Chapter 1: Introduction

Status

This is the second edition of the Food and Drug Administrations's (FDA) "Fish and Fishery Products Hazards and Controls Guide." This Guide relates to FDA's final regulations (21 CFR 123) that require processors of fish and fishery products to develop and implement Hazard Analysis Critical Control Point (HACCP) systems for their operations. Those final regulations were published in the *Federal Register* on December 18, 1995 and became effective on December 18, 1997. The codified portion of the regulations is included in Appendix 7.

FDA intends to revise and reissue this Guide from time to time as the state of knowledge advances relative to fish and fishery products hazards and controls. The agency will accept public comment on this second edition of the Guide for consideration in drafting the third edition. Such comments must be received within ninety days of the publication of a Notice of Availability for this Guide in the *Federal Register.* Comments received after that date will be considered for subsequent editions. Comments should be submitted to:

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

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

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

North Carolina Sea Grant
North Carolina State University
Box 8605
Raleigh, NC 27695

Purpose

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

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

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

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Scope & Limitations

The controls and practices provided in this Guide are recommendations and guidance to the fish and fishery products industry. This Guide provides information that would likely result in a HACCP plan that is acceptable to FDA. However, it is in no way a binding set of requirements. Processors may choose to use other control measures, as long as they provide an equivalent level of assurance of safety for the product.

The information contained in the tables in Chapter 3 and in Steps #10 and 11 in Chapters 4-20 provide guidance for determining which hazards are "reasonably likely to occur" in particular fish and fishery products under ordinary circumstances. The tables should not be used separately for this purpose. The tables list potential hazards for specific species and finished product types. This information must be combined with the information in the subsequent chapters to determine the likelihood of occurrence.

This Guide 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 Guide may be relevant to certain products under certain circumstances. In particular, processors should be alert to new or emerging problems (e.g., the occurrence of natural toxins in fish not previously associated with that toxin).

This Guide 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, allergic response to peanuts). However, where such hazards are presented by a fishery product that contains non-fishery ingredients, control must be included in the HACCP plan. Processors may use the principles included in this guide for assistance in developing appropriate controls for these hazards.

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

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

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

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

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

Changes in this Edition

Following is a summary of the most significant changes in this edition of the Guide:

- The following species are now listed in Table 3-1 (Potential Vertebrate Species Related Hazards), with relevant potential hazards identified:
  - Alligator;
  - Frog;
  - Herring roe;
  - *Scomberomorus cavalla* (under "spanish mackerel");

- *Microstomus kitt* and *Microstomus pacificus* (under "sole or flounder");
- *Pandalus jordani* (under "shrimp" or "pink shrimp");

- The following are no longer listed in Table 3-1 (Potential Vertebrate Species Related Hazards) or Table 3-2 (Potential Invertebrate Species Related Hazards) as potential hazards for the indicated species:
  - histamine in atka mackerel;
  - ciguatera fish poison in spanish mackerel, except for *Scomberomorus cavalla*;
  - pathogens in squid;

- Parasites and histamine are now listed as potential hazards for *Pristipomoides spp.* (under "snapper") in Table 3-1 (Potential Vertebrate Species Related Hazards;

- Aquaculture drugs is now listed as a potential hazard for lobster in Table 3-2 (Potential Invertebrate Species Related Hazards);

- Hermetically sealed containers and product packed in oil are now listed in the "package type" column of Table 3-3 (Potential Process Related Hazards);

- The following are no longer listed in Table 3-3 (Potential Process Related Hazards) as potential hazards
  - Pathogen survival through cooking for partially cooked or uncooked prepared foods;
  - Pathogen growth as a result of time/temperature abuse for raw breaded fish, raw fish (except raw molluscan shellfish, vacuum packaged, modified atmosphere packaged, controlled atmosphere packaged, and hermetically sealed fish, and fish packed in oil);

- Pickled and salted fish are now specifically listed in Table 3-3 (Potential Process Related Hazards);

- Pathogen growth as a result of temperature abuse is now listed in Table 3-3 (Potential Process Related Hazards) as a potential hazard for fermented, acidified, pickled, salted, and low acid canned foods;

- The first edition of this Guide indicated (Chapters 4 and 12) that FDA would update the Guide by including advice on how to assess the significance of a potential pathogen hazard in raw fishery products that will be cooked by the consumer or end user before consumption. This Guide now indicates that FDA is not aware of any HACCP controls that may exist internationally for the control of pathogens in fish and fishery products that are intended to be fully cooked by the consumer or end user before consumption, other than a rigorous sanitation regime as part of either a prerequisite program or as part of HACCP itself. The Seafood HACCP Regulation requires such a regime. The proper application of sanitation controls is essential because of the likelihood that any pathogens that may be present in seafood products are introduced through poor handling practices (e.g. by the aquacultural producer, the fisherman, or the processor).

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

- The following changes have been made to Chapter 4 for consistency with 1997 Interstate Shellfish Sanitation Conference actions:
  - The use of raw consumption warnings on tags on molluscan shellfish shellstock containers is now recommended;
  - Controls relative to the identification of the harvester, the harvester's license, the approval status of the harvest waters, and time-of-harvest to time-of-refrigeration are now only recommended for the primary processor (Note: Similar changes in Chapters 6 and 9);

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- The freezing recommendations for parasite control contained in Chapter 5 have been changed as follows:
  - The -4˚F (-20˚C) freeze now refers to either internal (product) or external (ambient) temperature;
  - The -31˚F (-35˚C) freeze now refers to internal temperature;

- Chapter 5 now indicates that the parasite hazard may not need to be considered a significant hazard at retorting steps and other heating steps for parasite-containing species if the step is exceptionally lethal to the parasites (e.g. to the extent that significant under processing would still result in a safe product relative to parasites);

- The evisceration recommendations for PSP and ASP control in fin fish or crustaceans in Chapter 6 have been changed as follows:
  - Evisceration within 24 hours is no longer urged;
  - The hazard is no longer identified as significant if you eviscerate the finished product;

- The histamine control recommendations contained in Chapter 7 have been changed as follows:
  - Additional information is provided about the mechanisms of histamine formation;
  - Two control strategy examples are now provided for receipt by the primary processor: one based on harvest vessel records, sensory examination of the fish, and checks on the cooling media and internal temperature of the fish; and the other based on histamine testing, sensory examination of the fish, and checks on the cooling media and internal temperature of the fish;
  - New on-board cooling recommendations are included:
    - For fish other than tuna above 20 lbs., if the fish have not been exposed to temperatures above 83˚F (28.3˚C), the fish should be placed in refrigerated sea water or brine at 50˚F (10˚) or less within 9 hours of death, or placed in ice within 12 hours of death;
    - For tuna above 20 lbs, or if the fish have been exposed to temperatures above 83˚F (28.3˚C), the internal temperature of the fish should be brought to 50˚F (10˚C) or less within 6 hours of death;
  - Recognition is included that fish that have been handled particularly well on-board the harvest vessel may be able to safely withstand somewhat more exposure than four hours at temperatures above 40˚F (4.4˚C) during post-harvest handling;
  - The sample size recommended for histamine analysis when such analysis is used as a monitoring tool is one fish per ton if the fish are greater than or equal to 20 lbs. each, or two fish per ton if the fish are smaller than 20 lbs.;
  - The recommendations relative to histamine analysis as a corrective action have been changed;
  - Cooking (e.g. canned tuna “precooking”) and post cooking steps are now identified as unlikely critical control points if sanitation practices are sufficient to prevent recontamination with enzyme-forming bacteria;
  - Another corrective action option is included for receipt by the secondary processor - hold pending evaluation of total time/temperature exposure;
  - Documentation of prior 24-week frozen storage is now recommended, if you rely on this measure for extended in-plant processing time at unrefrigerated temperatures;

- The environmental chemical contaminants and pesticides control recommendations contained in Chapter 9 have been changed as follows:
  - Making sure that incoming fish have not been harvested from waters that are under certain (not all) consumption advisories is now recommended if you are the primary processor of a fish with this hazard;
  - Evidence of producer participation in a third-party audited Quality Assurance Program is now included as a control strategy example for this hazard;
  - Another verification option is now included for use in combination with supplier’s certificates - quarterly testing;
  - Methyl mercury is now included in Table 9-1 (Environmental Chemical Contaminant and Pesticide Tolerances, Action Levels, and Guidance Levels);
  - Another corrective action option is now included in the event that supplier’s certification is missing - testing;

- Receiving records are now recommended to be used in combination with supplier's certificates, if you choose that control approach;

- The aquaculture drugs control recommendations contained in Chapter 11 have been changed as follows:
  - Evidence of producer participation in a third-party audited Quality Assurance Program is now included as a control strategy example for this hazard;
  - Another verification option is now included for use in combination with supplier's certificates - quarterly testing;
  - Aquaculture drugs is now identified as a significant hazard in lobster pounds and a control strategy example is provided;
  - Cautions are now provided for the use of rapid analytical methods for aquaculture drug screening;
  - The recommended frequency of on-farm visits to check drug usage practices, if you choose that control approach, is now once per year;
  - Receiving records are now recommended to be used in combination with supplier's certificates, if you choose that control approach;

- The recommendations for the control of pathogen growth and toxin formation as a result of time/temperature abuse contained in Chapter 12 have been changed as follows:
  - Safe time limits for exposure of microbiologically sensitive products are now based on product internal temperature, rather than ambient temperature, with a recommendation that you may need to study fluctuations in your product's internal temperature under normal operating conditions if you chose to apply these limits to the monitoring of ambient temperature;
  - Control of cooling after a cook step is no longer urged before the product is significantly handled, if you cook the product sufficiently to kill *Clostridium perfringens* and *Bacillus cereus*, cool the product in the same container in which it was cooked, and strictly adhere to good sanitation practices;
  - Another corrective action option is now included in the event that transit time/temperature controls are inadequate at time of receipt - hold the product and evaluated it based on its total time/temperature exposure;
  - Another version of a sample portion of a HACCP plan for the time/temperature control strategy example is provided, typical of the East coast blue crab processing technique;
  - Information is now provided about the significance of *Clostridium perfringens* and *Bacillus cereus*;

- The recommendations for the control of *Clostridium botulinum* toxin formation contained in Chapter 13 have been changed as follows:
  - *C. botulinum* toxin formation is now identified as a significant hazard in products that are packaged in hermetically sealed containers or in oil, even if they have not been hot smoked or vacuum packaged;
  - A control strategy example is now provided for refrigerated "pickled" fish and similar products that are not subject to 21 CFR 114 (the acidified foods regulations);
  - Control recommendations are now included for the prevention of *C. botulinum* toxin formation during processing, in addition to the prior recommendations relative to storage. The sample portion of a HACCP plan for vacuum packaged, hot-smoked salmon included in Table 13-1 now lists cooling after smoking and in-process refrigerated storage as critical control points;
  - The recommended storage critical limit for products that have been processed to control *C. botulinum* type E and nonproteolytic types B and F is 50˚F (10˚C) rather than 38˚F (3.3˚C);
  - Corrective action options are now included in the event that finished product samples show that the water phase salt level and/or nitrite level is below the critical limit, if you chose that control approach;
  - Scientific process establishment is now recommended for brining, dry salting, drying, pickling, and formulation steps when they are critical in the prevention of this hazard, unless you select finished product analysis as your control strategy;

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- Quarterly finished product testing is now recommended as a verification procedure for smoked, smoke-flavored, salted, and "pickled" and similar products;

- Another corrective action option is now included in the event that the critical limits for *Staphylococcus aureus* toxin formation in hydrated batter mixes, contained in Chapter 15, are not met — test for the toxin in the hydrated batter mix;

- Additional information is now included in Chapter 16 for the establishment for minimum cooking processes;

- Another corrective action option is now included in the event that the container sealing critical limits established for the prevention of recontamination after pasteurization, contained in Chapter 18, are not met — repack the product;

- The recommended monitoring frequencies for the control of food and color additives, contained in Chapter 19, have been changed as follows:
  - Monitoring of prelabeled packaging material is now recommended at the rate of one label from each pallet;
  - Monitoring of on-site computer generated labels is now recommended to be daily;

- The flow of the CCP Decision Tree contained in Appendix 3 is corrected;

- A number of changes have been made to the Limiting Conditions for Pathogen Growth information contained in Table A-1 (Appendix 4) including the addition of information on *Clostridium perfringens* and *Bacillus cereus*, and the separation of information on *Staphylococcus aureus* into information on growth and information on toxin formation.

- The Time/Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Seafoods contained in Table A-2 (Appendix 4) are now based on product internal temperature, rather than ambient temperature;

- The following changes have been made to Table A-3 (Appendix 5), FDA & EPA Guidance Levels:
  - Mouse lethality is no longer referred to with respect to *Vibrio vulnificus* pathogenicity;
  - The tolerance for oxytetracycline is now 2.0 ppm;
  - A zero tolerance for unapproved drugs, except under special circumstances, is now listed;
  - The methyl mercury action level of 1.0 ppm is now listed;

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

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

Additional Copies

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

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

Multiple copies may be obtained from:

National Technical Information Service
U.S. Department of Commerce
703-487-4650

This guide is also available electronically at:

http://www.fda.gov

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