

Using the FDA's *Fish and Fishery Products Hazards and Controls Guidance* to Develop HACCP Plans for Fish and Fisheries Products¹

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This Ask IFAS document is the third in the *Seafood Guide* series and provides information to the seafood industry on how to develop a seafood HACCP plan effectively.

Title 21 Code of Federal Regulation – Part 123 includes seafood Hazard Analysis Critical Control Point (HACCP) regulation, which requires processors and importers of fish and fishery products to develop and implement a HACCP plan to maintain the safety of their products and prevent foodborne outbreak (FDA 2023). The United States Food and Drug Administration (FDA)'s *Fish and Fishery Products Hazards and Controls* guidance (Figure 1) is a comprehensive document that outlines the FDA's current recommendations for controlling seafood's process- and species-related hazards (FDA 2022). The FDA's guidance is an instrumental tool for developing a seafood HACCP plan. This Ask IFAS publication provides an overview of the guidance's format and how to use it effectively to develop a seafood HACCP plan. The PDF version of the guidance is available for free at [Florida Sea Grant](#) and [FDA's](#) websites. The printed version is available for [purchase](#) at the UF/IFAS Bookstore. The guidance also allows seafood processors and importers to use alternative approaches if the approaches meet the requirements of the applicable statutes and regulations.



Figure 1. FDA's *Fish and Fishery Products Hazards and Controls* guidance.

Credits: FDA's *Fish and Fishery Products Hazards and Controls* guidance.

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The Format of the FDA's Guidance

The FDA's guidance is updated intermittently to make sure its content reflects any updates in the regulation and science. The processors are responsible for updating their HACCP plan if any update in the guidance affects the hazards associated with their fish species and process. Page number style can help readers to distinguish updated contents from original contents in FDA's guidance. Figure 2 has provided examples of the page numbering formats. The chapters that have the original content show a "traditional" style of numbering (e.g., Chapter 4, p. 75) whereas chapters that have been updated have "- style" numbering (e.g., Chapter 9, p. 9-1).

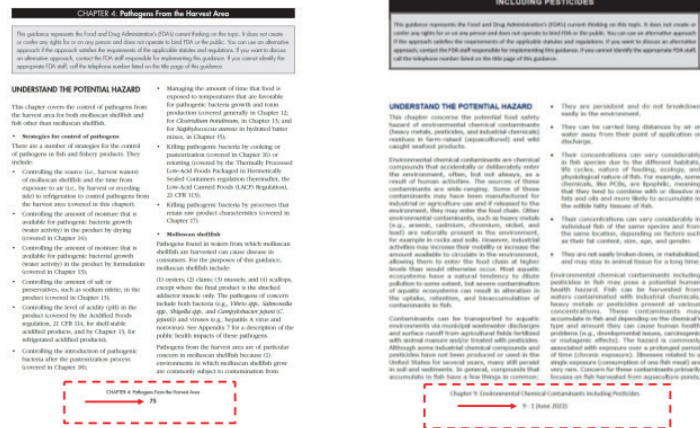


Figure 2. Examples of chapters' numbering formats of the *Fish and Fishery Products Hazards and Controls* guidance. Chapter 4 (left) is original whereas chapter 9 (right) has been updated. Credits: FDA's *Fish and Fishery Products Hazards and Controls* guidance.

The FDA's guidance document includes 21 chapters, 12 appendices, and 2 addendums. Table 1 includes the chapters, appendices, and their associated page number in the guidance document.

Notes on Chapter 3

The FDA's guidance has systematically divided the potential biological, chemical, and physical hazards into species- and process-related hazards in Chapter 3. Chapter 3 includes three tables for identifying species- and process-related hazards as follows:

1. *Table 3-2*, "Potential Vertebrate Species-Related Hazards," contains a list of potential hazards that are associated with specific species of vertebrates (species with backbones).
2. *Table 3-3*, "Potential Invertebrate Species-Related Hazards," contains a list of potential hazards that are associated with specific species of invertebrates (species without backbones).

3. *Table 3-4*, "Potential Process-Related Hazards," contains a list of potential hazards that are associated with specific finished fishery products, as a result of the finished product form, the package type, and the method of distribution and storage.

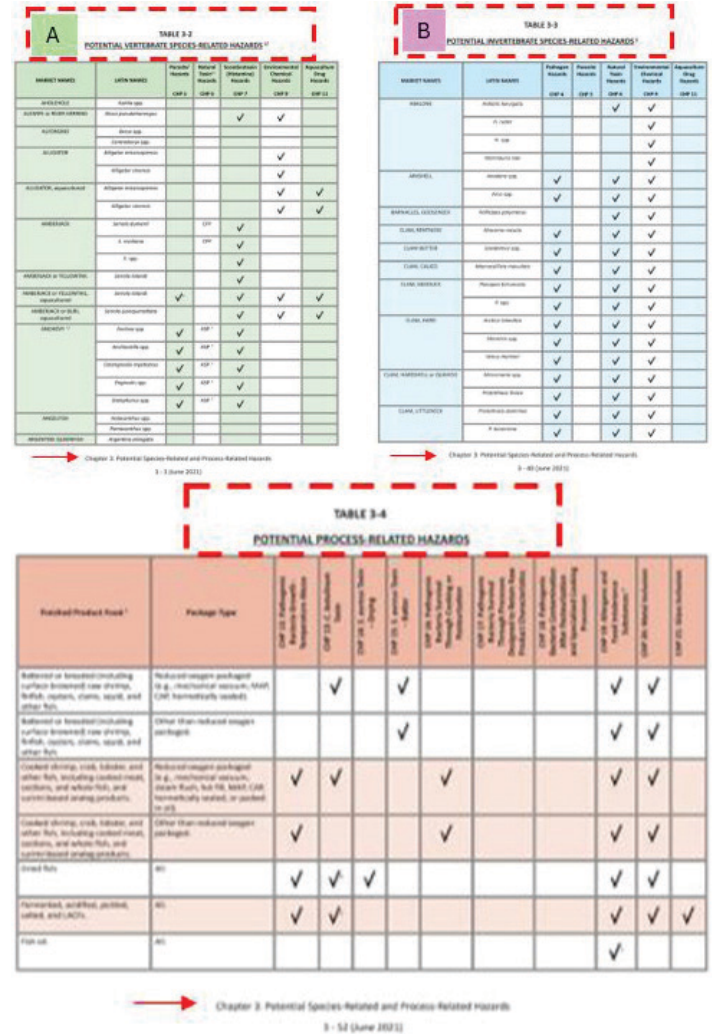


Figure 3. Chapter 3 (A and B) potential species-related hazards tables and (C) process-related hazards table. Credits: FDA's *Fish and Fishery Products Hazards and Controls* guidance.

These tables are in alphabetical order with the market names of the species. Seafood processors can also identify the market name of their products using the "FDA Seafood List" (FDA 2022).

Notes on Chapters 4 to 21

Chapters 4 to 21 of the FDA's guidance contain the information for various species- and process-related hazards. These chapters have the exact same format, and understanding the format is imperative for effective use of the guidance document. The sections of chapters of the guidance document are illustrated below, using Chapter 16, "Pathogenic Bacteria Survival Through Cooking or Pasteurization," as an example.

1. UNDERSTAND THE POTENTIAL HAZARD: This section includes background information about the hazard.

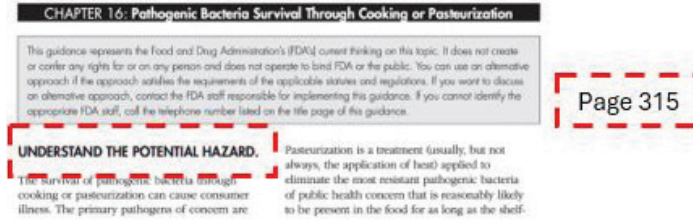


Figure 4. The introduction page for Chapter 16 of the FDA guidance document.
Credits: FDA's *Fish and Fishery Products Hazards and Controls* guidance.

2. DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT: Using this section, you can identify whether the potential hazard is significant and reasonably likely to happen.

3. IDENTIFY CRITICAL CONTROL POINTS: Use this section to identify if the potential hazard should be controlled at a specific step in the processing or not. Any step of the processing where the hazards should be controlled to prevent foodborne outbreak will be considered a CCP.

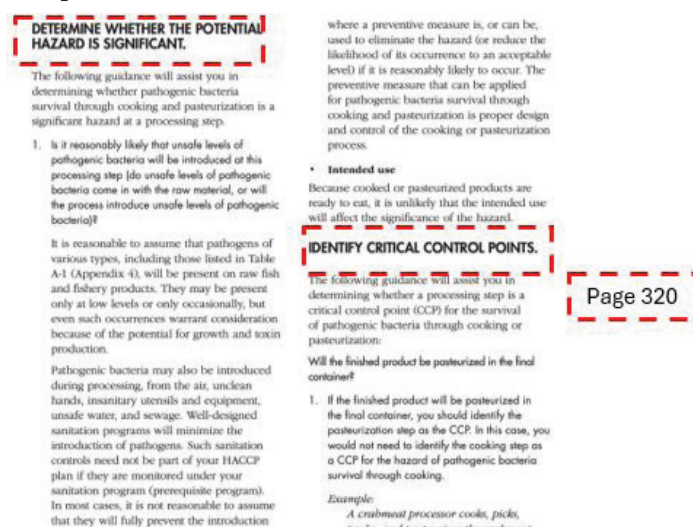


Figure 5. Chapter 16 sections for identifying significant hazards and Critical Control Points in the FDA guidance.
Credits: FDA's *Fish and Fishery Products Hazards and Controls* guidance.

4. DEVELOP A CONTROL STRATEGY: Using this section in each chapter, you can set critical limits for the species- or process-related hazard and establish your monitoring procedures, corrective actions, record-keeping system, and verification procedures.

Additionally, each chapter has an example of a portion of a HACCP plan for a specific control strategy that is provided at the end of chapter. These examples can be used as resources for developing the HACCP plan. However, the FDA's guidance text must be used to understand the full recommendation for developing the HACCP plan.

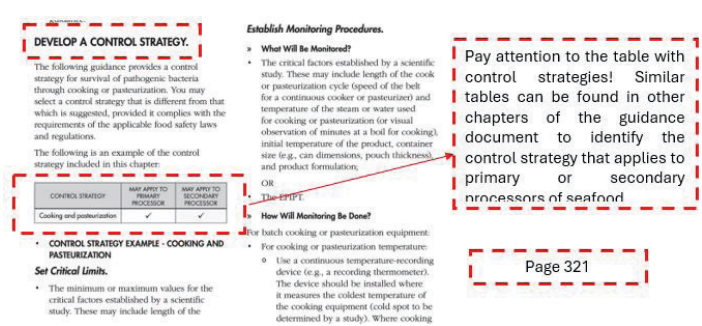


Figure 6. Chapter 16 sections for developing control strategy in the FDA guidance. Pay attention to the table with control strategies! Similar tables can be found in other chapters of the guidance document to identify the control strategy that applies to primary or secondary processors of seafood.
Credits: FDA's *Fish and Fishery Products Hazards and Controls* guidance.

TABLE 16-1

CONTROL STRATEGY EXAMPLE - COOKING AND PASTEURIZATION (COOKING MODE)

This table is an example of a HACCP plan for a continuous cooking and pasteurization process. It is provided for illustrative purposes only.

Pathogenic bacteria survival through cooking and pasteurization may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards to determine commonly used and additional pathogenic bacteria growth temperature ranges during processing, food and color additives, and metal leaching.

Example Only
See Text for Full Revisions/Modifications

CCP	IDENTIFY THE HAZARD	CRITICAL LIMITS FOR EACH IDENTIFIED HAZARD	MONITORING	CORRECTIVE ACTION	RECORD	VERIFICATION
Cooking	Pathogenic bacteria survival	Minimum cook time: 15 minutes	Visual observation with stopwatch	Stop line and alter rate and substitution	Cooking record	Randomly audit and verify the thermal process (verify substitution)
		Maximum cook temperature: 212°F (100°C)	Digital time and temperature data logger	Continuous, real-time check of recorded data every 30 seconds	Cooking record	Check the data logger for accuracy and compare with manual readings. If it is operational but not printing, stop operations, check it daily, or the beginning of operations, and confirm it runs per plan.
		Maximum storage rate of consumption	Storage rate	Visual and other sensory (see manual) for change or subtle adjustment	Cooking record	Check the data logger. Stop operations, check it daily, or the beginning of operations, and confirm it runs per plan.

*Note: The critical limits in this example are for illustrative purposes only and are not related to any recommended process.

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Figure 7. Chapter 16 HACCP plan example in the FDA guidance.
Credits: FDA's *Fish and Fishery Products Hazards and Controls* guidance.

How to Use the FDA's Guidance to Develop a HACCP Plan

The FDA's guidance document provides a series of 18 steps to seafood processors to conduct the hazard analysis and develop a HACCP plan. The corresponding Hazard Analysis Worksheet and HACCP plan form are developed by the Seafood HACCP Alliance and can be downloaded from Florida Sea Grant's website. However, there are no standardized forms, and seafood processors can use other forms as long as they have the required components for developing a HACCP plan. Figure 8 shows the overview of HACCP plan development steps.

Additional Information

1. When using tables in Chapter 3, pay attention to the superscripts in the table. These can affect your hazard identification. At the end of each table in Chapter 3, you can find the detailed description of each superscript. The example in Figure 9 shows the importance of these superscripts for hazard identification.

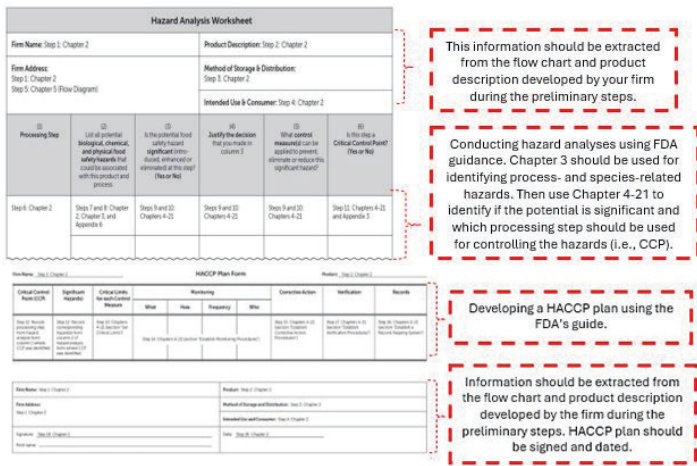


Figure 8. Overview of the HACCP plan development steps. Credits: FDA's *Fish and Fishery Products Hazards and Controls* guidance.

- When using Table 3-4 of the FDA's guidance for identifying the process-related hazards, pay attention to the packaging types because they can affect the process-related hazard identification.
- When developing a seafood HACCP plan, conduct a hazard identification for any other ingredients and processes that are involved in the production of fisheries products (e.g., rice acidification in sushi preparation, or ingredients such as egg and wheat for bread and battering the products).

Conclusion

The FDA's *Fish and Fishery Products Hazards and Controls* guidance is a resource that includes the agency's current thinking and recommendations for fish and fishery products processors and importers to develop and implement a HACCP plan. The guidance document can be used to identify the process- and species-related biological, chemical, and physical hazards, identify the CCP, and develop the seafood HACCP plan.

References

FDA. 2023. "CFR—Code of Federal Regulations Title 21." <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=120.6>

FDA. 2022. *Fish and Fishery Products Hazards and Controls*. Fourth edition. <https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls>

FDA. 2022. "Guidance for Industry: The Seafood List FDA's Guide to Determine Acceptable Seafood Names." <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-seafood-list-fdas-guide-determine-acceptable-seafood-names>

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS¹⁷

MARKET NAMES	LATIN NAMES	Parasitic Hazards	Natural Toxin ⁴	Scrombrotoxin (Histamine) Hazard ⁴	Environmental Chemical Hazards	Aquaculture Drug Hazards
		CHP 5	CHP 6	CHP 7	CHP 9	CHP 11
GRUNION	<i>Leuresthes tenuis</i>					
GRUNT	<i>Anchoa mitchilli</i>					
	<i>Conionca nobilis</i>					
	<i>Micropogonias undulatus</i>					
	<i>Orthopristis chrysoptera</i>					
	<i>Pomadasys commersonnii</i>					
GRUNT or CARALINA	<i>Anchoa hepsetus</i>					
GRUNT or MARGATE	<i>Anchoa hepsetus</i>					
	<i>Anchoa hepsetus</i>					
GRUNT or SHEETLIPS	<i>Plectrobelone sp.</i>					
HAZDOCK	<i>Melanogrammus aeglefinus</i>					
HAKE	<i>Urophycis sp.</i>					
HALIBUT	<i>Hippoglossus spp.</i>	✓				
HALIBUT, aquaculture	<i>Hippoglossus spp.</i>	✓			✓	✓
HALETTY SKIFFTON	<i>Ambloplites castris</i>					

TABLE 3-2
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS¹⁷

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Pay attention to superscripts 17 and 4 for descriptions provided below.

ACKNOWLEDGMENTS: ASP = Atlantic Seafood Processing; GFP = Gulf of Mexico Fish Processing; GPP = Gulf of Mexico Fish Processing; MT = Mid-Atlantic Fish Processing; PFP = Parasitic Fish Processing; and PPF = Parasitic Fish Processing.

FOOTNOTES:

- This hazard does not apply to offshore catch (e.g., areas not subject to domestic containment (discharge)) because that the species listed is associated with this species only in the Eastern Pacific Ocean.
- This hazard applies where the processor has knowledge or has reason to know that the parasite containing fish is likely to be consumed without a process sufficient to kill the parasite, or where the processor, importer, dealer, or retailer for the product to be so consumed.
- Species that normally have a parasite hazard as a result of consuming infected prey apparently do not have the same parasite hazard when caught only on a particular boat in an aquaculture operation. See Chapter 3 for further information.
- This hazard only applies if the product is marketed uncooked.
- American, yellowtail, Spanish mackerel, king mackerel, and other scrombrotoxin-forming fish are sometimes marketed incorrectly as halibut.
- The scientific name for this species has changed since the previous edition of the guidance.
- The market name for this species has been changed since the previous edition of this guidance.
- This hazard does not apply to products intended for animal feed or fish oil products but does apply to products intended for direct human consumption of the muscle and to species components, such as fish protein concentrates that are to be used as food additives.
- This hazard only applies to food products for human consumption, such as fish proteins used as dietary ingredients.
- Parasitic fish.
- PFH has been associated with fish from the sea coast of Florida specifically in the following counties: Volusia, Brevard, Indian River, St. Lucie, and Martin.
- There have been no reported outbreaks or PFH diseases associated with this species as of May 2016.
- Salmonella is the only species to be affected for importation from Japan based on the agreement between US FDA and the government of Japan.
- Other National Marine Fisheries Service may be applicable to this species. Refer to Chapter 3 for distribution.
- Many of the fish and fisheries of fish listed in this table have been identified with specific natural marine toxins as a result of illnesses/outbreaks which have occurred or have been identified through research. For further information regarding each toxin refer to Chapter 3 and its references.
- The toxin has been identified through an FDA research project. However, the toxin levels found do not exceed the established guidance levels and/or have not been associated with illnesses.
- Other National Marine Fisheries Service may be applicable to this species. Refer to Chapter 3 for distribution.
- FDA recommends consuming these species of fish only as appropriate.
- This hazard only applies to fish from the harvest area as a potential species-related hazard if you suspect, label, or intend for the product to be so consumed. See Chapter 4 for guidance on controlling pathogens from the harvest area.

Figure 9. Explanation of superscripts 4 and 17 in Chapter 3 tables in the FDA guidance. Based on the superscript 4 description, a parasite is listed as a potential hazard for aquaculture halibut, but that hazard is shown to get introduced to the fish via consumption of infected prey in the wild. It is not a hazard for fish raised in an aquaculture setting with pelleted feed. Based on superscript 17, a pathogen from the harvest area is a potentially significant hazard if the product is ready to eat raw. If the intended use of the product is to be cooked by consumers, pathogens from the harvest area should not be considered a species-related hazard. Credits: FDA's *Fish and Fishery Products Hazards and Controls* guidance.

CHAPTER 16: Pathogenic Bacteria Survival Through Cooking or Pasteurization

This guidance represents the Food and Drug Administration's (FDA) 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.

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UNDERSTAND THE POTENTIAL HAZARD. The survival of pathogenic bacteria through cooking or pasteurization can cause consumer illness. The primary pathogens of concern are:

Pasteurization is a treatment (usually, but not always, the application of heat) applied to eliminate the most resistant pathogenic bacteria of public health concern that is reasonably likely to be present in the food for as long as the shelf-

Figure 10. FDA guidance for process-related hazards table indicating that different package types can affect the hazard identification. Credits: FDA's *Fish and Fishery Products Hazards and Controls* guidance.

Table 1. FDA's *Fish and Fishery Products Hazards and Controls* guidance sections and page numbers since last updated in June 2022.

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