U.S. FOOD & DRUG ADMINISTRATION

Guidance on the Control of Marine Biotoxins in Seafood Intended for Interstate Commerce

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Center for Food Safety & Applied Nutrition

U.S. FOOD & DRUG ADMINISTRATION

FDA Mission

The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

CFSAN is responsible for ensuring the nation's seafood supply, both domestic and imported, is safe, sanitary, wholesome, and honestly labeled.

Division of Seafood Safety Functional Statement

- Develop regulations, guidance, policy, programs, position papers and advisory opinions, and recommend research priorities;
- Examine and appraise implementation of regulations, domestic and foreign programs, and bilateral agreements;
- Review industry petitions and regulatory activities; provide expert scientific testimony to support the actions; and provide technical review of laboratory analyses supporting proposed enforcement actions;
- Provide expert advice to the Center Director, Deputy Center Directors, and other key Agency and government officials, and serves as principal liaison to industry, international and other organizations; and
- Develop model regulations, and provide scientific/technical support, training, evaluation and certification for State and international shellfish programs.

Regulations

- **Federal Food, Drug, and Cosmetic Act (FD&C)**
  - Sec. 402 Adulterated Food
  - Sec. 403 Misbranded Food
  - Sec. 801 Imports and Exports
- **Code of Federal Regulation (21 CFR)**
  - Part 117 Subpart B Current good manufacturing practice
  - Part 113 Thermally processed low-acid foods packages in hermetically sealed containers
  - Part 114 Acidified foods
  - Part 123 Fish and fishery products (Seafood HACCP)
  - Part 161 Fish and shellfish standards of identity

Seafood HACCP

- Hazard Analysis Critical Control Point
- Preventive system of hazard control that can be used by processors to ensure the safety of their products and reduce the risk of illness for consumers
- Published December 1995
- Effective December 1997
- Every processor must conduct a hazard analysis
- Every processor must have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazard(s) that is/are likely to occur

Seafood HACCP:

- Applies to
  - domestic processors of products intended for consumption in the United States
  - foreign processors of products intended for consumption in the United States
  - importers
    - U.S. owner
    - Consignee at time of entry
    - U.S. representative of foreign owner/consignee

- Failure to apply HACCP causes the seafood processed under those conditions to be adulterated under Section 402(a)(4) of the FD&C Act

Fish and Fishery Products Hazards and Controls Guidance

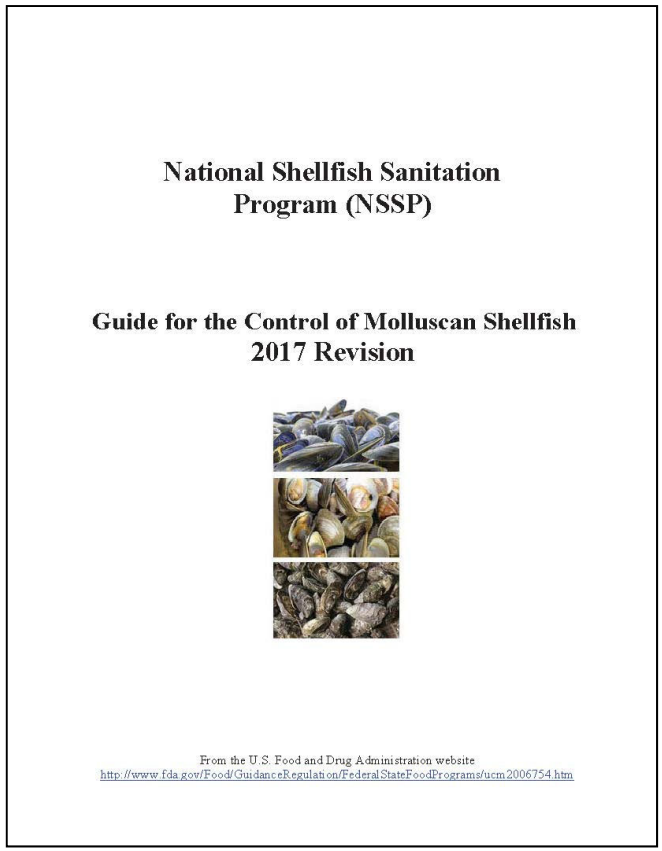
- 4th Edition – April 2011
  - Individual chapter updates
- Assist processors in the development of HACCP plans
  - Identify product hazards and formulate control strategies
- Help consumers and public understand commercial seafood safety in terms of hazards & controls
- Serve as a tool for federal & state regulatory officials in HACCP plan evaluation

Interstate Shellfish Sanitation Conference

- Fosters and promotes shellfish sanitation through cooperation of
  - FDA, NOAA (NMFS), EPA, states, industry, academia
- Shellfish covered
  - oysters, clams, mussels [scallops, except when adductor only]
  - shucked or in shell, raw (including PHP), frozen or unfrozen, whole or in part
- http://www.issc.org

National Shellfish Sanitation Program

- Cooperative program for the sanitary control of shellfish
- Guide for the Control of Molluscan Shellfish
  - http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm
- Includes guidance levels and methods for HAB toxins and pathogens in shellfish


National Shellfish Sanitation Program (NSSP)

Guide for the Control of Molluscan Shellfish
2017 Revision

From the U.S. Food and Drug Administration website
http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm

Marine Biotoxin Guidance Levels

- **Paralytic Shellfish Poisoning (PSP)**

  ≥ 80 µg/100 grams

- **Neurotoxin Shellfish Poisoning (NSP)**

  ≥ 0.8 mg/kg BTX-2 eq (20 MU/100 grams); 5,000 *Karenia brevis* cells/L

- **Azaspiracid Shellfish Poisoning (AZP)**

  ≥ 0.16 mg/kg AZA-1 eq

- **Diarrhetic Shellfish Poisoning (DSP)**

  ≥ 0.16 mg/kg total okadaic acid eq

- **Amnesic Shellfish Poisoning (ASP)**

  ≥ 20 mg/kg domoic acid

  > 30 mg/kg domoic acid for Dungeness crab viscera

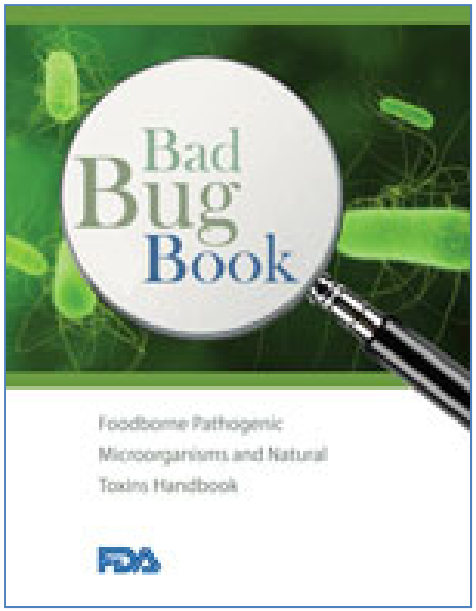
- **Ciguatera Fish Poisoning (CFP)**

  ≥ 0.01 g/kg P-CTX-1 eq

  ≥ 0.1 µg/kg C-CTX-1 eq

Human Health Effects

- PSP
  - Tingling, numbness, paralysis, respiratory paralysis
- ASP
  - Confusion, short-term memory loss, seizures, diarrhea
- NSP
  - Tingling, numbness, aches, vomiting, diarrhea
- DSP
  - Gastrointestinal symptoms, chills, headache, fever
- AZP
  - Nausea, vomiting, diarrhea, abdominal cramps
- CFP
  - Nausea, vomiting, diarrhea, numbness, tingling, itching, sensitivity to temperature extremes, cardiovascular symptoms



Marine Biotoxin Control in Seafood

- Seafood (Non-Bivalves) – Seafood HACCP
- Specific Ciguatera Guidance
  - Recommend that primary processors not obtain known ciguatera fish species from regions known to have or are considered emerging for ciguatera
- www.fda.gov/seafood

Growing Area Classification: Biotoxins

Section II Model Ordinance

Chapter IV Shellstock Growing Areas

@.03 Growing Area Classification

A(5) May be in closed status because of the presence of biotoxins and shall be returned to the open status when @.04 conditions are met

B(1) Approved classification – growing area is not contaminated with marine biotoxins

@.04 Marine Biotoxin Control

B(4) Except the Authority shall classify as prohibited growing areas where shellfish are highly or frequently affected by biotoxins that the situation cannot be safely managed; may use conditionally approved classification for areas affected by biotoxins

Marine Biotoxin Management

Section II Model Ordinance
Chapter IV Shellstock Growing Areas

@.04 Marine Biotoxin Control

B. Marine Biotoxin Management Plan

- Areas implicated in an illness outbreak or where toxin-producing phytoplankton are known to occur
- Toxins are prone to accumulate in shellfish
- When toxins are reasonably likely to occur
- Representative water/shellfish samples shall be collected during harvest periods
  - Water samples analyzed for toxin-producing phytoplankton
  - Shellfish samples tested for biotoxins

~Traditional Routine Monitoring Program

Marine Biotoxin Management

Section II Model Ordinance

Chapter IV Shellstock Growing Areas

@.04 Marine Biotoxin Control

B. Marine Biotoxin Management Plan

(1) Authority shall develop a marine biotoxin management plan.

(2) Plan shall define procedures and resources to:

- Maintain a routine shellfish sampling and assay program;*
- Close growing areas and embargo shellfish;
- Prevent harvesting of contaminated species;
- Provide for product recall;
- Disseminate toxic algal information to adjacent states, shellfish industry, and local health agencies;
- Coordinate actions by Authorities and federal agencies; and
- Establish reopening criteria.

Marine Biotoxin Management

Section II Model Ordinance

Chapter IV Shellstock Growing Areas

@.04 Marine Biotoxin Control

B. Marine Biotoxin Management Plan

- Maintain a routine shellfish sampling and assay program:
- Establishment of:
  - appropriate shellfish screening levels;
  - Appropriate shellfish screening/testing methods;
  - Appropriate laboratories/analysts to conduct shellfish screening and testing methods;
  - A sampling plan;
  - Other controls as necessary.

Marine Biotoxin Management

Section II Model Ordinance

Chapter IV Shellstock Growing Areas

@.04 Marine Biotoxin Control

B. Marine Biotoxin Management Plan

(3) The Authority may use precautionary closures

- Based on screening or phytoplankton sampling results, as described in the management plan.
- The precautionary closures may be lifted:
  - If confirmatory testing using an approved method shows shellfish biotoxins are not ≥ established criteria; or
  - When screening or phytoplankton sample results indicate that the precautionary closure was not necessary.

Marine Biotoxin Management

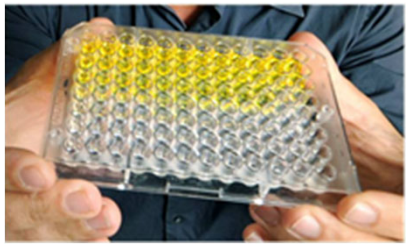
Section II Model Ordinance Chapter IV Shellstock Growing Areas

@.04 Marine Biotoxin Control

B. Marine Biotoxin Management Plan

(5) States may allow controlled harvesting in designated parts of closed areas through agreements and MOUs.

- With strict assurances of safety
- Requires pre-harvest screening
  - Establish screening levels, screening methods, labs/analysts, representative sampling plan
- And end product testing
  - Establish end product testing methods, labs/analysts, representative sampling plans
- Establish other controls as necessary



Marine Biotoxin Management

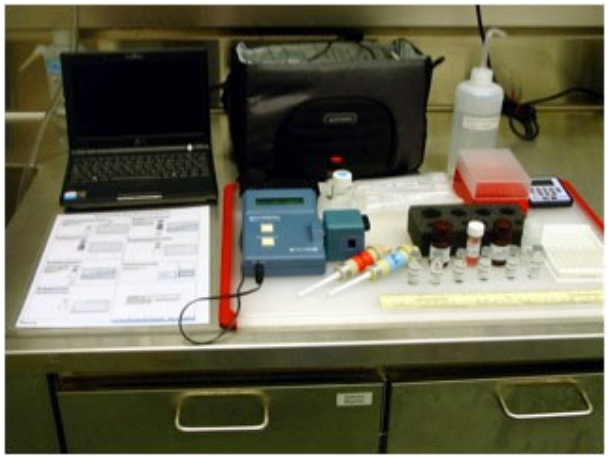
Section II Model Ordinance Chapter
IV Shellstock Growing Areas

@.04 Marine Biotoxin Control

B. Marine Biotoxin Management Plan

(6) Harvesting may be allowed in Federal waters where toxins are known to occur through agreements and MOUs and in cooperation with Federal agencies.

- Shall provide strict safety assurances
- Requires pre-harvest screening (onboard screening)
  - Training using onboard screening method
  - Minimum of 5 samples
- Requires dockside testing
  - Minimum of 7 samples
  - NSSP method
  - Lab conforming to the NSSP



Approved Limited Use Methods

Section IV Guidance Documents

Chapter II Growing Areas

.14 Approved NSSP Laboratory Tests

	ASP	PSP	NSP	Growing Area	Onboard	Relay	End Product
Abraxis ELISA		X			X		
SRT		X		X	X	X	
Reveal ASP	X			X	X	X	
RBA		X		X	X	X	
NSP ELISA			X	X	X	X	X

Footnotes:

Approved Methods For Biotoxins

Section IV Guidance Documents

Chapter II Growing Areas

.14 Approved NSSP Laboratory Tests

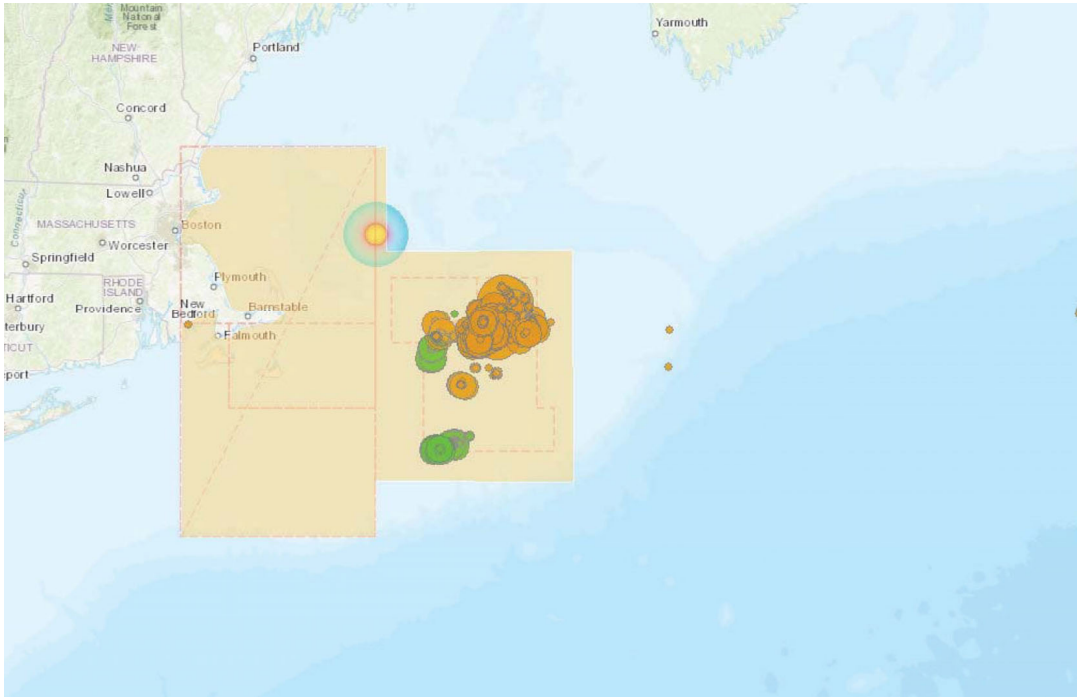
	ASP	DSP	NSP	PSP	Growing Area	Dockside	Relay
APHA MBA			X	X	X	X	X
RBA				X	X	X	X
PCOX				X	X	X	X
LC-MS/MS		X			X	X	X
HPLC	X				X	X	X

Footnotes:

Marine Biotoxin Mapping Tool

Under Development

- Collecting data and developing data visualization tool for marine biotoxins in Federal waters to inform marine biotoxin control and assist with aquaculture siting



Marine Biotoxin Contingency

Section II Model Ordinance
Chapter IV Shellstock Growing Areas

@.04 Marine Biotoxin Control

A. Contingency Plan

For growing areas in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred or caused an illness outbreak

First U.S. report of shellfish harvesting closures due to confirmed okadaic acid in Texas Gulf coast oysters

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Marine Biotoxin Contingency

Section II Model Ordinance

Chapter IV Shellstock Growing Areas

@.04 Marine Biotoxin Control

A. Contingency Plan

(1) Authority shall develop a marine biotoxin contingency plan.

(2) Plan shall define procedures and resources to:

- Initiate an emergency shellfish sampling and assay program;
- Close growing areas and embargo shellfish;
- Prevent harvesting of contaminated species;
- Provide for product recall;
- Disseminate toxic algal information to adjacent states, shellfish industry, and local health agencies;
- Coordinate actions by Authorities and federal agencies; and
- Establish reopening criteria.

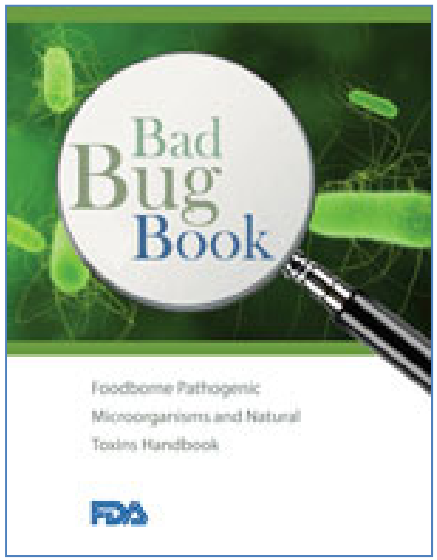
Marine Biotoxin Control

Summary

- FDA is responsible for seafood safety in interstate commerce
- FDA employs regulations to ensure seafood safety
- FDA develops guidance and conducts research to aid processors and states with seafood safety implementation
- FDA has established guidance levels for PSP, ASP, NSP, DSP, AZP, and CFP toxins
- FDA works with the ISSC to develop NSSP requirements and guidance on marine biotoxins for molluscan shellfish
- FDA conducts literature searches and research as needed to address emerging toxins

Additional FDA Resources on Marine Biotoxins in Seafood

- Bad Bug Book
  - https://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf
- Marine Biotoxin Management Video
  - https://www.fda.gov/seafood



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