

# ***Fish and Fishery Products Hazards and Controls Guidance Updates***

**AGSTC**

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# Overview

- The *Fish and Fishery Products Hazards and Controls Guidance* document
- 4<sup>th</sup> Edition Updates
- Purpose of the *Fish and Fishery Products Hazards and controls Guidance*
- Future Publications



# *Fish and Fishery Products Hazards and Controls Guidance*

- First published through the Federal Register – February 1997
- Created as adjunct to the 21 CFR Part 123
- Fourth Edition was published in April 2011
- Living document as of August 2019



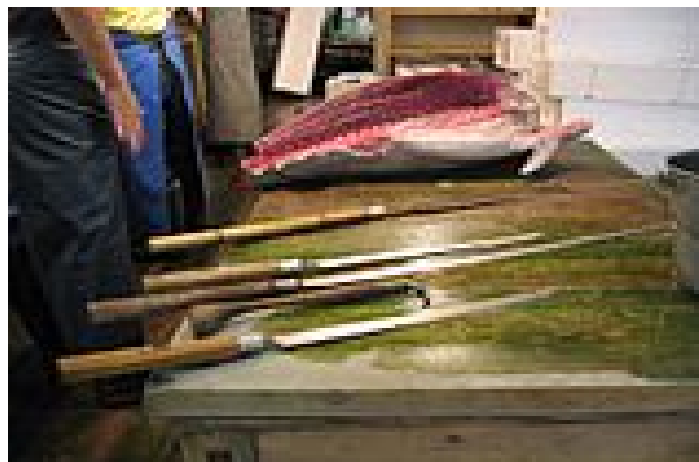
# *The Guide IS:*

- A compendium of controls and practices that serve as recommendations and guidance for the fish and fishery products industry to identify hazards and develop a HACCP plan based on individual practices and processes
- Information provided by FDA is based on ORDINARY circumstances of seafood practices and processes.



# *The Guide Is NOT:*

- *The Guide* is not a binding set of requirements:
  - Processors may choose to use other control measures, as long as the measures provide an equivalent degree of assurance that the product will be safe.
- *The Guide* is not a substitute for the performance of a hazard analysis
- *The Guide* does not cover every situation
- *The Guide* does not restrict flexibility with the development of hazard controls.
- *The Guide* is NOT all inclusive.





# *The Guide* 4<sup>th</sup> Ed August 2019

- *The Guide* Name
- Table of Contents
- The Guidance to Industry
- Appearance of tables
- Chapter 3: Potential Species-Related and Process-Related Hazards
- Chapter 6: Natural Toxins
- Chapter 19: Undeclared Major Food Allergens and Food Intolerance Substances
- Appendix 5 – FDA and EPA Safety Levels in Regulations and Guidance
- **NEW** Appendix 9 – Allergen Cleaning and Sanitation
- **NEW** Appendix 10 – Allergen Cross-Contact Prevention

# Guidance to Industry

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:

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

# Table Appearances

**TABLE 3-2  
POTENTIAL VERTEBRATE SPECIES-RELATED HAZARDS<sup>17</sup>**

MARKET NAMES	LATIN NAMES	Parasite <sup>3</sup> Hazards	Natural Toxin <sup>13</sup> Hazards	Scombrotoxin (Histamine) Hazards	Environmental Chemical Hazards	Aquaculture Drug Hazards
		CHP 5	CHP 6	CHP 7	CHP 9	CHP 11
AHOLEHOLE	<i>Kuhlia</i> spp.					
ALEWIFE or RIVER HERRING	<i>Alosa pseudoharengus</i>			✓	✓	

**TABLE 6-1**

**Control Strategy Example 1 – SOURCE CONTROL FOR FISH OTHER THAN MOLLUSCAN SHELLFISH**

This example table illustrates a hypothetical application of the control strategy just presented in “Control Strategy Example 1 – Source Control for Fish Other Than Molluscan Shellfish.” The example illustrates the basic control for natural toxins by a primary processor receiving locally harvested grouper. It is provided for illustrative purposes only.

Natural toxins may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential species or process related hazards.

**Example Only: See Text for Full Recommendations**

(1)	(2)	(3)	(4) (5) (6) (7) Monitoring				(8)	(9)	(10)
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification
Receiving fresh fish - Grouper	Natural toxins - ciguatoxin	Grouper may not be received when a harvest location is under a regulatory or	Harvest vessel records to ensure harvest locations are not identified	Visual examination of harvest vessel records for harvest	Records for every lot of grouper received	Receiving employee with knowledge of harvest	Reject lot  Discontinue use of the supplier until evidence	Receiving record	Review monitoring and corrective action records within 1 week



# Appendix 5: FDA and EPA Safety Levels in Regulations and Guidance

TABLE A-5  
 FDA AND EPA SAFETY LEVELS IN REGULATIONS AND GUIDANCE

## NATURAL TOXINS

Products	Levels	References
Bivalve shellfish <sup>11</sup>	Azaspiracid <sup>2, 6</sup> (Azaspiracid Shellfish Poisoning (AZP)): <ul style="list-style-type: none"> <li>≥ 0.16 mg/kg azaspiracid-1 equivalents (i.e., combined azaspiracid-1, -2, and -3)</li> </ul>	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish
Clams, mussels, oysters, and whole and roe-on scallops, fresh, frozen, or canned <sup>11</sup>	Brevetoxin <sup>5, 6</sup> (Neurotoxic Shellfish Poisoning (NSP)): <ul style="list-style-type: none"> <li>≥ 0.8 mg/kg (20 mouse units/100 g) brevetoxin-2 equivalent or 5,000 cells/L</li> </ul>	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish
Finfish (primarily reef fish)	Ciguatoxin <sup>4</sup> (Ciguatera Fish Poisoning (CFP)): <ul style="list-style-type: none"> <li>Caribbean ciguatoxins: ≥ 0.1 µg/kg Caribbean</li> </ul>	Dickey, R.W. and S.M. Plakas. 2010. Ciguatera: A public health perspective. <i>Toxicol</i> 56(2): 123-136.

# *The Guide* 4<sup>th</sup> Ed March 2020

- *The Guide* Name
- The Guidance to Industry
- Table of Contents
- Appendix 5: FDA and EPA Safety Levels in Regulations and Guidance

# *The Guide* 4<sup>th</sup> Ed June 2021

- *The Guide* Name
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- Chapter 3: Potential Species-Related and Process-Related Hazards
- Chapter 11: Aquaculture Drugs
- **NEW** Appendix 11: Approved Drugs
- **NEW** Appendix 12: Unapproved Drugs

# *The Guide* 4<sup>th</sup> Ed June 2021 (cont.)

- Appendix 1: Forms
- Appendix 2: Sample Product Flow Diagram
- Appendix 3: Critical Control Point Decision Tree
- Appendix 8: Procedures for Safe and Sanitary Processing and Importing of Fish and Fishery Products
- **NEW** Addendum 1: Fish and Fishery Products (21 CFR 123) and Control of Communicable Diseases (21 CFR 1240.60)
- **NEW** Addendum 2: current Good Manufacturing Practices (cGMP)

# Future Publications

- We consider *The Guide* a living document moving forward
- Updates will be published as they are prepared
- *The Guide* has been published as a peer reviewed document. That will continue.
- Federal Register Notification
- List Serve Notification



# Edits Post Publication



- Edits Post Publication
- Reposting after editing
- Announcement of corrected Chapters/Appendixes

# FDA Seafood Information

- Website
  - [www.fda.gov/seafood](http://www.fda.gov/seafood)
- Subscribe to Seafood Safety Updates
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# THANK YOU





