



Seafood HACCP

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July 21, 2011



"Seafood HACCP Regulation"

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

21 CFR 123

- Proposed: March 3, 1994
- Final rule: December 18, 1995
- Implementation: December 18, 1997



Why 2 years for Implementation?

- Industry – Processors, domestic and foreign
- FDA – Inspection system
- Industry - Importers

SGR 129

Fish and Fishery Products
Hazards and Controls Guidance
Fourth Edition - APRIL 2011



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
OFFICE OF FOOD SAFETY



Fish and Fishery Products Hazards and Controls Guidance

4th Edition - April 2011



"Guidance" Disclaimer

This guidance represents the agency's current thinking on the hazards associated with fish and fishery products and appropriate controls for those hazards. ... An alternative approach may be used if such approach **satisfies the requirements** of the applicable statute and regulations.



Application to Imports

FOOD AND DRUG ADMINISTRATION
COMPLIANCE PROGRAM GUIDANCE MANUAL

PROGRAM

7303.844

CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

SUBJECT:

IMPORT SEAFOOD PRODUCTS COMPLIANCE PROGRAM

IMPLEMENTATION DATE

July 1, 2010

COMPLETION DATE

Continuing

DATA REPORTING

PRODUCT CODES

PRODUCT/ASSIGNMENT CODES

INDUSTRY CODE 16, USE APPROPRIATE
PRODUCT CODES

1. REPORT INSPECTIONS UNDER THE
FOLLOWING PACS:
03844H HACCP Inspection of
Importers



Risk Prioritization

- Refrigerated seafood products packed in Reduced Oxygen Packaging (ROP) (e.g., vacuum packaging, modified atmospheric packaging, hermetically sealed containers)
- Raw (fresh and fresh frozen) molluscan shellfish from uncertified shippers



Risk Prioritization

- Ready-to-eat fish or fishery products using any of the following processes:
 - (1) cooking or pasteurization process (e.g., cooked shrimp, crabmeat, cooked lobster, cooked crayfish, pasteurized crabmeat, surimi-based analogs, etc.)
 - (2) hot or cold smoking process



Risk Prioritization

- Seafood mixes: Combination of seafood products either all raw, all cooked, or a mixture of raw and cooked product
- Scombrototoxin-forming (histamine-forming) species
- Aquacultured seafood
- Stuffed seafood products



Risk Approach

- Ready-to-eat fish or fishery products that have not undergone a heat treatment
- Salt-cured, and/or air-dried, un-eviscerated fish, such as Kapchunka, or bloaters
- Acidified and low acid canned foods (LACF)



Warning Letter to Foreign Supplier

... a representative of the United States Food and Drug Administration (FDA) conducted an inspection of a fish and fishery products importer in the United States: ... That importer was found to be importing Frozen Cooked Shrimp from your processing facility. **During the inspection of that importer**, we collected a copy of your firm's HACCP plan for your "Frozen Cooked shrimp". **Our evaluation of that HACCP plan** (copy attached) revealed serious deviations from the requirements of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123).



Warning Letter to Importer

...we **inspected your seafood importer establishment**, We found that you have a serious violation of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation As an importer of fish or fishery products, you must operate in accordance with the requirements of Part 123. In accordance with 21 CFR 123.12(d), there must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with 21 CFR Part 123. **If assurances do not exist** that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under 21 CFR Part 123, the fish or fishery products **will appear to be adulterated** under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4) and **will be denied entry**. Because our inspection identified a serious violation for 21 CFR Part 123, your fresh and pasteurized crabmeat are adulterated under Section 402(a)(4) of the Act (21 U.S.C. § 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

Your significant violation is as follows:

1. You must implement an affirmative step which ensures that the fish and fishery product(s) you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for fresh and pasteurized crabmeat from **[redacted]**.



Import Alerts

- Import Alert #16-120
 - Detention Without Physical Examination of Fish/Fishery Products from Foreign Processors (Mfrs.) Not in Compliance with Seafood HACCP
- Import Alert # 16-119
 - Detention Without Physical Examination Of Fish And Fishery Products For Importer And Foreign Processor (Manuf) Combinations



Seafood HACCP

21 CFR 123.6

(a) *Hazard analysis.*

(b) *The HACCP plan*

21 CFR 123.12 –
Special
Requirements for
Imported Products

FSMA

Sec. 103

(b) Hazard Analysis

(c) Preventive Controls

Sec. 301 Foreign
supplier Verification
Program



Importer Requirements

- Written Import Verification Procedures:
 - specifications that are designed to ensure that all imported products are not adulterated as defined by the Act.
 - affirmative steps that will be taken to ensure that products being offered for entry are actually produced under controls that meet U.S. Seafood HACCP regulations.
 - the maintenance of records documenting the affirmative steps taken.



Options for Affirmative Steps

- Obtain foreign processor HACCP and sanitation monitoring records for each lot.
- Obtain either a continuing or lot-by-lot certificate from the foreign government inspection authority or competent third party certifying that the product was processed in accordance with the HACCP regulations.
- Regularly inspect the supplier's processing facilities to ensure that the product is processed in accordance with the HACCP regulation.
- Maintain a copy of the processor's HACCP plan along with a written guarantee that the product is processed in accordance with the regulation.
- Periodically test the imported seafood products and maintain a written guarantee that product is processed in accordance with the regulation.



Thank you