## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

# Food and Drug Administration

#### 21 CFR Parts 123 and 1240

[Docket No. 93N-0195]

RIN 0910-AA10

# Procedures for the Safe and Sanitary Processing and Importing of Fish and **Fishery Products**

AGENCY: Food and Drug Administration,

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is adopting final regulations to ensure the safe and sanitary processing of fish and fishery products (hereinafter referred to as seafood), including imported seafood. The regulations mandate the application of Hazard Analysis Critical Control Point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control that can be used by processors to ensure the safety of their products to consumers. FDA is issuing these regulations because a system of preventive controls is the most effective and efficient way to ensure that these products are safe.

**DATES:** Effective December 18, 1997. Submit written comments on the information collection requirements by February 16, 1996.

**ADDRESSES:** Submit written comments on the information collection requirements to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857

## FOR FURTHER INFORMATION CONTACT:

Philip C. Spiller, Center for Food Safety and Applied Nutrition (HFS-401), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3133.

For further information concerning the guidance entitled "Fish and Fishery Products Hazards and Controls Guide, contact: Donald W. Kraemer (address above).

SUPPLEMENTARY INFORMATION: The contents of this preamble are listed in the following outline:

Table of Contents

- I. Background
  - A. The Proposal
  - B. Factual Basis for the Proposal— Summary
- II. The Comments
  - A. Legal Basis
  - 1. Introduction
  - 2. General Authority
  - 3. Insanitary Conditions

- 4. Records
- 5. Relevance of Section 404 of the Act
- B. HACCP Pro and Con
- 1. Overview
- 2. The Significance of the Illness Data
- 3. Exempt Specific Industry Segments?
- 4. Would Voluntary HACCP be Superior?
- 5. Other Issues
- C. Should Some Types of Processors be Exempt?
- 1. Exempt Low Risk?
- 2. Exempt Small Processors?
- D. Definitions
- General
- 2. Cooked, Ready-to-Eat Fishery Product
- 3. Critical Control Point (CCP)
- 4. Critical Limit (CL)
- 5. Fish
- 6. Fishery Product
- 7. Food Šafety Hazard
- 8. Harvester
- 9. Importer
- 10. Lot of Molluscan Shellfish
- 11. Molluscan Shellfish
- 12. Potable Water
- 13. Preventive Measure
- 14. Process Monitoring Instument
- 15. Processing and Processor
- a. Vessels, carriers, and retail
- b. Warehouses
- c. Other processing operations
- 16. Scombroid Toxin Forming Species
- 17. Shellfish Control Authority
- 18. Smoked and Smoke-Flavored Fishery **Products**
- E. The HACCP Plan
- 1. Preliminary Steps
- 2. Conducting a Hazard Analysis
- 3. Types of Hazards
- 4. When is a Hazard Reasonably Likely to Occur?
- 5. The Plan: Specific Considerations
- 6. Positive Versus Negative Recordkeeping
- Signing the Plan
- 8. Relationship to Parts 113 and 114
- 9. Sanitation in the Plan
- 10. Nonsafety Issues
- 11. "Shall Render Adulterated"
- F. Corrective Actions
- 1. Should Corrective Actions be Predetermined?
- 2. Assessing the Product for Safety
- 3. Documenting Corrective Actions
- G. Verification
- 1. Overview and Comments
- 2. Need for Verification Requirement in Regulations
- 3. Verifying the HACCP Plan
- 4. Verifying the Implementation of the Plan
- 5. Product Testing
- 6. Records Review
- 7. Verifying the Hazard Analysis
- H. Consumer Complaints
- 1. Background
- 2. Consumer Complaints as Verification Tools
- 3. Agency Access to Consumer Complaints
- I. Records
- 1. Details and Signatures
- 2. Retention and Storage
- 3. Confidentiality of Records
- 4. Agency Access to Records
- 5. Agency Copying of Records
- J. Training
- 1. The Need for Mandatory Training
- 2. Who Should Provide Training?

- 3. Should Training be "Grandfathered?"
- 4. Course Curriculum
- 5. Do Importers Need Training?
- 6. Testing and Retraining
- 7. Gradations of Training
- 8. Duties of the Trained Individual
- K. Sanitation
- 1. Background
- 2. Should the Regulations Deal with Sanitation?
- 3. Why Isn't Part 110 (21 CFR Part 110) Adequate to Deal with Sanitation Concerns?
- 4. Why Isn't the Proposed Approach Appropriate?
- 5. What is the Appropriate Approach to Sanitation?
- a. Inclusion of Sanitation Controls in **HACCP Plans**
- 6. Monitoring and Corrective Actions
- 7. Records
- L. Imports
- 1. Background
- 2. Should Imports be Subject to These Regulations?
- Should Importers be Subject to These Regulations?
- 4. Memoranda of Understanding (MOU's)
- 5. Importer Verification Procedures
- 6. Affirmative Steps: General
- 7. Foreign Processor HACCP Plans
- 8. Other Affirmative Steps
- 9. Importer Records
- 10. Determination of Compliance
- M. Guidelines or Regulations?
- 1. Background
- 2. Cooked, Ready-to-Eat Products and Scombroid Species
- 3. Smoked and Smoke-Flavored Fishery Products
- N. Molluscan Shellfish
- 1. Background
- 2. Should There be Specific Requirements for Raw Molluscan Shellfish?
- 3. Cooked Versus Raw Molluscan Shellfish
- 4. Shellfish Control Authorities
- 5. Shellfish From Federal Waters
- 6. Tagging and Recordkeeping Requirements
- 7. Other Considerations
- O. Compliance and Effective Date
- 1. Effective Date
- 2. Public Meetings
- 3. Penalties for Noncompliance 4. Preapproval of HACCP Plans
- 5. Filing Plans With FDA6. Third Party-Approval
- 7. The First Inspection
- 8. Role of the FDA Investigator
- 9. Disagreements and Appeals
- 10. Status of the "Guide"
- 11. Trade with the EU
- 12. Measuring Program Success
- P. Other Issues
- 1. Relationship to Other Programs
- "Whistleblower" Protection 3. Separation of Quality Control (QC) and
- Production
- 4. Education
- 5. Traceback Mechanisms 6. Tribal Governments
- 7. HACCP System Improvements
- III. Paperwork Reduction Act of 1995
- IV. Economic Impact
- A. Introduction