



The Seafood Hazard Guide, 4th edition: Summary of Changes and Recommendations

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Introduction

The U.S. Food and Drug Administration's "Fish and Fisheries Products Hazards and Controls Guidance" (FDA Hazard Guide) was updated to its fourth edition in April 2011. It introduced changes and recommended control strategies for seafood processing operations.

We recommend that processors:

1. Obtain a copy of the fourth edition of the FDA Hazard Guide and review the summary of changes from the third edition, starting on page 3 of Section B: Changes in this Edition. Refer to the side panel for information on how to obtain a copy of the FDA Hazard Guide.
2. Review Tables 3-2, 3-3, and 3-4 in Chapter 3 to see if the changes apply to the species and products you work with. Carefully review the chapters that are applicable to your product and process.
3. Reassess your Hazard Analysis and Critical Control Point (HACCP) plan for any changes and additional hazards that were not included in your hazard analysis. Make sure to sign and date the HACCP plan after the reassessment.

Key Changes

Potential Species and Process-Related Hazards (Chapter 3)

Table 3-1 (New)

Provides actual examples of misbranding that could allow for potential species-related hazards to be overlooked, not only for regulatory purposes, but also for food safety significance.

Tables 3-2, 3-3, and 3-4

Certain seafood species have been added, others have been deleted. Some species have new hazards, while other hazards have been deleted. For example, all crabs now have environmental chemicals and pesticide listed as potential hazards.

Seafood Hazards Control Strategies (Chapters 4-21)

Each chapter provides strategies to control hazards that are specific to product and process conditions.

The control strategies you select will depend on whether you are a primary processor or secondary processor. A **primary processor** takes possession or receives the fish/shellfish from the harvester

FDA Hazard Guide

FDA's Fish and Fisheries Products Hazards and Controls Guidance, 4th edition



The FDA Hazard Guide can assist the seafood industry in evaluating hazards in its products and processes and in designing an HACCP plan to control them. Federal and state regulators use this guide to evaluate your hazard analysis and HACCP plan.

To buy or download a copy of the FDA Hazard Guide, go to <http://ifasbooks.ifas.ufl.edu/c-8-haccp-seafood.aspx>.

To watch a video of the changes to the FDA Hazard Guide, go to <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm>



(harvest vessel, aquaculture farm, etc.). A **secondary processor** receives the fish/shellfish from a primary or other processor.

Once you select a control strategy, follow the recommendations to develop critical limits, monitoring procedures, corrective actions, verification procedures, and a recordkeeping system for your HACCP plan.

Time and Temperature Controls (Chapters 7 and 12)

These chapters include time and temperature controls during transit, storage, cooling after cooking, and unrefrigerated processing of cooked, ready-to-eat products; raw, ready-to-eat products; and pasteurized products, such as crabmeat or histamine-forming fish.

When transit times are longer than four hours, check that:

- The product is accompanied by transport records that show temperature was maintained at or below 40 degrees Fahrenheit (F) **throughout transit**.
- If ice is used, check a representative number of products received to make sure they are adequately surrounded or covered by ice.
- If frozen gel packs are used, check a representative sample for the quantity and frozen status of the cooling media, and the internal temperature of the fish at receipt.

When transit times are less than four hours (Chapters 7 and 12):

- Check the internal temperature of a representative number of containers and products, as well as the transit time.

During refrigerated storage:

- Use a continuous, temperature-recording device and perform a visual check at least once a day.
- If ice is used, check a representative number of containers for adequate ice.
- Immersing the mechanical temperature sensor in a liquid is recommended to prevent minor fluctuations in temperature and to better reflect the actual temperature of the stored product.
- High-temperature alarms are no longer recommended for monitoring temperatures during storage or processing.

When processing under unrefrigerated conditions:

- There are time and temperature control options for handling raw, ready-to-eat and cooked, ready-to-eat products in Chapter 12, Table 12-5, Page 236. For example, during processing of cooked, ready-to-eat products such as crabmeat, the processor has a total of five hours to process the product (i.e., picking and packing), as long as the internal temperature of the crabmeat is held between 50 F and 70 F.
- If the product will be exposed to temperatures higher than 70 F, shorter time and temperature options are included in Table 12-5.

Monitoring a representative number of containers:

- The FDA Hazard Guide provides information about the number of representative containers, fish, and products to sample for monitoring internal product temperatures or quantity, and the adequacy of ice or gel packs at receiving and storage.

HACCP: Hazard Analysis and Critical Control Point, Training Curriculum, 6th edition



This book is the companion publication to the FDA's "Fish and Fishery Products Hazards and Controls Guidance," fourth edition. Use this book for training purposes.

To obtain a free, downloadable PDF version of the 6th edition of the training curriculum, go to www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm.

Accuracy and Calibration Frequencies of Temperature-Monitoring Devices (Throughout the Guide)

The following guidance is provided for accuracy checks and calibration frequencies of temperature-monitoring devices, such as thermometers.

Accuracy Checks

Before using the device for the first time:

- Immerse it in an ice slurry (32 F) if it's going to be used at cold temperatures.
- Immerse it in boiling water (212 F) if it's going to be used at or near the boiling point.
- Do a combination of the above if it will be used at or near room temperature.
- Compare the temperature reading against a National Institute of Standards and Technology (NIST) traceable thermometer.

For ongoing use:

Before use, check accuracy daily using one of the methods listed above or follow the calibration frequency recommended by the device manufacturer and the accuracy history of the device.

Calibration

- Perform annual calibration against an NIST-traceable thermometer using a two-temperature point method, “bracketing” the temperature at which the device is going to be used.
- Calibrate more frequently if recommended by the manufacturer.
- Maintain a log of these accuracy and calibration checks as part of the HACCP plan verification procedures.

Key Changes to Certain Seafood Hazards (Chapters 4, 6, 9, and 17)

Pathogens, Natural Toxins, and Environmental Chemicals in Molluscan Shellfish*

The primary processor bears the burden of proof for these hazards. Pathogens from the harvest area (Chapter 4) and natural toxins (Chapter 6) focus primarily on molluscan shellfish, including oysters, clams, mussels, and scallops (uneviscerated).

For control of environmental chemical hazards in molluscan shellfish and fish (Chapter 9), a reference to harvesting from approved harvest waters will suffice.

Chapter 17 introduces postharvest processing methods to reduce or eliminate certain pathogens from shellfish, primarily for the consumption of raw oysters.

Parasite Controls (Chapter 5)

Some additional seafood species with the potential for parasites have been included in Table 3-2, and additional parasites have been identified in Chapter 5. Processors for whom parasites are significant must exercise adequate controls or show proper documentation to assure that parasites have been controlled either at the primary or secondary processor or at the final retail level.

* Cross-reference these recommendations with those of the National Seafood Sector Council (NSSC) and the Interstate Shellfish Sanitation Conference (ISSC). Refer to the side panel for more information.

Web Resources for Seafood Processors

- Instructions for calibration and accuracy of thermometers:
Seafood Network Information Center – <http://seafood.oregonstate.edu/>
- Information on upcoming HACCP trainings:
Association of Food and Drug Officials – www.afdo.org/
Seafood Network Information Center – <http://seafood.oregonstate.edu/>
- NSSC and ISSC – www.issc.org/Contacts/Virginia.aspx
- Downloadable HACCP and sanitation templates, forms:
Seafood Network Information Center – seafood.oregonstate.edu/
- Online trainings:
Good Manufacturing Practices for Supervisors, offered by Cornell University (fee) – <https://institute-forfoodsafety.cornell.edu/>

**Virginia Seafood Agricultural
Research and Extension Center
in Hampton, Va.**

- Regional training center for seafood HACCP, seafood safety and quality, sensory evaluations, sanitation programs, Good Manufacturing Practices (GMP), food allergens, and more.
- Education and outreach programs offered in both English and Spanish.
- Thermal process validations, energy audits, machine vision, and composting.
- Food and environmental microbiological sampling, shelf-life evaluations, and new product development.
- Recirculating marine aquaculture, Good Aquaculture Practices, International Recirculating Marine Aquaculture Training Center.
- Business and marketing, community development, new value-added products.

Histamine Formation: Transit, Processing, and Storage Controls (Chapter 7)

The control strategies have not changed but additional details were added and should be carefully reviewed to ensure your HACCP plan effectively controls the hazard, as outlined by the revised guidance. The goal is to maintain product temperature at or below 40 F during transit, processing, and storage.

Harvest vessel records at receiving by primary processor:

Controls are based on harvest vessel records and a sensory examination for decomposition by a trained employee of a representative sample of fish (118 fish per lot) to assure proper onboard chilling and internal temperature.

No harvest vessel records at receiving by primary processor:

Controls are by sensory examination and the internal product temperature at receiving of a representative number of fish (i.e., more than 12 fish per lot), as well as histamine testing of a representative number of fish (18 fish per lot) taken at the anterior loin portion of the fish.

For time and temperature controls during transit, storage, cooling after cooking, and unrefrigerated processing, refer to the previous section.

Aquaculture Drugs (Chapter 11)

The primary processor is responsible for applying controls during production and transit. More approved drugs have been added. Transporting live fish is now recognized as a potential hazard, and controls are recommended during transit.

Seafood in Reduced-Oxygen Packaging (Chapter 13)

For refrigerated, raw, unpreserved fish and unpasteurized, cooked, fishery products, use either (1) packaging that provides an oxygen transmission rate (OTR) of at least 10,000 cubic centimeters per square meter (10,000 cc/m²) for 24 hours at 24 degrees Celsius (C); or (2) place a time and temperature indicator (TTI) on the smallest unit package (consumer-packaged size unit); or (3) conduct studies to evaluate the effectiveness of other preventive measures.

For frozen products packed in reduced-oxygen packaging, include a labeling statement for handling that reads “**Keep frozen until use. Thaw under refrigeration immediately before use.**” This can be monitored at the labeling step CCP.

Cooking and Pasteurization Controls (Chapter 16)

Chapter 16 covers controls for pasteurization and cooking based on the targeted organism. Cooking is based on a process to eliminate *Listeria monocytogenes*; pasteurization is based on a process to eliminate *Clostridium botulinum*.

Food Allergens and Other Additives (Chapter 19)

Fish and crustaceans are two of the eight major food allergens identified by the FDA. Control for allergens is recommended at the time when the label is applied to the product, rather than on receipt of the labels. The acceptable market name of the fish or crustacean (such as crab, lobster, or shrimp) is to be included on the label.

There is clarification as to when additives, such as sulfiting agents, need to be included in the ingredient list.

**For more information, visit our website at
www.ares.vaes.vt.edu/virginia-seafood/
or call 757-727-4861.**

www.ext.vt.edu

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