > 0.1 ppm	40 CFR 180.500
Crayfish	Imazethapyr: • > 0.15 ppm	40 CFR 180.447

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

Products	Levels	References
Fish and Shellfish, molluscs	Imidacloprid: • Fish: > 0.05 ppm • Shellfish, and molluscs: > 0.05 ppm	40 CFR 180.472
All fish [10]	Methylmercury [2]: • ≥ 1.0 ppm	Sec. 540.600 Compliance Policy Guide
All fish [10]	Mirex: • ≥ 0.1 ppm (edible portion)	Sec. 575.100 Compliance Policy Guide
Crayfish	Pendimethalin: • >0.05 ppm	40 CFR 180.361
Fish, • Fish • Shellfish, crustacean, and • Shellfish, mollusc [13]	Penoxsulam [1]: • Fish: > 0.01 ppm; • Shellfish, crustacean: > 0.01 ppm; • Shellfish, mollusc: > 0.02 ppm	40 CFR 180.605
All fish [10]	Polychlorinated Biphenyls [1]. (PCBs): • ≥ 2.0 ppm (edible portion)	21 CFR 109.30
Crayfish	Propanil • >0.05 ppm	40 CFR 180.274
Fish – Shellfish, crustacean	Quizalofop ethyl • > 0.04 ppm	40 CFR 180.441
Fish – freshwater finfish, and Fish – Shellfish, crustacean [13]	Saflufenacil [1]: • > 0.01 ppm	40 CFR 180.649

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

Products	Levels	References
Fish, Fish – Shellfish, crustacean, and Fish – shellfish, mollusc [13]	Spinosad [1]: • > 4.0 ppm	40 CFR 180.495
Fish and shellfish [4]	Triclopyr and its metabolites and degradates [1]: • Fish: > 3.0 ppm. • Shellfish: >3.5 ppm	40 CFR 180.417
Fish – • Freshwater finfish, • Saltwater finfish, • Shellfish, crustacean, and • Shellfish mollusc [13]	Topramezone [1]: • > 0.05 ppm	40 CFR 180.612

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

NATURAL TOXINS

Products	Levels	References
Bivalve shellfish [11]	Azaspiracid [3, 6] (Azaspiracid Shellfish Poisoning (AZP)): • ≥ 0.16 mg/kg azaspiracid-1 equivalents (i.e., combined azaspiracid-1, -2, and -3)	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish
Clams, mussels, oysters, and whole and roe-on scallops, fresh, frozen, or canned [11]	Brevetoxin [5, 6] (Neurotoxic Shellfish Poisoning (NSP)): • ≥ 0.8 mg/kg (20 mouse units/100 g) brevetoxin-2 equivalent or 5,000 cells/L	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish
Finfish (primarily reef fish)	Ciguatoxin [4] (Ciguatera Fish Poisoning (CFP)): • Caribbean ciguatoxins: ≥ 0.1 µg/kg Caribbean ciguatoxin-1 (C-CTX-1) equivalents; • Indian ciguatoxins: Guidance levels have yet to be established; • Pacific ciguatoxins: ≥ 0.01 µg/kg Pacific ciguatoxin-1 (P-CTX-1) equivalents	Dickey, R.W. and S.M. Plakas. 2010. Ciguatera: A public health perspective. Toxicon 56(2): 123-136. Dickey, R. W. 2008. Ciguatera toxins: chemistry, toxicology, and detection, p. 479–500. In L. M. Botana (ed.), Seafood and freshwater toxins: pharmacology, physiology, and detection, 2nd ed. CRC Press/Taylor & Francis
All fish [10]	Domoic acid [6] (Amnesic Shellfish Poisoning (ASP)): • ≥ 20 mg/kg domoic acid (except Dungeness crab viscera); • > 30 mg/kg domoic acid (Dungeness crab viscera ONLY)	Compliance Program 7303.842. National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish: FDA Memorandum, Director, Office of Seafood. Marine Biotoxins in Dungeness Crab. January 14, 1993
Clams, mussels, oysters, and whole and roe-on scallops, fresh, frozen, or canned [11]	Okadaic acid [3] (Diarrhetic Shellfish Poisoning (DSP)): • ≥ 0.16 mg/kg total okadaic acid equivalents (i.e., combined free okadaic acid, dinophysistoxins-1 and -2, and their acyl-esters)	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

Products	Levels	References
All fish [10]	Saxitoxin [3, 6] (Paralytic Shellfish Poisoning (PSP)): • ≥ 0.8 mg/kg saxitoxin equivalent (80 µg/100 g)	Sec. 540.250 Compliance Policy Guide. Compliance Program 7303.842

PHYSICAL

Products	Levels	References
All fish 10	Hard or sharp foreign object: • Generally, 0.3 (7 mm) – 1.0 (25 mm) in length	Sec. 555.425 Compliance Policy Guide

TABLE A-5
FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

ACRONYMS: MPN = Most probable number; **CTX** = ciguatoxin.

FOOTNOTES:

1. These values are tolerances. (Reference: 21CFR 109, 21CFR 556 and 40 CFR 180).
2. Refer to Chapter 10 – Methylmercury for additional information.
3. AZP, DSP, and PSP equivalents are based on chemical abundance as determined by instrumental analysis. In some cases (i.e. AZP, DSP, and PSP), toxicity equivalent factors (TEFs) may be available and should be considered in determining total toxin equivalents.
4. CFP equivalents are based on in vitro (cell culture bioassay) toxicity.
5. NSP equivalents are based on in vivo (mouse bioassay toxicity).
6. Refer to the National Shellfish Sanitation Program: Guide for Control of Molluscan Shellfish for details on approved methodologies for Biotoxin analysis of molluscan shellfish. (https://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm).
7. Refer to Chapter 6 – Natural Toxins for additional information.
8. Guidance levels used to confirm illnesses (i.e., CFP), inform advisories for at risk harvest areas (i.e., CFP) and/or make a determination for harvest area closures (i.e., ASP, AZP, DSP, NSP, and PSP.) Guidance levels are not intended to be identified in the HACCP plan as a control measure.
9. These values are import tolerances (Reference: https://www.fda.gov/animalveterinary/products/importexports/ucm315830.htm).
10. The term "fish" and "fishery products" are defined in the Fish and Fishery Products Regulation (21 CFR 123.3(d) and 123.3(e)) as follows:
    - Fish – 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
    - Fishery products – any human food product in which fish is a characterizing ingredient.
11. The term "shellfish" is defined in the NSSP as all species of:
    a. Oysters, clams, or mussels, whether:
        i. Shucked or in the shell;
        ii. Raw, including post-harvest processed;
        iii. Frozen or unfrozen;
        iv. Whole or in part; and
    b. Scallops in any form, except when the final product form is the adductor muscle only.
12. Detectable by methods equivalent to FDA's Bacteriological Analytical Manual.
13. Products and "fish" are defined through EPA's References. Refer to the EPA for explanation.

NOTES:

APPENDIX 6: **Japanese and Hawaiian Vernacular Names for Fish Eaten Raw**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

- Table A-1 contains a list of Japanese vernacular names and their corresponding U.S. market names;
- Table A-2 contains a list of Hawaiian vernacular names and their corresponding U.S. market names.

These tables are not intended to be a complete list of species consumed raw.

TABLE A-1
COMMONLY USED JAPANESE VERNACULAR NAMES FOR FISH EATEN RAW WITH CORRESPONDING U.S. MARKET NAMES

WHEN THE JAPANESE VERNACULAR NAME IS …	THE U.S. MARKET NAME IS …
AINAME	GREENLING
AJI	MACKEREL, JACK
AKA-GAI	CLAM, ARKSHELL
AKAMANBO	OPAH
AKAUO	MONKFISH
AKODAI	MONKFISH
AKOU-DAI	ROCKFISH, RED
AMADAI	TILEFISH
AMAEBI	PRAWN, SWEET
ANAGO, HAMO	CONGER EEL
ANKOU	MONKFISH
AOYAGI	CLAM, SURF
ASARI	CLAM, SHORT NECKED
AWABI	ABALONE
AYU	SMELT
BAIGAI	WHELK
BORA	MULLET, GRAY
BURL	YELLOWTAIL
DOJYOU	LOACH
EBI	SHRIMP, FRESHWATER
EBI	SHRIMP, PINK
EBODAI	BUTTERFISH
ESO	LIZARDFISH
EZOBORA	WHELK
FUEFUKIDAI	EMPEROR
FUGU	PUFFER
FUGU	GLOBEFISH
FUNA	CARP
GARIGANI	CRAYFISH
GIN-SAKE	SALMON, COHO
HAKKAKU	SCULPIN
HAMACHI	YELLOWTAIL
HAMAGURI	CLAM
HANASAKI KANI	CRAB, HANASAKI
HATA	GROUPER
HAYA	DACE
HAZE	GOBY
HIGEDARA	LINGCOD
HIRAAJI	JACK
HIRAME	FLUKE, FLOUNDER
HIUCHIDAI	ORANGE ROUGHY
HOSHI-GAREI	FLOUNDER
HOTARUIKA	SQUID
HOTATE-GAI	SCALLOP, GIANT
HOUBOU	SEA ROBIN
HOYA	SEA SQUIRT
IBODAI	BUTTERFISH
IIDAKO	OCTOPUS

TABLE A-1
COMMONLY USED JAPANESE VERNACULAR NAMES FOR FISH EATEN RAW WITH CORRESPONDING U.S. MARKET NAMES

WHEN THE JAPANESE VERNACULAR NAME IS …	THE U.S. MARKET NAME IS …
IKA	SQUID
IKANAGO	SAND EEL
IKURA	SALMON, ROE
INADA	YELLOWTAIL
ISAKI	GRUNT
ISAKI	GRUNT OR SWEETLIPS
ISEEBI	LOBSTER
ISEEBI	LOBSTER, NORWAY
ISEEBI	LOBSTER, SLIPPER
ISHIDAI, ISHIGAKIDAI	KNIFEJAW
ISHIMOCHI GUCHI	CROAKER
ITOYORIDAI	THREADFIN BREAM
IWANA	CHAR
IWASHI	SARDINE
JNADA	YELLOWTAIL
KAJ I KA	SCULPIN
KAMASU	BARRACUDA
KAMASUSAWARA	WAHOO
KANI	CRAB, BROWN
KANI	CRAB, DEEP SEA
KANI	CRAB, KING
KANI	CRAB, SNOW
KAREI	FLOUNDER
KASAGO	ROCKFISH
KATSUO	BONITO
KATSUO	SMALL TUNA
KAWAHAGI	TRIGGERFISH
KAWAHGI	FILEFISH
KEGANI (KANI)	CRAB, KEGANI
KIJIHATA	GROUPER
KINK	THORNEYHEAD
KINME	ALFONSINO
KINMEDAI	ALFONSINO
KINTOKIDAI	BIGEYE
KISU	JAPANESE WHITING
KOBUDAI, BUDAI	PARROTFISH
KOCHI	FLATFISH
KOHADA	GIZZARD SHAD
KOHADA	SHAD
KOI	CARP
KOIKA	CUTTLEFISH
KONOSHIRO	GIZZARD SHAD
KOSHODAI	GRUNT OR SWEETLIPS
KURAGE	JELLYFISH
KURODAI	PORGY
KURUMA-EBI	SHRIMP, TIGER PRAWN
KYABIA	CAVIAR
KYURINO	SMELT
MA-DAKO TAKO	OCTOPUS
MA-IKA	CUTTLEFISH

TABLE A-1
COMMONLY USED JAPANESE VERNACULAR NAMES FOR FISH EATEN RAW WITH CORRESPONDING U.S. MARKET NAMES

WHEN THE JAPANESE VERNACULAR NAME IS …	THE U.S. MARKET NAME IS …
MADAI	SEA BREAM
MAGURO	TUNA
MAIWASHI	SARDINE
MAKOGAREI	FLOUNDER
MANAGA TSUO, ECHIOPIA	POMFRET
MANBOH	SUNFISH, OCEAN
MANDAI	OPAH
MEBARU	ROCKFISH
MEDAL	BLUENOSE
MEKAJIKI	SWORDFISH
MIRU-GAI	CLAM, GEODUCK
MIZUDAKO	OCTOPUS
MIZUIK	SQUID
MONGOIKA	CUTTLEFISH
MONGORAKAWAHAGI	TRIGGERFISH
NAMAKO	SEA CUCUMBER
NIBE	CROAKER
NIJI-MASU	TROUT, RAINBOW
NISHIN	HERRING
O'HYOU	HALIBUT
ODORI	SHRIMP, TIGER PRAWN
OKAMASU	BARRACUDA
OKAMSU	BARRACUDA
ONAGADAI	SNAPPER
SABA	MACKEREL
SAIRA	SAURY
SAKANA	FISH
SAKE	SALMON, CHUM
SAME	SHARK
SAMMA	SAURY
SANMA	SAURY
SAWAGANI	RIVER CRAB
SAYORI, SAVORI	HALFBEAK
SAZAE	TOP SHELL
SAZAE	TURBOT, SHELL
SHINKO	SHAD
SHIIRA	MAHI-MAHI
SHIMAAJI	JACK
SHISHAMO	CAPELIN AND ROE
SHITA-BIRAME	SOLE
SHIZU	BUTTERFISH
SUJI-KO	SALMON, ROE
SUKESODORA	POLLOCK AND ROE
SUMIIKA	CUTTLEFISH
SURUMEIKA	SQUID
SUZUKI	SEA BASS
SWARA	MACKEREL, SPANISH
TACHIUO	CUTTLEFISH
TAI	SEA BREAM, RED SNAPPER
TAKO	OCTOPUS

TABLE A-1 COMMONLY USED JAPANESE VERNACULAR NAMES FOR FISH EATEN RAW WITH CORRESPONDING U.S. MARKET NAMES	
WHEN THE JAPANESE VERNACULAR NAME IS …	THE U.S. MARKET NAME IS …
TARA	COD AND ROE/MILT
TARUMI FEUDA	SNAPPER
TARUMI FEUDAI	SNAPPER
TENEGADAKO	OCTOPUS
TOBIUO	FLYING FISH
TORIGAI	COCKLE
TORO	TUNA
TSUBUGAI	WHELK
UMAZURAHAGI	TRIGGERFISH
UNAGI	EEL
UNI	SEA URCHIN ROE
WAKASAGI	SMELT
WARASA	YELLOWTAIL
YAMAME	SALMON, CHERRY
YARIIKA	SQUID
Y ANAGI-GAREI	FLOUNDER
ZUWAI-GANI	CRAB, SNOW

TABLE A-2 COMMONLY USED HAWAIIAN VERNACULAR NAMES FOR FISH EATEN RAW WITH CORRESPONDING U.S. MARKET NAME	
WHEN THE HAWAIIAN VERNACULAR NAME IS …	THE U.S. MARKET NAME IS …
A'AWA	HOGFISH
A'U	BLUE MARLIN
A'U	BLACK MARLIN, SILVER MARLIN
A'U LEPE	SAILFISH
A'UKU	SWORDFISH
AHA	NEEDLEFISH
AHI	YELLOWFIN TUNA
AHI PALAHA	ALBACORE
AHOLEHOLE	AHOLHOLE
AKU	SKIPJACK TUNA
AKULE	BIGEYE SCAD
ALA'IHI	SQUIRRELFISH
AMA'AMA	MULLET
API	SAILFIN TANG
AUWEKE, MOANA KALI	GOLDSADDLE GOATFISH
AWA	MILKFISH
AWEOWEO	BIGEYE TUNA
DEEPSEA MOI	BEARDFISH
EHU	SQUIRRELFISH SNAPPER
HAHALALU	BIGEYE SCAD
HAPU'UPU'U	SEALE'S GROUPER
HE'E MAULI	OCTOPUS
HEBE	SHORTNOSE SPEARFISH
HILU	BLACK STRIPED WRASSE
IHEIHE	HALFBEAK
KAHALA	AMBERJACK
KAKU	BARRACUDA
KALA	UNICORNFISH
KALEKALE	VON SIEBOLD'S SNAPPER
KAMANU	RAINBOW RUNNER
KAWAKAWA	KAWAKAWA
KAWELE'A	JAPANESE BARRACUDA
KOLE	YELLOW-EYED SURGEON
KUMU	WHITE SADDLE GOATFISH
KUPIPI	GRAY DAMSELFISH
LAI	LEATHERBACK
LAINIHI	RAZOR WRASSE
MAHIMAHI	DOLPHIN FISH
MAHIMAHI	SMALL DOLPHIN FISH
MAI'I'I	BLACK AND BROWN SURGEON
MAILKO	BLUELINED SURGEON
MAKIAWA	SARDINE
MAKUA	OCEAN SUNFISH
MALOLO	FLYING FISH
MAMO	SERGEANT MAJOR DAMSEL
MANINI	CONVICT TANG
MOANA	MANYBAR GOATFISH
MOI	THREADFIN
MU	PORGY
NA'ENA'A	ORANGE SPOT WRASSE

TABLE A-2 COMMONLY USED HAWAIIAN VERNACULAR NAMES FOR FISH EATEN RAW WITH CORRESPONDING U.S. MARKET NAME	
WHEN THE HAWAIIAN VERNACULAR NAME IS …	THE U.S. MARKET NAME IS …
NENUE	RUDDERFISH
NUNU	TRUMPETFISH
O'OPU KAI NOHU	LARGE-HEADED SCORPION
OILIPA	BLUELINED LEATHER JACKET
OIO	BONEFISH
ONO	WAHOO
OPAH	MOONFISH
OPAKAPAKA	PINK SNAPPER
OPELU	MACKEREL SCAD
PAKI'I	FLOUNDER
PAKU'IKU'I	ACHILLES TANG
PALANI	DUSSUMIER'S SURGEON
PANUUNUHU	GAIMARD'S PARROTFISH
PAPAIKUALOA	KONA CRAB
PO'ONUI	BIGEYE TUNA
PO'OPA'A	HAWKFISH
PO'OU	ROSE-COLORED WRASSE
POMFRET	POMFRET
PUALU	ELONGATE SURGEONFISH
PUHIUHA	WHITE EEL
ROI	ARGUS GROUPER
SAMOAN CRAB	MANGROVE
SQUID	PURPLEBACK FLYING SQUID
STRIPED MARLIN	STRIPED MARLIN
TA'APE	BLUE-STRIPED SNAPPER
TO'AU	BLACK TAIL SNAPPER
U'U	SQUIRRELFISH
UHU	PARROTFISH
UKIUKI	BRIGHAM'S SNAPPER
UKU	GRAY JOBFISH, SNAPPER
ULA	SPINY LOBSTER
ULAPAPA	SLIPPER LOBSTER
ULUA	THICK-LIPPED TREVALLY
ULUA KIHIKIHI	THREADFIN JACK
UOAUOA	MULLET
UPAPALU	CARDINAL FISH
WALU	OILFISH
WHITE WEKE	WHITE/SAMOAN GOATFISH

BIBLIOGRAPHY.

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

- Organization for Economic Co-operation and Development. 1995. Multilingual dictionary of fish and fish products. Fishing News Book. University Press, Cambridge.
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- Tinker, S. W. 1991. Fishes of Hawaii. Hawaiian Service, Inc., Honolulu HI.

APPENDIX 7: **Bacterial and Viral Pathogens of Greatest Concern in Seafood Processing - Public Health Impacts**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

Bacillus cereus (*B. cereus*) is the bacterium responsible for *B. cereus* food poisoning. An estimated 27,400 foodborne cases of *B. cereus* food poisoning occur annually in the United States. There are two forms of the intoxication: one causes diarrhea, starting from 6 to 15 hours after consumption, and the other causes vomiting and nausea, starting from 30 minutes to 6 hours after consumption. Symptoms in both forms last about 24 hours. Everyone is susceptible to *B. cereus* food poisoning

Campylobacter jejuni (*C. jejuni*) is the bacterium responsible for campylobacteriosis. An estimated 1,960,000 foodborne cases of campylobacteriosis occur annually in the United States. Symptoms include: diarrhea, fever, abdominal pain, nausea, headache, and muscle pain. Symptoms start from 2 to 5 days after consumption and last from 7 to 10 days. Everyone is susceptible to infection by *C. jejuni.*

Clostridium botulinum (*C. botulinum*) toxin is the toxin responsible for botulism. An estimated 58 foodborne cases of botulism occur annually in the United States. Symptoms include: weakness; vertigo; double vision; difficulty in speaking, swallowing, and breathing; abdominal swelling; constipation; paralysis; and death. Symptoms start from 18 to 36 hours after consumption. Everyone is susceptible to intoxication by *C. botulinum* toxin; only a few micrograms of the toxin can cause illness. Mortality is high; without the antitoxin and respiratory support, death is likely.

Clostridium perfringens (*C. perfringens*) is the bacterium responsible for perfringens food poisoning. An estimated 249,000 foodborne cases of perfringens food poisoning occur annually in the United States. Symptoms include: abdominal cramps and diarrhea. Symptoms start from 8 hours to 1 day after consumption and last for about a day.

Everyone is susceptible to perfringens food poisoning, but it is more common in the young and elderly.

While most *Escherichia coli* (*E. coli*) are non-pathogenic, certain strains of the bacterium are responsible for four types of illness: gastroenteritis or infantile diarrhea, caused by enteropathogenic *E. coli* (EPEC); travelers' diarrhea, caused by enterotoxigenic *E. coli* (ETEC); bacillary dysentery, caused by enteroinvasive *E. coli* (EIEC); and hemorrhagic colitis, caused by enterohemorrhagic *E. coli* (EHEC). EHEC is the most severe, with potential for serious consequences, such as hemolytic uremic syndrome, particularly in young children. An estimated 173,000 foodborne cases from all four types of *E. coli* occur annually in the United States. Symptoms vary for the different forms of illness, but include: abdominal pain, diarrhea, vomiting, fever, chills, dehydration, electrolyte imbalance, high body fluid acidity, and general discomfort. Symptoms start from 8 hours to 9 days after consumption and last from 6 hours to 19 days, with both periods varying significantly between the illness types. Everyone is susceptible to all forms of infection from *E. coli*, but EPEC is most commonly associated with infants, and all types tend to result in more severe symptoms in the very young and elderly.

Hepatitis A virus is responsible for foodborne hepatitis. An estimated 4,200 foodborne cases of hepatitis A occur annually in the United States. Symptoms include: fever, malaise, nausea, anorexia, abdominal discomfort, and jaundice. Symptoms start from 10 to 50 days after consumption and last 1 to 2 weeks. Unless previously infected or immunized, everyone is susceptible to infection by hepatitis A virus.

Listeria monocytogenes (*L. monocytogenes*) is the bacterium responsible for listeriosis. An estimated 2,500 foodborne cases of listeriosis occur annually in the United States. *L. monocytogenes* can produce mild flu-like symptoms in all individuals. However, in susceptible individuals, including pregnant women, newborns, and the immunocompromised, it can result in more severe symptoms, which include: septicemia, meningitis, encephalitis, spontaneous abortion, and stillbirth. Symptoms start from

3 days to 3 weeks after consumption. Mortality is high in those that display the more severe symptoms.

Norovirus (also known as Norwalk-like virus) is a major cause of viral gastroenteritis. An estimated 9,200,000 foodborne cases of norovirus occur annually in the United States. Symptoms include: diarrhea, nausea, vomiting, abdominal cramps, headache, body ache, and low-grade fever. Symptoms start from 2 to 4 days after consumption and generally last 2½ days. Everyone is susceptible to infection by norovirus.

Salmonella spp. is the bacterium responsible for salmonellosis. An estimated 1,340,000 cases of foodborne salmonellosis occur annually in the United States. Symptoms include: nausea, vomiting, abdominal cramps, diarrhea, fever, and headache. Symptoms start from 6 hours to 2 days after consumption and generally last from 1 to 2 days. The most severe form, typhoid fever, is caused by *Salmonella typhi*. Everyone is susceptible to infection by *Salmonella spp.,* but symptoms are most severe in the elderly, infants, and the infirmed. Infections by *Salmonella spp.* and other closely related bacterial pathogens, such as *Shigella spp., E. coli*, and *Yersinia enterocolitica* infections can lead to chronic reactive arthritic symptoms in pre-disposed individuals.

Shigella spp. is the bacterium responsible for shigellosis. An estimated 89,600 foodborne cases of shigellosis occur annually in the United States. Symptoms include: abdominal pain; cramps; diarrhea; fever; vomiting; blood, pus, or mucus in stools; continuous or frequent urges for bowel movement; and death. Symptoms start from

12 hours to 2 days after consumption and last from 1 to 2 weeks. Everyone is susceptible to infection by *Shigella spp.*

Staphylococcus aureus (*S. aureus*) is the bacterium responsible for staphylococcal food poisoning. An estimated 185,000 foodborne cases of staphylococcal food poisoning occur annually in the United States. Symptoms include: vomiting, diarrhea, abdominal pain, nausea, and weakness. Symptoms usually start within 4 hours of consumption. Everyone is susceptible to intoxication by *S. aureus* toxin, with more severe symptoms, including occasional death, occurring in infants, the elderly, and debilitated persons.

Vibrio cholerae (*V. cholerae*) O1 and O139 are the bacteria responsible for Asiatic or epidemic cholera. No major outbreaks of this disease have occurred in the United States since 1911, but an estimated 49 sporadic foodborne cases occur annually (including *V. cholerae* non-O1 and non-O139). Symptoms include: mild-to-severe diarrhea, abdominal cramps, nausea, vomiting, dehydration, shock, and death. Symptoms start from 6 hours to 5 days after consumption. Everyone is susceptible to infection by *V. cholerae* O1 and O139, but those with weakened immunity, reduced stomach acidity, or malnutrition may suffer more severe forms of the illness.

V. cholerae non-O1 and non-O139 are bacteria that are also responsible for vibriosis. *V. cholerae* non-O1 and non-O139 may also cause gastroenteritis and, rarely, septicemia. The

symptoms of gastroenteritis include: diarrhea, abdominal cramps, fever, vomiting, and nausea. Symptoms start from 6 hours to 3 days after consumption and last from 6 to 7 days. Everyone is susceptible to gastroenteritis from *V. cholerae* non-O1 and non-O139, but septicemia usually develops only in those with underlying chronic disease.

Vibrio parahaemolyticus (*V. parahaemolyticus*) is another bacterium that is responsible for vibriosis. An estimated 3,600 foodborne cases of vibriosis from *V. parahaemolyticus* occur annually in the United States. Vibriosis from *V. parahaemolyticus*, as with *Vibrio vulnificus*, may cause gastroenteritis and primary septicemia, although primary septicemia is uncommon with *V. parahaemolyticus*. The symptoms of gastroenteritis include: diarrhea; abdominal cramps, nausea, vomiting, headache, fever, and chills. Symptoms start from 4 hours to 4 days after consumption and last for about 2½ days. Everyone is susceptible to gastroenteritis from *V. parahaemolyticus*, but septicemia usually develops only in those with underlying chronic disease.

Vibrio vulnificus (*V. vulnificus*) is another bacterium that is responsible for vibriosis. An estimated 47 foodborne cases of vibriosis caused by *V. vulnificus* (mostly septicemia) occur annually in the United States, about half of those resulting in death. Vibriosis caused by *V. vulnificus* can take one of two forms, gastroenteritis and primary septicemia. The symptoms of gastroenteritis include: nausea, chills, and fever. The symptoms of primary septicemia include: septic shock and death. Symptoms of gastroenteritis start from 16 hours to 2 days after consumption, and death from septicemia may occur within 36 hours. Everyone is susceptible to gastroenteritis from *V. vulnificus*, but septicemia usually develops only in those with underlying chronic disease, particularly liver disease.

Yersinia enterocolitica (Y. enterocolitica) is the bacterium responsible for yersiniosis. An estimated 86,700 foodborne cases of yersiniosis occur annually in the United States. Symptoms include: fever, abdominal pain, diarrhea, vomiting, arthritis, and, rarely, septicemia. Symptoms start from 3 to 7 days after consumption and last from 1 to 3 days. Everyone is susceptible to infection by *Y. enterocolitica*, but symptoms are more severe in the very young, debilitated, elderly, and immunocompromised.

BIBLIOGRAPHY.

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

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APPENDIX 8: **PROCEDURES FOR SAFE AND SANITARY PROCESSING AND IMPORTING OF FISH AND FISHERY PRODUCTS**

Due to the updated structure of the Fish and Fishery Products Hazards and Controls Guidance document and to ensure ease of access, the information from this Appendix has been permanently relocated to Addendum 1: Regulations - Fish and Fishery Products (Part 123) and Control of Communicable Diseases (Part 1240.60).

APPENDIX 9: **ALLERGEN CROSS-CONTACT PREVENTION**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

INTRODUCTION.

In addition to effective cleaning and sanitation controls, processors should also consider processing controls to prevent or minimize the likelihood of the allergen cross-contact.

Allergen cross-contact may result in the un-intentional introduction of allergens into foods that do not properly declare the allergens on the labels. Allergen cross-contact controls are intended to provide separation by time and space between allergen-containing products and non-allergen-containing products, or between products consisting of or containing different allergens. These controls should be considered at all points in processing where cross-contact or inaccurate allergen declarations can be prevented. Controls may be considered at specific processing steps and should include comprehensive procedures such as process scheduling, traffic control, physical segregation, and air filtration. Allergen cross-contact controls should also be considered and used when creating and processing new product samples for public consumption. Development of written procedures and posting appropriate allergen cross-contact control procedures will help ensure the consistency in the application of controls. Implementation of a recordkeeping system provides a method of tracing ingredients and labels and identifying their disposition. The development and oversight of processing cross-contact controls requires an understanding of the allergens and the health hazard they present in addition to effective methods for prevention of allergen cross-contact.

Seafood processors must meet the requirements of 21 CFR 117.4. This regulation requires that all individuals engaged in manufacturing, processing, packing and holding food (including temporary and seasonal personnel) and supervisors must have the education, training, or experience necessary to ensure the production of safe food as appropriate to their assigned duties and that supervisory staff have the knowledge necessary to supervise the production of safe food. Seafood processors must ensure that their employees have been trained in the controls necessary to prevent allergen cross-contact. Since this training is specific to food safety, records of the training must be maintained in accordance with 21 CFR 117.4. The training should, at a minimum:

- Identify allergens and the hazard they present to sensitive individuals;
- Cover the principles of allergen cross-contact prevention; and
- Specifically cover the processor's allergen cross-contact prevention protocols, including corrective actions, and the required recordkeeping.

The following recommendations may not apply to every type of facility and situation. FDA has identified these recommendations as a means of assisting facilities as foundational information for them to better understand and evaluate or create an allergen cross-contact control program based on the needs of their facility. These are recommendations and considerations only. FDA does not legally require firms to adopt any of the recommendations.

RECEIVING.

Preventing allergen cross-contact begins when labels and ingredients are received at a facility. Consider the following when receiving materials to control allergen cross-contact as appropriate for the facility needs:

- Compare the received preprinted labels and the labels of ingredients received against product specifications. Check for any changes in the list of declared allergenic ingredients. Segregate and hold ingredients and labels whose allergen declarations do not match the product specification in a defined area with restricted access. The segregated ingredients and labels should be tagged to indicate that they should not be used. Close attention should be paid to sub-ingredients.

- Inspect materials for damaged packaging and exposed/leaking materials. Damaged packages should be removed, sealed and segregated from the shipment for return to the supplier or destroyed. Handle damaged containers of allergens in a manner that prevents allergen cross-contact during receipt and storage, if they must be accepted with the shipment. Segregation areas should be clearly identified, and damaged packages should be marked as not to be used. Do not move damaged or leaking containers or packages into production areas unless allergen-containing ingredients or materials have been contained.

- Clearly identify the allergen content on packages (e.g., case, pallet, bag, or carton) of incoming ingredients immediately upon receipt to ensure that the allergen content of each can be clearly identified during storage and on the production floor when in use. A color-code system that is easily understood and preferably identifies the specific allergen hazard can be utilized.

  Note: Ensure color codes are clear, and not in conflict with other coding schemes in use at the facility.

- Establish and implement controls to ensure the integrity of ingredients received in bulk including those delivered by railcar or tanker. For example, verification of tanker and/or railcar cleaning for allergens (e.g. hopper, boxcar, tanker, etc. wash-tags), prior load information, clean transfer areas and equipment cleaning.
    - Reject the shipment if identified requirements have not been met.

STORAGE.

Storage of allergens and allergen-containing materials should be done to minimize the risk of allergen cross-contact in a facility. Consider the following when establishing and implementing procedures to control allergen cross-contact during storage that are appropriate for your facility:

- Segregate allergen-containing ingredients. Use of separate storage areas (e.g. dedicated allergen storage room, or shelving) provides a physical separation for allergen and non-allergen-containing ingredients. The physical separation should ensure that allergen-containing ingredients are stored in a warehouse, cooler, or storage areas where they do not come in contact with each other or any non-allergen containing ingredient. This dedicated area should only be used for allergen-containing ingredients and not used for non-allergen-containing ingredients or other products at any time.

- Establish procedures for staging and storage of food allergens and allergen-containing ingredients below non-allergens when dedicated areas are not available. This will help to prevent inadvertent cross-contact in the event that the packaging material used to store the allergen is damaged and subsequent leakage occurs.

- Use color coding, tagging, or other distinctive marks to identify containers of ingredients or foods that contain different food allergens when practical. This could include using colored shrink-wrap or colored placards, distinct pallets, and unique totes or bins. A dedicated color may be assigned to each of the major allergens defined by FALCPA. For example, prominently post a chart in key processing and ingredient storage areas that identifies the assignment of the major food allergen and its corresponding color.

  Note: Ensure the color codes are clear, and not in conflict with other color coding schemes being used in the facility.

- Use dedicated bins or containers that can be closed in a secure manner for storing allergen-containing ingredients and allergen-containing products.

- Establish procedures to ensure that non-allergen-containing ingredients or products are not mixed with allergen-containing materials, or that different allergens are not mixed when using bulk storage tanks or silos. Use visual identifiers (such as tags or labels), computerized verification checks, lockouts over valve openings, and requirements that inspections and sign-offs on a valve and tank set up before receiving or using material in a tank or silo as appropriate.

- Establish procedures to inspect warehouse handling equipment (dollies, forklifts, etc.) used to transport the ingredients containing allergens.

- Establish and implement procedures for damaged packaging or containers and the resulting spills or leaks of allergen-containing ingredients or products.

PROCESSING.

Allergen cross-contact can be prevented during food processing by providing separation in time and space between allergen-containing materials and non-allergen-containing materials, and between materials containing different allergens. The appropriate allergen control measures are facility and product dependent. When choosing which measures to take, the processor should consider the properties of the allergenic ingredients being used, the nature of the processing system and production facility, the product being produced, and the manufacturing processes.

A. Facility, equipment and process design

Allergen cross-contact of ingredients, in-process materials and final product can be minimized by utilizing dedicated facilities, processing and packaging lines, and equipment. The following considerations should be made when designing the facility, equipment and processes to prevent allergen cross-contact:

- Incorporate features in overall plant layout and process design that will minimize the potential for allergen cross-contact.

- Design traffic patterns (e.g., avoid crossovers of open production lines) in the facility to prevent allergen cross-contact. Develop a unidirectional traffic flow to avoid unrestricted movement of employees between allergen-containing and allergen-free zones in the plant. For example, designing in a buffer room or clean area between the two zones.

- Establish air flow controls in the facility, to prevent airborne allergen particulate matter from being brought into allergen-free zones (e.g. introduce a positive air pressure environment in the packaging area or use micro air filtration).

- Provide shielding, permanent and/or temporary partitions, covers, and catch pans to protect exposed unpacked product as necessary.

- Review facility and process design for new installations or upgrades to assess for the potential of allergen cross-contact.

- Configure processing lines with sufficient space or physical barriers between them to minimize any allergen cross-contact as a result of normal product spillage and splattering from processing or cleaning.

- Consider dedicating a section of the facility for processing of products containing specific allergens as appropriate and/or practical.

- Consider the configuration and use of your processing lines:

    - Use separate processing lines for products that contain different types of allergens, when possible.

    - Line crossovers should be avoided

    - Enclosing processing equipment

- Dedicate utensils, employee apparel (e.g., aprons and gloves), and tools to specific processing lines or products, when possible. The utensils, employee apparel, and tools should be subjected to an allergen cleaning and sanitation procedure after use and stored in a manner to prevent allergen cross-contact.

- Use dedicated color coded equipment, tools, employee apparel, and utensils for handling allergen-containing ingredients or finished products, when possible.

- Restrict employee movement in facilities to minimize the spread of allergen-containing residues to non-allergen-containing products. Visually identify employees that work on lines

containing different allergens (e.g., different color uniforms). In addition:

  - Restrict personnel from working between processing lines containing allergenic ingredients and non-allergenic ingredients during the same shift.

  - Implement procedures for requesting change of work clothing when employees move from an allergen to a non-allergen area, for example, in dusty environments. Likewise, gloves and hats can be unintended carriers of dust and seeds and should be changed as often as necessary to prevent allergen cross-contact.

  - Initiate controls of personnel movement and practices to prevent allergen cross-contact during breaks and meals.

- Utilize a valve system for closed processing lines to effectively move and clear allergenic and non-allergenic ingredients through the facility. Consider the following when valves are used:

  - Ensure that all valves are clearly marked.

  - Inspect valves routinely for potential leaks.

  - Ensure valves are secured into the appropriate position.

- Control the movement of materials to minimize the spread of allergenic materials throughout the facility.

  - Ensure allergen-containing materials are covered, contained, and identified when in transit in the facility.

  - Move collection bins, totes, and containers with allergen-containing materials, ingredients, and wastes in a manner that prevents allergen cross-contact with other processing lines.

  - Collect and contain waste materials (e.g., spills, defective and unusable products, used ingredient packaging) on a continuous basis, especially those containing allergens, during production. Contain the waste materials in sealable containers such as covered collection bins, totes, and containers. These bins, totes, and containers should be labeled and/or color coded to identify which allergens they contain.

- Develop and implement procedures to minimize aerosolized allergenic material. For example, dust generation and accumulation on equipment can be minimized by adding liquid ingredients to mixers before or at the same time as powders, using dust collection systems (i.e., local exhaust, ventilation systems and/or vacuum systems), controlling surrounding dust sources, and covering equipment.

- Stage allergen-containing materials in designated areas before opening, weighing or transferring them to the processing line. Care should be taken to prevent the allergen-containing materials from spreading outside the staging area(s). Position the staging area(s) so that potential exposure to allergens is minimized, such as locating the staging area immediately near point of entry into the product. The staging location should facilitate the transport of materials to the line without the need to cross other lines where non-allergen-containing products are produced.

- Control of allergen-containing and non-allergen containing oils for fryers. Control can be managed through product scheduling or use of dedicated fryers to minimize the risk of allergen cross-contact.

B. Production scheduling

Controlling the scheduling of production runs can be an effective method for preventing allergen cross-contact. Considerations that should be made are as follows:

- Implement production scheduling to separate the manufacture of allergen-containing products from non-allergen-containing products by time. A separation between allergen-containing products and non-allergen-containing products can be achieved by establishing a production order; that is, producing the foods in a sequence whereby the food with the fewest allergens or no allergen is produced first and the food with the most allergens is produced last, combined with effective allergen cleaning and sanitation procedures between changeover of productions containing different allergens.

- Add the allergenic ingredient as late in the production process as possible to minimize the amount of equipment and the time that the processor's production area comes in contact with the allergen.

- Cluster allergen-containing runs to reduce the number of required changeovers and to reduce the risk of allergen cross-contact.

REWORK AND WORK-IN-PROGRESS (WIP).

The term rework refers to finished or partially finished products that are reincorporated into the manufacturing process. Work-in-Progress (WIP) consists of partially finished products that are between different production stages/ steps. Both rework and WIP can increase the risk of introducing allergens, either by erroneous addition of allergen-containing rework/WIP into a product that does not contain the specific allergen(s) as ingredients, or by cross-contact of allergen-containing materials with non-allergen-containing materials through shared containers or utensils during holding or storage. Since rework/WIP containing an allergen is inherently risky to handle, processors should assess their rework and WIP processes, identify opportunities for cross-contact or accidental inclusion of unintentional allergens, and develop written procedures to prevent their occurrence.

Controls can include:

- Storage of rework and WIP materials in labelled closed containers indicating the contents. The labeling should be consistent with the coding used in your allergenic ingredients controls and identify the product (e.g., intended finished product, batch code, and REWORK, or WIP). Rework/WIP materials collected online and in the processing area should be collected in similarly marked containers. Assume that rework/WIP materials obtained from any step of the production process include all allergens identified in the intended finished product specification.

- Storage of rework and WIP materials in designated areas that are clearly marked.

- Implementation of measures, whenever practical, that require adding rework back into the production of only identical finished product, rather than another product with the same/ similar allergen components. If this is not feasible or practical, predetermine and identify what specific product to which rework materials may be added to and develop a system that tracks and ensures that rework materials are only incorporated into items on that predetermined list. The product specification for each of the predetermined products should identify all the allergens incorporated within the rework materials.

- Implementation of and maintaining a record-keeping system for monitoring allergens for the rework/ WIP material for comparison against the label of the new finished product to ensure the allergens from the rework/WIP material match.

- Attaching information sheet(s) to each container of rework/WIP that identifies the allergen-containing ingredient, name of product, the specific production line the materials will be added to, the date the rework/WIP was produced, and the batch and/or lot number to which the rework/WIP was added.

- Using a recordkeeping system to control, track, reconcile, and inventory rework/WIP. Certain information should be considered as necessary to track the movement of rework and WIP and be identified accordingly.

- Conducting mock internal ingredient traceability drills to assure the facility has the capability of tracing the path and final destination and/ or disposition of all rework, whether or not it was incorporated into finished food products or disposed of due to the lack of a suitable finished product match.

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NOTES:

APPENDIX 10: CLEANING AND SANITATION FOR THE CONTROL OF ALLERGENS

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

INTRODUCTION.

Appropriate cleaning procedures are essential for preventing allergen cross-contact in a processing facility, particularly when allergen-containing and non-allergen-containing foods or foods with different allergen-containing components are manufactured on the same processing lines. Cleaning is also essential for preventing transfer of allergens from soiled containers, utensils, employee apparel (e.g., aprons and gloves), and tools into food products. The main purpose of an allergen cleaning program is the removal of the allergens from areas of the processor, including processing and packaging equipment, food-contact surfaces, storage, employee wardrobe, and in the processing and packaging environment. It is important to understand that cleaning procedures targeting microbial hazards may not be adequate for allergen removal and therefore a processor will need to assess the adequacy of their cleaning and sanitation program(s) to ensure it is effective to remove allergens and prevent allergen cross-contact. This appendix has been created to assist a processor in developing a sanitation program and/or assess their current program to determine its adequacy and efficacy. The development and oversight of cleaning and sanitation controls require an understanding of allergens and the health hazard they present in addition to effective methods for cleaning and sanitation.

An effective sanitation program includes procedures, practices, and processes to ensure a facility is maintained in a condition that significantly minimizes or prevents the hazard of allergen cross-contact. The sanitation program should implement procedures and monitoring for the following:

- Cleanliness of food-contact surfaces, including food-contact surfaces of utensils, staff wardrobe, and equipment; and
- Employees overseeing this program should possess an understanding of the allergen hazard and the principles for control of cross-contact that are required to execute the program.

The following recommendations do not apply to every type of processor and situation. FDA has identified these recommendations as a means of assisting processors as foundational information for them to better understand and evaluate or create a cleaning and sanitization program based on the needs of their facility. These recommendations and considerations will assist a processor create and implement an effective cleaning and sanitation program for the control of allergens. FDA does not legally require processors to adopt the following sanitation and cleaning recommendations for the control of allergens. However, these recommendations and considerations will assist the processor comply with the regulatory requirements of the seafood HACCP regulation.

CLEANING CONTROLS FOR ALLERGENS.

A processor that uses allergenic ingredients should evaluate the risk of allergen cross-contact and implement cleaning methods that effectively prevent or eliminate allergen cross-contact when necessary. The cleaning methods should be appropriate for the processing environment, the equipment, the type of product/ingredient, and the identified allergen. The development and oversight of the cleaning methods may also require technical expertise in the characteristics of food allergens, types of food contact surfaces, additional cleaning procedures, and/or specific cleaning chemicals, in addition to routine cleaning protocols.

Development of written sanitation standard operating procedures (SSOPs) for allergen management is a helpful tool that can ensure the desired results and a consistent application of controls. Written procedures to include:

- All instructions necessary to ensure that equipment and utensils are effectively cleaned and sanitized along with instructions for monitoring of cleaning procedures and verifying cleanliness, including:
    - Identify what is intended to be cleaned (e.g., processing and transport equipment, utensil, food contact surface);
    - Define a frequency of cleaning specific to the removal of targeted allergenic food residues. This frequency may vary dependent upon processing schedules, the type of equipment used, products produced, and the allergens involved. The frequency should consider risk of cross-contact and be consistent with cGMPs;
    - Provide detailed instructions on equipment breakdown for cleaning, if appropriate;
    - Define specific protocols, chemicals, concentrations, temperature set-points, solution flow rates, or any other factors that are critical to the effectiveness of the cleaning process. Cleaning treatments should be appropriate for their specific use and that directly apply to the products and processes in the facility. For example, cleaning treatments required for removing allergenic food pastes are different from cleaning treatments required for removing allergenic foods that are in a liquid form. The methods should be based on validation studies that are either conducted by the processor or by outside agents (e.g., chemical or equipment manufacturer, scientific study);
    - Require use of freshly prepared cleaning solutions rather than reuse of cleaning solutions whenever possible. Reused cleaning solutions may not be effective at removing allergenic food residues and may also cause recontamination of surfaces with allergenic food residues. Reuse of cleaning solutions should be limited, however, if re-used cleaning solutions are used, then their effectiveness in allergen removal should be verified;
    - Establish written verification procedures, when appropriate;
    - Conduct verification testing using analytical methods (e.g., allergen-specific enzyme-linked immunosorbent assay (ELISA) kits; lateral flow devices (LFD) or dipsticks; protein swabs; adenosine triphosphate (ATP) swabs (or general protein swabs); or polymerase chain reaction (PCR) methods). Examples of use included:
        - Consider using qualitative ELISA testing of cleaned surfaces in combination with quantitative ELISA testing of finished product to validate allergen cleaning procedures;
        - ATP swabs can be used during ongoing verification of cleaning when they have been documented to function adequately for this purpose during the validation process. It is not recommended to use ATP swabs alone for allergen cleaning verification since ATP is present in most foods and is not a specific indicator for allergens;
        - Consider using these analytical methods on both the equipment **and** the rinse water to verify the removal of allergens if the facility utilizes clean-in-place (CIP) protocols;
        - When a product contains two or more allergens, validation procedures using analytical techniques should focus on the highest percent allergen within the formula or other considerations, such as allergens that are the most difficult to remove from the food processing environment;
        - Validate the efficacy of the analytical method(s) using a competent or accredited laboratory or trained personnel.
    - Ensure that the cleaning practices and procedures do not result in transfer of allergens to other areas of the facility and prevent the dispersal of allergenic materials during the cleaning process:

- Describe protocols for segregating, isolating and holding dirty equipment awaiting cleaning;
- Protect the clean equipment and clean areas from recontamination from allergenic materials;
- Prevent cleaned equipment from contact with overspray during cleaning of floors, walls, ceiling or other equipment;
- Use vacuums equipped with filters designed to capture allergenic particles to remove loose, dry particles from surfaces. Other cleaning methods may be needed to remove residues not removed with a vacuum cleaning step;
- Avoid the use of compressed air and grit blasting for removing food residue from difficult-to-clean areas or protect other equipment or areas from allergenic materials during cleaning. Compressed air and grit blasting can disperse allergens from one area to another;
- When overspray from a high-pressure water hose affects nearby food contact surfaces procedures should be in place to ensure affected food contact surfaces are adequately cleaned to prevent allergen cross-contact. Another option would be to avoid using high pressure water hoses that could spread and aerosolize allergenic materials during cleaning or protect other equipment or areas from allergenic materials during cleaning.

- Establish written **validation** procedures when necessary to ensure that cleaning methods are effective at removing allergenic food residue. They may include how to conduct visual examinations, identify testing methods, and frequency of verification. Visual monitoring should be conducted when equipment is still disassembled after cleaning. This applies to products where single or multiple allergens are utilized on the same processing equipment (e.g., fish, milk, wheat, eggs, tree nuts, peanuts, and/or soy in hot filled (soups), shrimp and French fries cooked in same oil fryolators; and batter/breading equipment of fish or non-fish products):
    - Conduct validation studies of the effectiveness of using "push-through" methods to clean food-contact surfaces to establish the critical factors for the process. Push-through methods are used when the processor pushes finished product (e.g., specific quantity of finished product from the following product cycle), salt, flour or other material through the processing line as a method to remove the allergens. Determine the amount of time or volume of material needed to purge all allergenic food from each piece of equipment cleaned with a "push-though" treatment to ensure that all equipment surfaces are "allergen clean";
    - Use CIP systems to clean processing equipment with validated protocols that have been examined for their effectiveness. CIP systems are beneficial because cleaning is automated and can be applied consistently once procedures are validated and monitored accordingly;
    - Validation of cleaning procedures should occur: at least annually; when introducing a new product(s) or allergenic ingredient(s); when introducing or implementing new cleaning procedures, equipment, or chemicals; or when modifying (reducing) cleaning frequencies.

SAMPLING PLAN IN SUPPORT OF VERIFICATION AND/OR VALIDATION ACTIVITIES.

Obtaining and analyzing samples from hand-held tools, employee apparel (e.g., aprons and gloves), equipment surfaces, rinse water, push-through material, ingredients and final product for the presence of allergenic food residue can help support and verify processor's sanitation control program.

Consider the following:

- Establish sampling procedures, which includes the identity of the allergen, the type of sample (e.g. ingredient, equipment surface, push-through material and/or rinse water), the amount of sample to take at each location, and the collection method (e.g. swab or container).
- Predetermine the locations for sampling on equipment surfaces taking into consideration areas that can be considered potentially food contact or directly impact food contact surfaces and are difficult to clean.

- Develop a valid sampling plan to accurately represent the condition of what is being sampled and the outcome of the cleaning and sanitation procedures for all pieces of equipment.

- Ensure that the sampling plan includes all the equipment where allergen build-up could occur, or residual allergenic proteins could be trapped [e.g., pneumatic lines (product contact) conveyor belts, fillers, mixers, silos, bulk tanks, packaging equipment, hand utensils, shovels, scrapers, aprons, and gloves]. The identification of equipment should be based on the processor's practices and allergenic ingredients.

- Obtain equipment pre- and post-cleaning swabs at multiple locations on each processing line. Swabs obtained pre-cleaning serve as positive control samples. When multiple lines are used, sample all lines for presence of allergenic food residue pre- and post-cleaning.

- Obtain push-through samples at multiple locations in the processing line. When multiple lines are used, obtain push-through samples for all processing lines.

- Use validated analytical testing procedures that are specific to the targeted allergen(s) and the type or matrix of sample(s) to be tested. Monitor analytical test kits to ensure they have not expired.

- Ensure that the proper control samples are used in all analyses and that the analytical method demonstrates an acceptable sensitivity, specificity, and reproducibility for detection of the targeted allergen.

- Define the final criteria for acceptance of analytical results.

- Establish and implement a training program for personnel who will collect samples and perform the analyses.

- Periodically, verify in-house testing by using an independent laboratory.

- Establish and implement corrective actions that address finished products that were affected by potential cross-contact conditions and correct the condition to prevent recurrences of the deviation (e.g., evaluating cleaning methods, conducting validation studies, re-training staff, and/or modifying operating procedures.)

BIBLIOGRAPHY.

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NOTES:

APPENDIX 11: APPROVED ANIMAL DRUGS FOR AQUACULTURE USE

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APPROVED ANIMAL DRUGS FOR AQUACULTURE

Animal Drugs for aquacultured food fish must meet human food safety standards assessed during the approval process. When a fish producer (farmer) or hatchery manager uses an approved drug for food fish as directed on the label, the treated fish are safe to eat.

The FDA-approved animal drugs for use in aquaculture, with information on their approved sponsor/supplier, species for which the approval has been granted, required withdrawal periods, and other conditions are listed below. Additional details on provisions of use (e.g., administration route, dosage level) can be obtained from the Code of Federal Regulations (CFR) as cited below; the labeling for the drug; and the FDA CVM Website, (the Animal Drugs @ FDA database: https://animaldrugsatfda.fda.gov/).

FDA's determination that these veterinary products are approved aquaculture drugs does not exempt facilities from complying with other federal, state, tribal, territorial, and local environmental requirements. For example, in the United States, facilities using these substances would still be required to comply with the National Pollutant Discharge Elimination System requirements.

- **Route of Administration: Immersion**
  - **Chloramine-T powder**

    Proprietary Name: HALAMID® AQUA (NADA 141-423)

    Active Ingredient: Chloramine-T trihydrate

    Supplier: Axcentive SARL, France

    Species/Class: Freshwater-reared salmonids, walleye, and freshwater-reared warmwater finfish

    Indication for Use (21 CFR 529.382):

    - For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium* spp.
    - For the control of mortality in walleye due to external columnaris disease associated with *Flavobacterium columnare*.
    - For the control of mortality in freshwater-reared warmwater finfish due to external columnaris disease associated with *Flavobacterium columnare.*

    Conditions of use:

    Marketing Status: This drug is approved as an Over-the-Counter (OTC) product, and a prescription is not required for uses consistent with the product label instructions.

    Extra-label use: A prescription from a licensed veterinarian is required to prescribe an extra-label use of Halamid® Aqua **to treat diseases or species not listed on the product label (21 CFR 529.382)**.

    Mandatory withdrawal time before harvest: Not established

    Tolerance Level: The tolerance for para-toluenesulfonamide (marker residue) is 0.90 ppm (900 ppb) in fish muscle/skin (21CFR556.118).

○ Formalin

Proprietary Name:	Supplier:
Formalin-F (NADA 137-687)	Natchez Animal Supply Co., USA
Formacide-B (ANADA 200-414)	B.L. Mitchell, Inc., USA
Parasite-S®(NADA 140-989)	Syndel USA, USA

Active Ingredient: Formalin: approximately 37% by weight of formaldehyde gas

Species/Class: All finfish and penaeid shrimp- as a parasiticide, and the eggs of all finfish and freshwater-reared finfish as a fungicide.

Indication for Use (21 CFR 529.1030):

Added to the environmental water as follows:

- All finfish-for the control of external protozoa (*Chilodonella* spp., *Costia* spp., *Epistylis* spp., *Ichthyophthirius* spp. *Scyphidia* spp. and *Trichodina* spp.) and the monogenetic trematode parasites (*Cleidodiscus* spp., *Dactylogyrus* spp., and *Gyrodactylus* spp.);
- All finfish eggs- for the control of fungi of the family Saprolegniaceae;
- Penaeid shrimp- for the control of protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.); and
- Freshwater-reared finfish-for control of mortality due to saprolegniasis associated with fungi in the family Saprolegniaceae.

Conditions of use:

Marketing Status: This drug is approved as an Over-the-Counter (OTC) product, and a prescription is not required for uses consistent with the product label instructions.

Extra-label use: A prescription from a licensed veterinarian is required to prescribe an extra-label use of Formalin-F and Parasite-S® **to treat diseases or species not listed on the product label (21 CFR 529.1030)**.

Mandatory withdrawal time before harvest: Not established

Tolerance Level: Not established (formalin does not bioaccumulate in animal tissue)

○ Hydrogen peroxide

Proprietary Name: 35% PEROX-AID® (NADA 141-255)

Active Ingredient: Hydrogen peroxide

Supplier: Syndel USA, USA

Species/Class: Freshwater-reared adult finfish, fingerlings and eggs

Indication for Use (21 CFR 529.1150):

- For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacteriurn branchiophilum*,
- for the control of mortality in freshwater-reared warmwater and coolwater finfish and channel catfish due to external colurnnaris disease (Flexibacler columnaris) associated with *Flavobacterium columnare*.
- For the control of mortality in freshwater-reared finfish eggs due to saprolegniasis associated with fungi in the family Saprolegniaceae,
- For the control of mortality in freshwater-reared warmwater and coldwater fingerling and adult finfish due to saprolegniasis associated with fungi in the family *Saprolegniaceae*, and
- For the treatment and control of mortality in freshwater-reared salmonids associated with *Gyrodactylus* spp.

Conditions of use:

Marketing Status: This drug is approved as an Over-the-Counter (OTC) product, and a prescription is not required for uses consistent with the product label instructions.

Extra-label use: A prescription from a licensed veterinarian is required to prescribe an extra-label use of 35% PEROX AID® **to treat diseases or species not listed on the product label (21 CFR 529.1150)**.

Mandatory withdrawal time before harvest: Not established

Tolerance Level: Not established

○ Oxytetracycline hydrochloride

Proprietary Name:	Supplier:
Tetroxy® 343 (ANADA200-247)	Bimeda Animal Health Limited, Ireland
Tetroxy® Aquatic (ANADA200-460)	Bimeda Animal Health Limited, Ireland
Pennox 343® (ANADA200-026)	Pharmgate Inc., USA
TERRAMYCIN-343®, TERRAMYCIN®, TERRAMYCIN® Soluble Powder Concentrate (NADA 008-622)	Zoetis Inc., USA
OXYMarine™, Oxytet® Soluble (ANADA 130-435)	Huvepharma EOOD, Bulgaria

Active Ingredient: Oxytetracycline hydrochloride

Species/Class: Finfish/fry and fingerling

Indication for Use (21 CFR 529.1660):

- To provide a new indication for the marking of skeletal tissues in finfish fry and fingerlings as an aid in identification.

Conditions of use:

Marketing Status: Federal law restricts this drug to use by or on the order of a licensed veterinarian (21 CFR 529.1660)

Mandatory withdrawal time before harvest: None.

Tolerance Level: The tolerance level of 2 ppm has been established for the sum of tetracycline residues (including oxytetracycline, chlortetracycline, and tetracycline) in finfish muscle tissue and lobster (21 CFR 556.500).

○ Tricaine methanesulfonate (MS-222)

Proprietary Name: Tricaine-S (ANADA 200-226)

Active Ingredient: Tricaine methanesulfonate

Supplier: Syndel USA, USA

Species/Class: For fish intended for human consumption, the use of drug is restricted to the following families: Ictaluridae, Salmonidae, Esocidae, and Percidae. In other fish, the drug should be limited to hatchery or laboratory use (21 CFR 529.2503).

Indication for Use (21 CFR 529.2503):

- For the temporary immobilization of fish, amphibians, and other aquatic, cold-blooded animals. Tricaine methanesulfonate is used as an aid in the handling of these animals during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, and transport.

Conditions of use:

Marketing Status: This drug is approved as an Over-the-Counter (OTC) product, and a prescription is not required.

Mandatory withdrawal time before harvest: 21 days of harvesting fish for food.

Tolerance Level: Not established

• Route of Administration: Injectable

○ Chorionic gonadotropin

Proprietary Name: Chorulon® (NADA 140-927)

Active Ingredient: Chorionic gonadotropin

Supplier: Intervet Inc., USA

Species/Class: Finfish

Indication for Use (21 CFR 522.1081):

For the use as an aid in improving spawning function in male and female brood finfish. The drug may be administered by intramuscular injection. The total dose should not exceed 25,000 I.U. chorionic gonadotropin in fish intended for human consumption.

Conditions of use:

Marketing Status: This drug is a prescription (Rx) product and the Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian (21 CFR 522.1081).

Mandatory withdrawal time before harvest: Not established.

Tolerance Level: Not established (21 CFR 556.304).

- **Route of Administration: Medicated Articles/ Feeds**

  - **Florfenicol**

Proprietary Name: Aquaflor® Type A Medicated Article (NADA 141-246)

Active Ingredient: Florfenicol

Supplier: Intervet Inc., USA

Species/Class:

- Salmonids, Freshwater-Reared
- Finfish, Freshwater-Reared
- Warmwater Finfish, Freshwater-Reared
- Catfish

Indication for Use (21 CFR 558.261):

- Warmwater Finfish- For the control of streptococcal septicemia associated with *Streptococcus iniae*.
- Salmonids- For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* and furunculosis associated with *Aeromonas salmonicida*.
- Finfish- For the control of mortality due to columnaris disease associated with *Flavobacterium columnare*.
- Catfish- For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*.

Conditions of use:

Marketing Status: This drug is approved as veterinary feed directive (VFD) product to use by or on the order of a licensed veterinarian. The expiration date of VFD for florfenicol medicated feeds for fish must not exceed 6 months from the date of issuance. Type A medicated articles and medicated feeds intended for use in fish shall bear the following: "Not for use in animals intended for breeding purposes." (21 CFR 558.261)

Extra-label use: Extra-label use of medicated feed containing florfenicol is prohibited (21CFR 558.6(a)(4) and (6). See Compliance Policy Guide (CPG) 615.115 for more information about extra-label use.

Mandatory withdrawal time before harvest: Feeds containing florfenicol must be withdrawn 15 days prior to slaughter (21 CFR 558.261).

Tolerance Level: The tolerance for florfenicol amine (the marker residue) in the target tissue (muscle or muscle/skin) is 1 ppm (21 CFR 556.283)

  - **Oxytetracycline dihydrate**

Proprietary Name: Terramycin® 100 for Fish and Terramycin® 200 for Fish (NADA 038-439)

Active Ingredient: Oxytetracycline dihydrate

Supplier: Phibro Animal Health Corp., USA

Species/Class:

- Salmonids
- Freshwater-Reared Oncorhynchus Mykiss
- Lobster
- Catfish, Reared
- Freshwater-Reared Salmonids
- Freshwater-reared salmonids weighing up to 55 grams
- Pacific Salmon, Reared

Indication for Use (21 CFR 558.450):

- Salmonids- for the control of ulcer disease caused by *Haemophilus piscium*, furunculosis caused by *Aeromonas salmonicida*, bacterial hemorrhagic septicemia caused by *Aeromonas hydrophila*, and pseudomonas disease.
- Freshwater-reared salmonids-for the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum*.
- Freshwater-reared Oncorhynchus mykiss-for the control of mortality due to columnaris disease associated with *Flavobacterium columnare*.
- Catfish-for the control of bacterial hemorrhagic septicemia caused by *Aeromonas hydrophila* and pseudomonas disease.
- Lobster-for the control of gaffkemia caused by *Aerococcus viridans*.
- Pacific Salmon-For marking of skeletal tissue.
- Freshwater-reared salmonids weighing up to 55 gram-For marking the skeletal tissue

Conditions of use:

Marketing Status: This drug is approved as veterinary feed directive (VFD) product to use by or on the order of a licensed veterinarian. The expiration date of VFD for oxytetracycline medicated feeds for fish must not exceed 6 months from the date of issuance (21 CFR 558.450).

Extra-label use: Extra-label use of medicated feed containing oxytetracycline dihydrate is prohibited (21CFR 558.6(a)(4) and (6). See Compliance Policy Guide (CPG) 615.115 for more information about extra-label use.

Mandatory withdrawal time before harvest: Withdrawal times vary with indication as follows:

- for marking skeletal tissue in Pacific salmon, 7 days;
- for disease control for catfish, salmonids, freshwater-reared salmonids, and Oncorhynchus mykiss, 21 days;
- for lobster, 30 days before harvesting lobsters (21 CFR 558.450).

Tolerance Level: The tolerance level of 2 ppm has been established for the sum of tetracycline residues (including oxytetracycline, chlortetracycline, and tetracycline) in finfish muscle tissue and lobster (21 CFR 556.500).

○ Sulfamerazine

Proprietary Name: Sulfamerazine Fish Grade (NADA 033-950)

Active Ingredient: Sulfamerazine

Supplier: Zoetis Inc., USA

Species/Class: Trout (Rainbow, Brook and Brown)

Indication for Use (21 CFR 558.582):

- For control of furunculosis caused by *Aeromonas salmonicida*.

Conditions of use:

Marketing Status: This drug is approved as veterinary feed directive (VFD) product to use by or on the order of a licensed veterinarian. The expiration date of VFD for sulfamerazine medicated feeds for fish must not exceed 6 months from the date of issuance (21 CFR 558.582)

Extra-label use: Extra-label use of medicated feed containing sulfamerazine is prohibited (21CFR 558.6(a)(4) and (6). See Compliance Policy Guide (CPG) 615.115 for more information about extra-label use.

Mandatory withdrawal time before harvest: Feeds containing sulfamerazine must be withdrawn 21 days before slaughter (21 CFR 558.582)

Tolerance Level: The tolerance of zero is established for residues of sulfamerazine (N1 -[4-methyl-2-pyrimidinyl] sulfanilamide) in the edible tissues of trout (21 CFR 556.660).

○ Ormetoprim/Sulfadimethoxine combination

Proprietary Name: Romet-30® (NADA 125-933)

Active Ingredient: Sulfadimethoxine and Ormetoprim combination (5:1)

Supplier: Pharmaq AS, Norway

Species/Class: Salmonids (trout and salmon), Catfish

Indication for Use (21 CFR 558.575):

- For the control of bacterial infections in catfish caused by *Edwardsiella ictaluri* (enteric septicemia of catfish).
- For control of furunculosis in salmonids (trout and salmon) caused by *Aeromonas salmonicida*.

Conditions of use:

Marketing Status: This drug is approved as veterinary feed directive (VFD) Type A medicated product to use by or on the order of a licensed veterinarian. The expiration date of VFD for sulfadimethoxine/ormetoprim medicated feeds for fish must not exceed 6 months from the date of issuance. VFDs for sulfadimethoxine and ormetoprim shall not be refilled (21 CFR 558.575).

Extra-label use: Extra-label use of medicated feed containing sulfadimethoxine and ormetoprim is prohibited (21CFR 558.6(a)(4) and (6). See Compliance Policy Guide (CPG) 615.115 for more information about extra-label use.

Mandatory withdrawal time before harvest: Feed containing sulfadimethoxine/ormetoprim must be withdrawn before slaughter as follows: salmonids - 42 days; catfish -3 days (21 CFR 558.575).

Tolerance Level:

- The tolerance for sulfadimethoxine in the edible tissue is 0.1 ppm (100 ppb) (21 CFR 556.490).
- The tolerance level for ormetoprim in the edible tissue is 0.1 ppm (100 ppb) (21 CFR 556.640).

BIBLIOGRAPHY

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- U.S. Food and Drug Administration. Implantation or injectable dosage form new animal drugs. In Code of Federal Regulations, 21 CFR 522. U.S. Government Printing Office, Washington, DC. (https://www.ecfr.gov/cgi-bin/text-idx?SID=569e121f743184a034ffff345ce6efab&mc=true&node=pt21.6.522&rgn=div5)

- U.S. Food and Drug Administration. Certain other dosage form new animal drugs. In Code of Federal Regulations, 21 CFR 529. U.S. Government Printing Office, Washington, DC. (https://www.ecfr.gov/cgi-bin/text-idx?SID=569e121f743184a034ffff345ce6efab&mc=true&node=pt21.6.529&rgn=div5)

- U.S. Food and Administration. Tolerances for residues of new animal drugs in food. In Code of Federal Regulations, 21 CFR 556. U.S. Government Printing Office, Washington, DC. (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=556)

- U.S. Food and Drug Administration. New animal drugs for use in feed. In Code of Federal Regulations, 21CFR 558 U.S. Government Printing Office, Washington, DC. (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=558%0C)

- World Health Organization. (2017). WHO guidelines on use of medically important antimicrobials in food-producing animals. World Health Organization. (https://apps.who.int/iris/handle/10665/258970) License: CC BY-NC-SA 3.0 IGO

NOTES:

APPENDIX 12: UNAPPROVED ANIMAL DRUGS FOR AQUACULTURE

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UNAPPROVED ANIMAL DRUGS FOR AQUACULTURE

The following list identifies unapproved new animal drugs of low regulatory priority and provides their indicated use and usage levels (CVM's Policy and Procedures Manual Attachment: "Enforcement Priorities for Drug use in Aquaculture" Guide 1240.4200 https://www.fda.gov/media/70193/download)

- **Acetic acid**

  Used in a 1,000 to 2,000 ppm dip for 1 to 10 minutes as a parasiticide for fish.

- **Calcium chloride**

  Used to increase water calcium concentration to ensure proper egg hardening. Dosages used would be those necessary to raise calcium concentration to 10 to 20 ppm CaCO3. Used up to 150 ppm indefinitely to increase the hardness of water for holding and transporting fish to enable fish to maintain osmotic balance.

- **Calcium oxide**

  Used as an external protozoacide for fingerlings to adult fish at a concentration of 2,000 mg/L for 5 seconds.

- **Carbon dioxide gas**

  Used for anesthetic purposes in 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 in marine salmonids at all life stages.

- **Ice**

  Used to reduce the metabolic rate of fish during transport.

- **Magnesium sulfate**

  Used to treat external monogenic trematode infestations and external crustacean infestations in freshwater fish species at all life stages. Fish are immersed in a 30,000 mg MgSO4/L and 7,000 mg NaCl/L solution for 5 to 10 minutes.

- **Onion (whole form)**

  Used to treat external crustacean parasites and to deter sea lice from infesting the external surface of salmonids at all life stages.

- **Papain**

  Used in a 0.2% solution to remove the gelatinous matrix of fish egg masses 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 to 2,000 mg/L.

- **Povidone iodine**

  Used in a 100ppm 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% solution for an indefinite period as an osmoregulatory aid for the relief of stress and prevention of shock, and in a 3% solution for 10 to 30 minutes as a parasiticide.

- **Sodium sulfite**

  Used in a 1.5% solution for 5 to 8 minutes to treat eggs 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 4 hours during water hardening. Sac fry are immersed in an aqueous solution of up to 1,000 ppm for up to 1 hour.

- **Urea and tannic acid**

  Used to denature the adhesive component of fish eggs at concentrations of 15 g urea and 20 g 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.

BIBLIOGRAPHY

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NOTES:

ADDENDUM 1: FISH AND FISHERY PRODUCTS (21 CFR 123) AND CONTROL OF COMMUNICABLE DISEASES (21 CFR 1240.60)

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

TITLE 21 OF THE CODE OF FEDERAL REGULATIONS

PART 123 – FISH AND FISHERY PRODUCTS

SUBPART A – GENERAL PROVISIONS

SUBPART B – SMOKED AND SMOKE - FLAVORED FISHERY PRODUCTS

SUBPART C – RAW MOLLUSCAN SHELLFISH

AUTHORITY: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 241l, 264.

SOURCE: 60 FR 65197, Dec. 18, 1995, unless otherwise noted.

SUBPART A – GENERAL PROVISIONS

§ 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the Act) and in parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110 and 117 do not govern such terms where used in this part. 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) P*reventive 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 processing 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.

[60 FR 65197, Dec. 18, 1995, as amended at 80 FR 56167, Sept. 17, 2015]

§ 123.5 Current good manufacturing practice.

(a) Except as provided by § 117.5(b), parts 110 and 117 of this chapter apply 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.

[60 FR 65197, Dec. 18, 1995, as amended at 80 FR 56167, Sept. 17, 2015]

§ 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 performed 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 know-ledge 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 § 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 § 123.8(a);

(7) Provide for a recordkeeping system that docu-ments 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 onsite 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 § 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 § 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 require-ments 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 processors overall implementation of its HACCP plan, if one is required.

§ 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 appro-priate 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 § 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 § 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 § 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 correction actions taken in accordance wiht this section shall be fully documented in records that are subject to verification in accordance with § 123.8(a)(3)(ii) and the recordkeeping requirements of § 123.9.

§ 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 pro-duct 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 § 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 § 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 per-forming 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 § 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 accor-dance with § 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 § 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 § 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 § 123.9.

§ 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 § 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 § 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 § 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of § 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.

§ 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 § 123.6(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in § 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in § 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in § 123.8(c); and

(c) Performing the record review required by § 123.8(a)(3); The trained individual need not be an employee of the processor.

§ 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 and in subpart B of part 117 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 § 123.9.

(d) *Relationship to HACCP plan.* Sanitation controls may be included in the HACCP plan, required by § 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.

[60 FR 65197, Dec. 18, 1995, as amended at 80 FR 56167, Sept. 17, 2015]

§ 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 pro-cessor that the im-ported fish or fishery product is processed in accordance with the requirements of the 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 § 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 and Smoke-Flavored Fishery Products

§ 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

§ 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

§ 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.

§ 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 § 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 §

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 § 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

1. 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).

2. Section 1240.3 is amended by revising paragraph (r), and by adding new paragraphs (s), (t) and (u) to read as follows:

§ 1240.3 General Definitions.

a. *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.

b. *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

c. *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.

d. *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

3. 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:

§ 1240.60 Molluscan Shellfish

a. A person shall not offer for transportation, or transport, in interstate traffic any molluscan shellfish handled or stored in such an insanitary manner, or grown in an area so contaminated, as to render such molluscan shellfish likely to become agents in, and their transportation likely to contribute to the spread of communicable disease from one State or possession to another.

b. All shellstock shall 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). 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.

[40 FR 5620, Feb. 6, 1975, as amended at 60 FR 65202, Dec. 18, 1995]

NOTES:

ADDENDUM 2: CURRENT GOOD MANUFACTURING PRACTICES (CGMP)

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

TITLE 21 OF THE CODE OF FEDERAL REGULATIONS

PART 117 – CURRENT GOOD MANUFACTURING PRACTICES…..

SUBPART B – CURRENT GOOD MANUFACTURING PRACTICE

SUBPART B – CURRENT GOOD MANUFACTURING PRACTICE

§117.10 Personnel.

The management of the establishment must take reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (*e.g.,* by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

(1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by

hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

§117.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

(5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (*i.e.,* manufacturing, processing, packing, and holding). The plant must:

(1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

(2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.

(3) Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

§117.35 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.* (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(c) *Pest control.* Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

(1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary,

be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(e) *Sanitation of non-food-contact surfaces.* Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

(f) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

§117.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

(a) *Water supply.* The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.* Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

(e) *Hand-washing facilities.* Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) *Rubbish and offal disposal.* Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

§117.40 Equipment and utensils.

(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

§117.80 Processes and controls.

(a) *General.* (1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

(b) *Raw materials and other ingredients.* (1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

(2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

(5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(6) Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.

(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

(c) *Manufacturing operations.* (1) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

(6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected,

they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

(8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.

(9) Food, raw materials, and other ingredients that are adulterated:

(i) Must be disposed of in a manner that protects against the contamination of other food; or

(ii) If the adulterated food is capable of being reconditioned, it must be:

(A) Reconditioned (if appropriate) using a method that has been proven to be effective; or

(B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

(11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

(12) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

(14) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.

(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with §117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

§117.95 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in §507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

[80 FR 56337, Sept. 17, 2015]

§117.110 Defect action levels.

(a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at*http://www.fda.gov/pchfrule* and at*http://www.fda.gov*.

NOTES: