

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

Fourth Edition – June 2021

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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., *Neocyttus* 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:
 - Scombrototoxin (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 Biotxin 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: “Scombrototoxin (Histamine) Formation” has been modified with the following recommendations as of April 2011:

- 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.

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 cholerae* non-O1 and non-O139 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:

- o 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

- o 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

- o 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

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

OR

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

For cooked, ready-to-eat products:

- o 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

- o 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

- o 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

- o 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

- o 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

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

OR

- o 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/m²/24 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.

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 $F_{194^{\circ}\text{F}} (F_{90^{\circ}\text{C}}) = 10$ 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.

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 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.

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;
- Quinalofop 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: