

Fish and Fishery Products  
Hazards and Controls Guidance  
Fourth Edition – APRIL 2011



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

**Fourth Edition – April 2011**

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U.S. Department of Health and Human Services  
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**Note:** *This document was corrected on August 3, 2011. The Agency corrected a typographical error appearing in the April 2011 version of this document. The Agency corrected "15%" to "1.5%" so that the sentence in "Chapter 11: Aquaculture Drugs" now reads "Sodium sulfite Used in a 1.5% solution for 5 to 8 minutes to treat eggs in order to improve their hatchability."*

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NOTES:

# Guidance for the Industry: Fish and Fishery Products Hazards and Controls Guidance

## Fourth Edition

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 describe 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.

## 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 the sanitation controls required by the Seafood HACCP Regulation. However, the maintenance of a sanitation monitoring program is an essential prerequisite to the development of a HACCP program. 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).

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. Changes in This Edition

Following is a summary of the most significant changes in this edition of the guidance document. In addition to using this summary list, you should carefully review the chapters that are applicable to your product and process.

The information contained throughout this guidance document is changed as follows:

The elements of a control strategy (i.e., critical limits, monitoring procedures, corrective action procedures, recordkeeping system, and verification procedures) are now consolidated for each control strategy. In most cases, an example of a HACCP plan follows the discussion of each control strategy;

- A bibliography is now located at the end of most chapters. References have been added and deleted for many of the chapters;
- Information on the mechanics of completing a HACCP plan, previously repeated in Chapters 4 through 21, is now contained in Chapter 2;
- Information on the potential public health consequences (i.e., illness or injury) of seafood safety hazards is now provided;
- Recommendations for specific job positions are no longer listed for “Who should perform the monitoring?” in Chapters 4 through 21;
- Additional information is now provided on the performance of accuracy checks and calibration of temperature-indicating devices (e.g., thermometers) and temperature-recording devices (e.g., recording thermometers); and
- Reference is no longer made to the intended issuance by FDA of guidance on the development of Sanitation Standard Operating Procedures (SSOPs) and sanitation monitoring or guidance on the development of importer verification procedures.

The recommendations in Chapter 2 for conducting a hazard analysis and developing a HACCP plan are changed as follows:

- Additional information that is broadly applicable to these tasks, also contained in the companion document to this guidance, “HACCP: Hazard Analysis Critical Control Point Training Curriculum,” developed by the Seafood HACCP Alliance for Training and Education, is now included.

The information in Chapter 3 for identifying potential species-related and process-related hazards is changed as follows:

- Information is now provided on how illicit species substitution can impact on the identification of potential species-related hazards.

The information contained in Table 3-2 (“Potential Vertebrate Species-Related Hazards”) is changed as follows:

- There are several scientific name changes to reflect changes in taxonomic conventions;
- Aholehole (*Kublia spp.*) is no longer listed as having a potential ciguatera fish poisoning (CFP) hazard;
- Amberjack or Yellowtail, Aquacultured (*Seriola lalandi*), is no longer listed as having a potential CFP hazard;
- Barramundi (*Lates calcarifer*) is now listed as a species that is aquacultured;
- Basa or Bocourti (*Pangasius bocourti*) is now listed as a species in U.S. commerce;
- Bass, Sea (*Dicentrarchus labrax*) is now listed as a species that is aquacultured;
- Bata (*Labeo bata*) is now listed as a species in U.S. commerce;
- Bream (*Abramis brama*) is now listed as a species that is aquacultured;
- Caparari (*Pseudoplatystoma tigrinum*) is now listed as a market name for a species previously referred to as catfish;
- Carp (*Barbonymus spp.*, *Hypophthalmichthys nobilis*, and *Carassius carassius*) is now listed as a species in U.S. commerce;
- Carp (*Hypophthalmichthys nobilis* and

- Carassius carassius*) is now listed as a species that is aquacultured;
- Cascarudo (*Callichthys callichthys*) is now listed as a market name for a species previously referred to as catfish;
  - Characin (*Leporinus obtusidens*) is now listed as a species in U.S. commerce;
  - Charal (*Chirostoma jordani*) is now listed as a species in U.S. commerce;
  - Chiring (*Apocryptes bato*) is now listed as a species in U.S. commerce;
  - Clarias Fish, or Walking Clarias Fish (*Clarias anguillaris* and *Clarias gariepinus*), is now listed as a market name for a species previously referred to as catfish, and is now listed as a species that is aquacultured;
  - Cobia (*Rachycentron canadum*) is now listed as a species that is aquacultured;
  - Coroata (*Platynemateichthys notatus*) is now listed as a market name for a species previously referred to as catfish;
  - Curimbata or Guramata (*Prochilodus lineatus*) is now listed as a species in U.S. commerce;
  - Cusk-eel (*Brotula clarkae*) is now listed as a species in U.S. commerce;
  - Dace (*Rhinichthys spp.*) is now listed as a species that is aquacultured;
  - Eel, Moray (*Muraena retifera*), is no longer listed as having a potential CFP hazard;
  - Featherback (*Notopterus notopterus*) is now listed as a species in U.S. commerce;
  - Flathead (*Platycephalus conatus*) is now listed as a species in U.S. commerce;
  - Flatwhiskered Fish (*Pinirampus pinirampu*) is now listed as a market name for a species previously referred to as catfish;
  - Frog (*Rana spp.*) is now listed as having a parasite hazard;
  - Gillbacker, or Gilleybaka (*Aspistor parkeri*), is now listed as a market name for a species previously referred to as catfish;
  - Goatfish (*Mulloidichthys vanicolensis*) is now listed as a species in U.S. commerce;
  - Goatfish (*Mulloidichthys spp.*, *Pseudupeneus spp.*, and *Upeneichthys lineatus*) is no longer listed as having a potential CFP hazard;
  - Goby (*Neogobius melanostomus*) is now listed as a species in U.S. commerce;
  - Grouper (*Anyperodon spp.*, *Caprodon schlegelii*, and *Diplectrum formosum*) is no longer listed as having a potential CFP hazard;
  - Grouper, or Coral Grouper (*Plectropomus spp.*), is now listed as a species in U.S. commerce;
  - Grouper, or Jewfish (*Epinephelus itajara*), is no longer listed as having a potential CFP hazard;
  - Herring, or Sea Herring, or Sild (*Clupea spp.*), is no longer listed as having a potential scombrototoxin (histamine) hazard associated with its roe;
  - Hind (*Epinephelus drummondhayi*) is no longer listed as having a potential CFP hazard;
  - Jack (*Carangoides bartholomaei*) is now listed as having a potential CFP hazard;
  - Jack (*Selene spp.*, *Urapsis secunda*, and *Oligoplites saurus*) is no longer listed as having a potential CFP hazard;
  - Jack or Crevalle (*Alectis indicus*) is no longer listed as having a potential CFP hazard;
  - Jack or Roosterfish (*Nematistius pectoralis*) is no longer listed as having a potential CFP hazard;
  - Jobfish (*Aprion spp.*) is now listed, and *Aprion virescens* is deleted because it is included in *Aprion spp.*;
  - Jobfish (*Aphareus spp.*, *Aprion spp.*, and *Pristipomoides spp.*) is no longer listed as having a potential scombrototoxin (histamine) hazard;
  - Kahawai (*Arripis spp.*) is no longer listed as having a potential CFP hazard;
  - Loach (*Somileptus gongota*) is now listed as a species in U.S. commerce;

- Mackerel, narrow-barred Spanish (*Scomberomorus commerson*), is now listed as having a potential CFP hazard;
- Menhaden (*Brevoortia spp.* and *Ethmidium maculatum*) is now listed as having a potential scombrototoxin (histamine) hazard for products intended for direct human consumption of the muscle and for aqueous components, such as fish protein concentrates, that are to be used as food additives. It is also listed as having a potential environmental chemical contaminant and pesticide hazard when the food products are intended for human consumption, such as oil extracts used as dietary ingredients;
- Oreo Dory (*Neocyttus spp.*) is now listed as a species in U.S. commerce;
- Oreo Dory (*Pseudocyttus spp.*) is now listed, and *Pseudocyttus maculates* is deleted because it is included in *Pseudocyttus spp.*;
- Pangasius or Shortbarbel (*Pangasius micronemus*) is now listed as a market name for a species previously referred to as catfish;
- Parrotfish (*Bolbometopon spp.*) is now listed as a species in U.S. commerce;
- Piramutaba or Laulao Fish (*Brachyplatystoma vaillanti*) is now listed as a market name for a species previously referred to as catfish;
- Puffer (*Fugu spp.*, now *Takifugu spp.*) is now listed as an aquacultured species;
- Puffer (*Sphoeroides annulatus*, *Sphoeroides nepheus*, *Sphoeroides spengleri*, and *Sphoeroides testudineus*, *Tetraodon spp.*) is now listed as a species in U.S. commerce;
- Puffer (*Fugu spp.*, now *Takifugu spp.*) is now listed as having a potential Paralytic Shellfish Poisoning (PSP) hazard;
- Rita (*Rita rita*) is now listed as a species in U.S. commerce;
- Rohu (*Labeo rohita*) is now listed as a species in U.S. commerce;
- Sailfish (*Istiophorus platypterus*) is now listed as a species in U.S. commerce;
- Salmon and roe (wild) (freshwater) (*Oncorhynchus spp.* and *Salmo salar*) is now listed as having a potential parasite hazard;
- Scad (*Trachurus spp.*) is now listed as having a potential scombrototoxin (histamine) hazard;
- Scad or Horse Mackerel (*Trachurus trachurus*) is now listed as a market name for a species previously referred to as only scad;
- Shad (*Alosa spp.*) is no longer listed as having a potential scombrototoxin (histamine) hazard associated with its roe;
- Shad, Hilsa (*Tenuialosa ilisha*), is now listed as a species in U.S. commerce;
- Snapper (*Etelis spp.* and *Pristipomoides spp.*) is no longer listed as having a potential CFP hazard;
- Snapper (*Pristipomoides spp.*) is no longer listed as having a potential scombrototoxin (histamine) hazard;
- Snapper (*Symphorus nematophorus*) is now listed as having a potential CFP hazard;
- Sorubim, or Surubi (*Pseudoplatystoma corruscans*), is now listed as a market name for a species previously referred to as catfish;
- Spearfish (*Tetrapturus spp.*) is now listed as having a potential scombrototoxin (histamine) hazard;
- Squirrelfish (*Holocentrus spp.*) is no longer listed as having a potential CFP hazard;
- Sutchi or Swai (*Pangasius hypophthalmus*) are now listed as market names for a species previously referred to as catfish and are now listed as species that are aquacultured;
- Tang (*Naso spp.*) is now listed as a species in U.S. commerce;
- Tang (*Tenthis spp.*) is no longer listed.
- Tang (*Zebrasoma spp.*) is no longer listed as having a potential CFP hazard;
- Tigerfish (*Datnioides microlepis* and *Datnioides polota*) is now listed as a species in U.S. commerce;
- Tin foil (*Barbonymus altus*) is now listed as a species in U.S. commerce;

- Trahira (*Hoplias malabaricus*) is now listed as a species in U.S. commerce;
- Triggerfish (*Canthidermis sufflamen* and *Melichthys niger*) is no longer listed as having a potential CFP hazard;
- Tuna (*Thunnus spp.*) is now listed as a genus that is aquacultured;
- Turbot (*Scophthalmus maximus*, now *Psetta maxima*) is now listed as a species that is aquacultured;
- Turtle (*Malaclemys spp.*, *Chelydra spp.*, *Apalone spp.*, and *Trachemys spp.*) is now listed as a species in U.S. commerce;
- Turtle, Aquacultured (*Malaclemys spp.*, *Chelydra spp.*, *Apalone spp.*, and *Trachemys spp.*), is now listed as a species in U.S. commerce;
- Unicornfish (*Naso unicornis*) is now listed as a species in U.S. commerce;
- Weakfish (*Cynoscion spp.*) is now listed as having a potential environmental chemical contaminant and pesticide hazard;
- Weakfish, or Bangamary (*Macrodon ancylodon*), is now listed as a market name for a species previously referred to as only weakfish;
- Whiskered Fish (*Arius spp.*) is now listed as a market name for a species previously referred to as sea catfish;
- Whiskered Fish, or Gafftopsail Fish (*Bagre marinus*), is now listed as a market name for a species previously referred to as sea catfish;
- Whiskered Fish, or Hardhead Whiskered Fish (*Ariopsis felis*), is now listed as a market name for a species previously referred to as sea catfish;
- Wrasse (*Cheilinus undulatus*) is now listed as a species in U.S. commerce;
- Yellowtail Amberjack (*Seriola lalandi*) is now listed as a species that is aquacultured and is no longer listed as having a potential CFP hazard;
- Zander (*Sander lucioperca*) is now listed as a species that is aquacultured.

The information contained in Table 3-3 (“Potential Invertebrate Species-Related Hazards”) is changed as follows:

- There are several scientific name changes to reflect changes in taxonomic conventions;
- Abalone (*Haliotis spp.*) is now listed as having a natural toxin hazard;
- Conch (*Lambis lambis*) is now listed as a species in U.S. commerce;
- Crab, all species are now listed as having a potential environmental chemical contaminant and pesticide hazard;
- Crab, Blue (*Callinectes sapidus*), is now listed as a species that is aquacultured;
- Crab, Japanese Freshwater (*Geothelphusa dehaani*), is now listed as a species in U.S. commerce;
- Crab, Sheep (*Loxorhynchus grandis*), is now listed as a species in U.S. commerce;
- Crab, Swamp (*Scylla serrata*), is now listed as a species in U.S. commerce;
- Murex, or Merex (*Murex brandaris*), is now listed as a species in U.S. commerce;
- Oyster (*Spondylus spp.*) is now listed as a species in U.S. commerce;
- Sea Squirt (*Styela spp.*) is now listed as a species in U.S. commerce;
- Shrimp (*Pleoticus muelleri*) is now listed as a species in U.S. commerce;
- Snail, Moon (*Polinices spp.*), is now listed as a species in U.S. commerce;
- Whelk (*Busycon spp.*) is now listed as having a potential natural toxin hazard.

The information contained in Table 3-4 (“Potential Process-Related Hazards”) is changed as follows:

- Fish oil is now listed as a food category;
- Changes have been made to be consistent with changes in Chapters 13, 16, and 17.

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

- 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.

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

- 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.

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

- Azaspiracid Poisoning (AZP) is now described, and an action level of 0.16 mg/kg is now provided;
- Information regarding potential molluscan shellfish toxins, pectenotoxins (PTXs) and yessotoxins (YTXs), is now provided, although FDA has no specific expectations for control of YTXs;
- An example of a HACCP plan is now provided for control of natural toxins in molluscan shellfish;
- The action level for Diarrhetic Shellfish Poisoning (DSP) is now listed as 0.16 ppm total okadaic acid equivalents;
- Action levels for CFP are now listed as 0.01 ppb for Pacific ciguatoxin and 0.1 ppb for Caribbean ciguatoxin;
- It is now noted that in 2008, FDA advised against the consumption of lobster tomalley because unusually high levels of PSP toxins were detected in that organ in lobsters caught in the waters of New England during a red tide event;
- CFP is now described as being associated with consumption of toxin-contaminated fish found in tropical or subtropical areas around the world between 35° north latitude and 35° south latitude, particularly the Caribbean Sea, Pacific Ocean, and Indian Ocean and in the Flower Garden Banks area in the northern Gulf of Mexico;
- Gempylotoxin is now described as being associated with orange roughy (*Hoplostethus atlanticus*) and oreo dory (*Alloctytus* spp., *Pseudocytus* spp. and *Neocytus* spp.) although in lesser amounts than escolar.

The recommendations in Chapter 7 for the control of scombrototoxin (histamine) formation are changed as follows:

- Information is now provided about the potential for scombrototoxin (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 scombrototoxin-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 scombrototoxin 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 scombrototoxin-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 scombrototoxin-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 scombrototoxin (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 scombrototoxin-forming bacteria and are subsequently handled in a manner where there is an opportunity for recontamination with scombrototoxin-forming bacteria;
- It is now acknowledged that it may be possible to control scombrototoxin 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.

The recommendations in Chapter 8 related to other decomposition-related hazards are changed as follows:

- 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.

The recommendations in Chapter 9 for the control of environmental chemical contaminants and pesticides are changed as follows:

- Toxic element guidance levels for arsenic, cadmium, lead, and nickel are no longer listed;
- Tolerance levels for endotoxin 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, which covers the control of methylmercury, 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.

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

- The potential for this hazard to occur during transportation of live fish is now recognized, and recommended controls are provided;
- An explanation of extra-label use of drugs is now provided, and a list of drugs prohibited for extra-label use is now listed;
- FDA high enforcement priority aquaculture drugs are now listed;
- Aquaflor® Type A Medicated Article (florfenicol) is now listed as an approved drug for catfish and salmonids;
- Aquaflor® CA1 is now listed as an approved drug for catfish or in fingerling to food fish as the sole ration for 10 consecutive days.
- 35% PEROX-AID® (hydrogen peroxide) is now listed as an approved drug for freshwater-reared salmonids and freshwater-reared cool water finfish and channel catfish;
- Terramycin® 200 for Fish (oxytetracycline dihydrate) Type C, is now listed as an approved drug for catfish, salmonids; and lobster;
- OxyMarine™, Oxytetracycline HCl Soluble Powder-343, Terramycin-343, TETROXY Aquatic is now listed as an approved drug for all finfish fry and fingerlings as an aid in identification;

- Quarterly raw material, in-process, or finished product testing is now recommended as a verification step for control strategies involving review of suppliers' certificates at receipt of raw materials, review of records of drug use at receipt of raw materials, and on-farm visits;
- When testing for aquaculture drugs 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 AOAC or equivalent method, or by analyzing proficiency samples).

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

- It is now recognized that *V. vulnificus*, *V. parahaemolyticus*, and *Vibrio cholerae* 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 135°F (57.2°C)) 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 135°F (57.2°C)) should be limited to 4 hours, as long as no more than 2 of those hours are between 70°F (21.1°C) and 135°F (57.2°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;

**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 135°F (57.2°C)) 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 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.

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

- 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<sup>2</sup>/24 hours at 24°C 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.
- 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;

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

- 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.
- For surimi-based products, soups, or sauces, the following pasteurization process is now recommended: a minimum cumulative, total lethality of  $F_{194^{\circ}\text{F}} (F_{90^{\circ}\text{C}}) = 10$  minutes, where  $z = 12.6^{\circ}\text{F} (7^{\circ}\text{C})$  for temperatures less than  $194^{\circ}\text{F} (90^{\circ}\text{C})$ , and  $z = 18^{\circ}\text{F} (10^{\circ}\text{C})$  for temperatures above  $194^{\circ}\text{F} (90^{\circ}\text{C})$ ;
- For dungeness crabmeat, the following pasteurization process is now recommended: a minimum cumulative total lethality of  $F_{194^{\circ}\text{F}} (F_{90^{\circ}\text{C}}) = 57$  minutes, where  $z = 15.5^{\circ}\text{F} (8.6^{\circ}\text{C})$ ;
- 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.

The recommendations in Chapter 15 for the control of *S. aureus* toxin formation in hydrated batter mixes are changed as follows:

- 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.

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

Chapter 17 is 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 as well.

The recommendations in Chapter 18 for the control of the introduction of pathogenic bacteria after pasteurization and specialized cooking processes are changed as follows:

- 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.

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

- Additional explanatory material on food allergens is now included, with information on the Food Allergen Labeling and Consumer Protection Act of 2004 and its impact on preventive controls for allergens;
- Additional information is now provided on the factors to be considered in judging when the presence of certain food intolerance substances and prohibited food and color additives is or is not reasonably likely to occur, such as the historical use of the substance and the expected level of sulfiting agent in the formulated finished food;
- Additional information is now provided on regulatory requirements for food additives.
- Corrective actions are now expanded to include steps that should be taken to regain control over the operation after a critical limit deviation, for consistency with guidance in the other chapters;
- It is now recommended that finished product labels be checked at time of labeling rather than at time of label receiving;
- It is now recommended that finished product testing be included as a verification step when review of suppliers' labeling is used as a monitoring procedure for the presence of sulfiting agents;

- The use of sulfiting agents in conch meat is now identified as a reasonably likely hazard.

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

- 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.

The recommendations in Chapter 21 for the control of glass inclusion are changed as follows:

- 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.

The Hazard Analysis Worksheet in Appendix 1 has been changed for consistency with the worksheet in the “HACCP: Hazard Analysis Critical Control Point Training Curriculum,” developed by the Seafood HACCP Alliance for Training and Education.

The recommendations in Appendix 4 for bacterial pathogen growth and inactivation are changed as follows:

- 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 41°F (-0.4 to 5°C); 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.

The safety levels listed in Appendix 5, Table A-5, “FDA and EPA Safety Levels in Regulations and Guidance,” are changed as follows:

- 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;
- A tolerance level for Florfenicol in channel catfish and freshwater-reared salmonids is now listed;

- The tolerance for oxytetracycline is now corrected to apply to all finfish and lobster;
- The tolerance for sulfamerazine is now corrected to apply to trout;
- A list of drugs prohibited for extra-label use is now provided;
- *V. parahaemolyticus* and *V. vulnificus* levels are now listed for post-harvest processed molluscan shellfish.

Appendix 6 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 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.

NOTES: