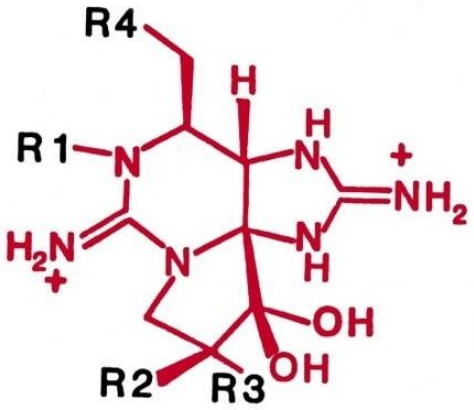
U.S. FOOD & DRUG ADMINISTRATION

Marine Biotoxin Management & Control



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Marine Biotoxins With Control Criteria

Section II Model Ordinance
Chapter IV Shellstock Growing Areas

@.04 Marine Biotoxin Control

C. Closed Status of Growing Areas

Closed Status Criteria

- PSP - 80 µg/100 grams
- NSP - 5,000 *Karenia brevis* cells/L or 20 MU/100 grams (0.8 mg BTX-2 eqs/kg)
- AZP - 0.16 mg azaspiracid-1 (AZA-1) eqs/kg (0.16 ppm)
- DSP – 0.16 mg okadaic acid (OA) eqs/kg (0.16 ppm)
- ASP - 2 mg domoic acid/100 grams (20 ppm)

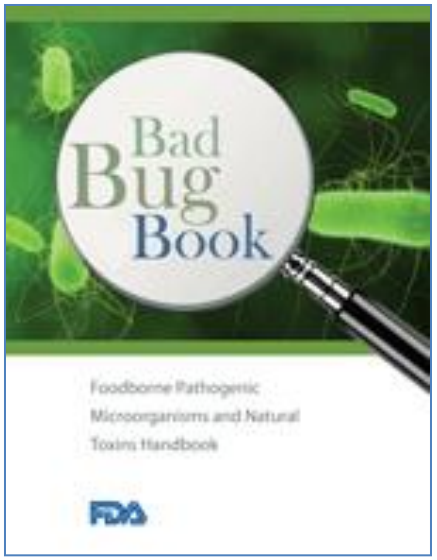
Need For Biotoxin Control In The NSSP

Section III Public Health Reasons & Explanations
Chapter IV Shellstock Growing Areas

- Paralytic Shellfish Poisoning - PSP
  - Tingling, numbness, paralysis, respiratory failure
- Amnesic Shellfish Poisoning - ASP
  - Confusion, short-term memory loss, seizures, diarrhea
- Neurotoxic Shellfish Poisoning - NSP
  - Tingling, numbness, aches, vomiting, diarrhea
- Diarrhetic Shellfish Poisoning - DSP
  - Gastrointestinal symptoms, chills, headache, fever
- Azaspiracid Shellfish Poisoning - AZP
  - Nausea, vomiting, diarrhea, abdominal cramps

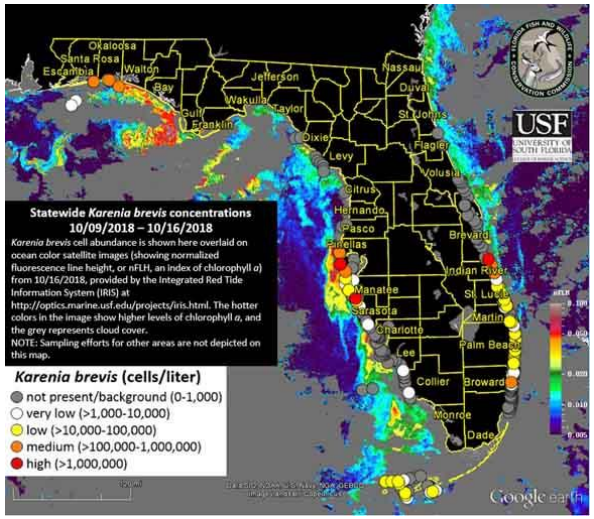
More Information on Marine Biotoxins

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



Expanding Need For Biotoxin Control

- Toxic algal blooms are increasing in
  - Frequency
  - Intensity
  - Duration
  - Spatial scale
- Biotoxin closures have occurred
  - in new areas for new toxins/toxic algae (e.g., domoic acid by *P. australis*)
  - for longer periods of time (e.g., NSP toxins in FL)



Heightened National Awareness

Media coverage and Congressional hearings highlight the significance of marine biotoxins

Congress Passes Buchanan Red Tide Bill

Red Tide Getting the Attention of Congress

A toxic algae bloom in Florida is slaughtering marine life by the masses

Senate subcommittee holds hearing on algal bloom monitoring and impacts

Southern California coast emerges as a toxic algae hot spot

NSF, NIEHS award $30 million for new research on links among oceans, lakes and human health - *Awards focus on marine and Great Lakes pathogens, such as toxins in harmful algae blooms*

In new cautionary approach, Maine shellfish areas will be closed at first sign of toxins

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

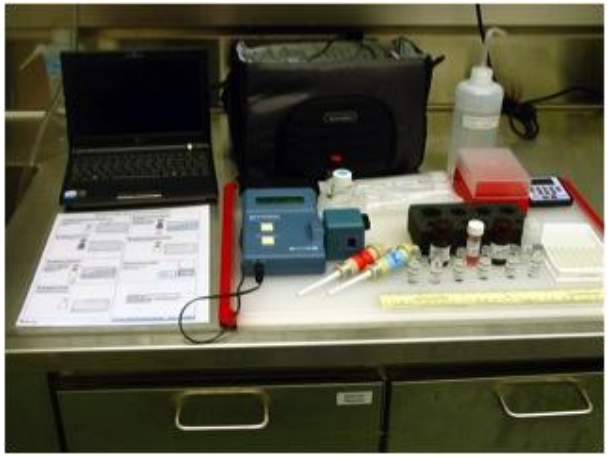
Section II Model Ordinance Chapter IV Shellstock Growing Areas

@.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

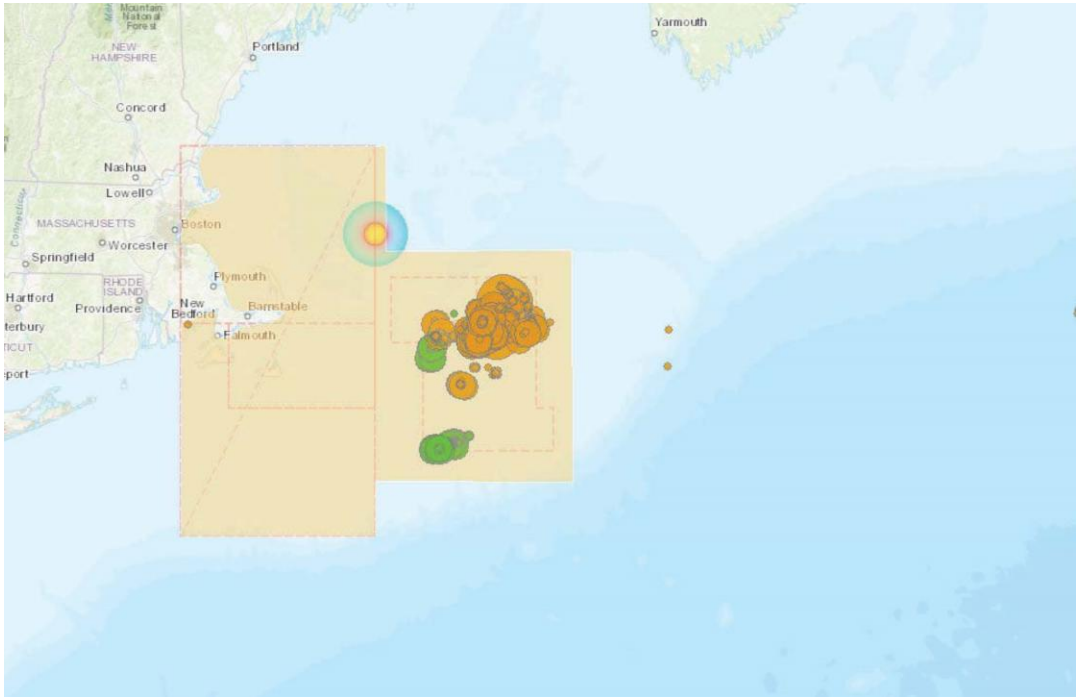
	ASP	DSP	NSP	PSP	Growing Area	Dockside	Relay
APHA MBA			X	X	X	X	X
RBA				X	X	X	X
PCOX				X	X	X	X
LC-MS/MS		X			X	X	X
HPLC	X				X	X	X

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

Jonathan R. Deeds [a,*], Kirk Wiles [b], Gary B. Heideman, VI [b], Kevin D. White [a], Ann Abraham [c]

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 Contingency

Summary

- Biotoxins could be used for making classification decisions
- Authorities are required to have marine biotoxin management and contingency plans
- The marine biotoxin management plan is for toxins known to occur in an area or where illness outbreaks have occurred
- The marine biotoxin contingency plan is for emerging toxins
- Traditional routine monitoring is used for state waters where toxins are known to occur
- End product testing with pre-harvest screening is used for closed state waters where toxins occur
- Onboard screening dockside testing is used in Federal waters where toxins are known to occur

Marine Biotoxin Control

Next Steps

- FDA & Abraxis collaboration to enhance user experience and broaden application with Abraxis PSP Shipboard ELISA Kit for Onboard Screening
- ISSC Biotoxin Committee considerations for alternative biotoxin control strategies

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