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National Shellfish Sanitation Program Five Marine Biotoxin Strategies, Challenges for Offshore Bivalve Molluscan Shellfish Harvest

September 26, 2023

*World Seafood Congress in Association with the
13th International Conference on Molluscan Seafood Safety*

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International Affairs, Trade, and Commerce | Seafood Inspection Program
NOAA Fisheries | U.S. Department of Commerce*

National Shellfish Sanitation Program (NSSP)

Guide for the Control of Molluscan Shellfish 2019 Revision



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



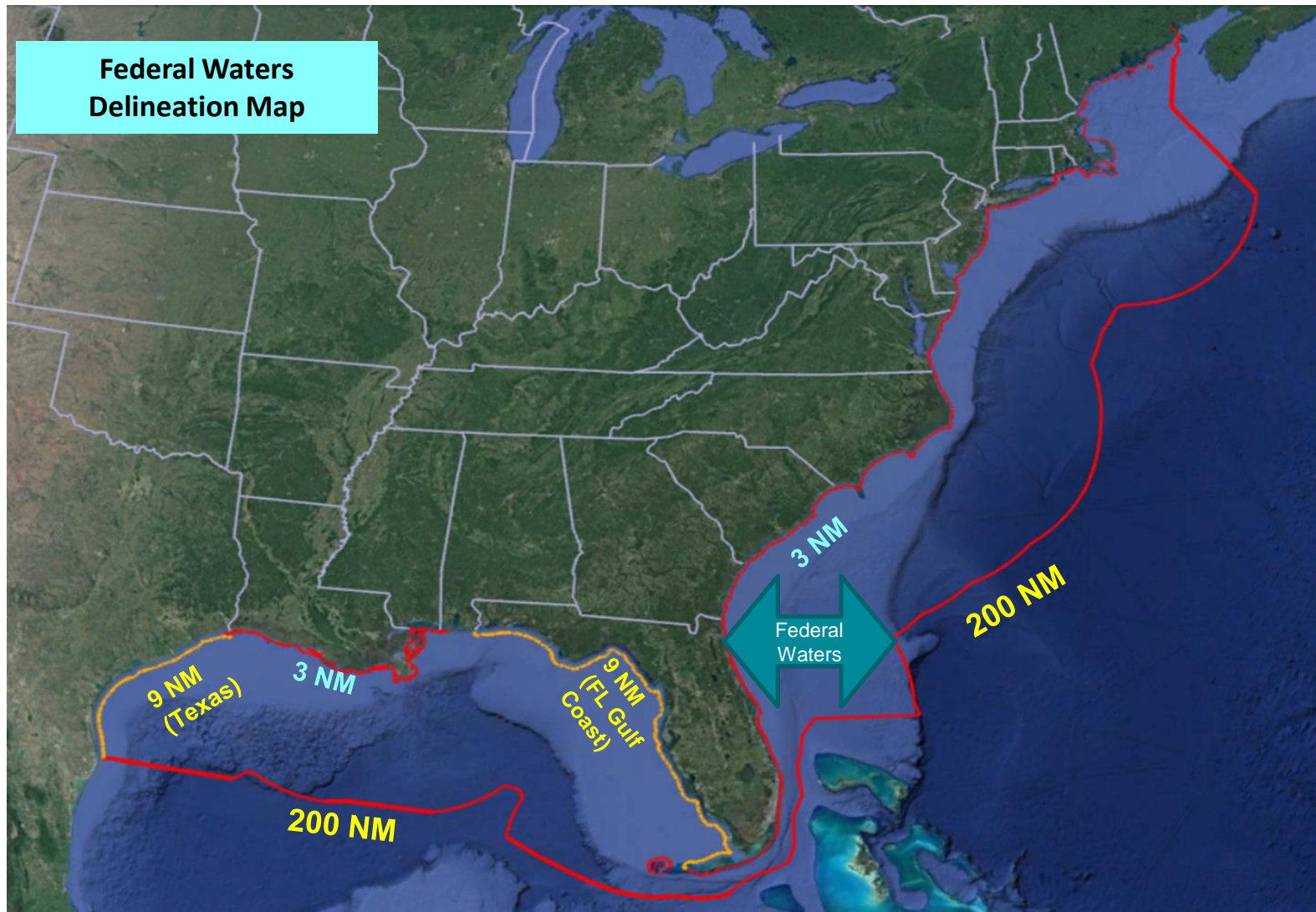
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NSSP

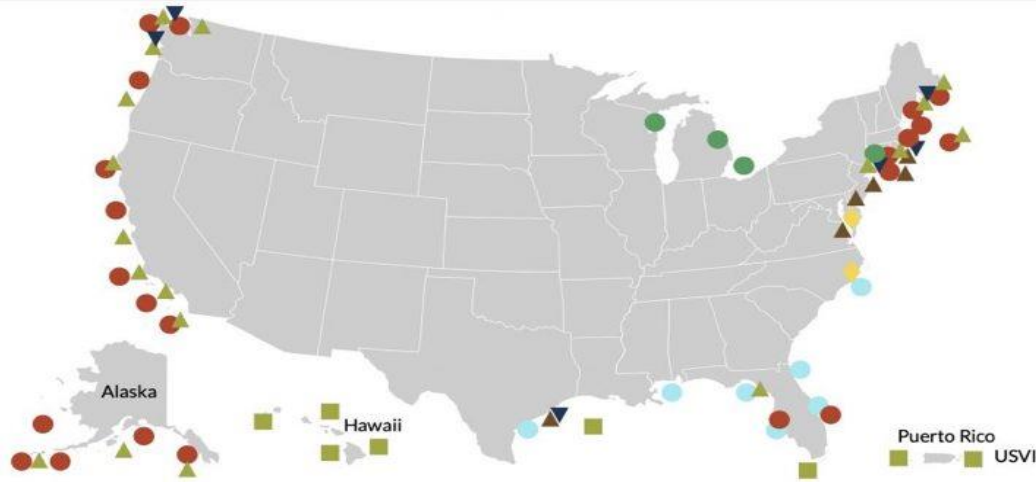
- ❖ Cooperative program between federal government, participating states, and tribes where states are the primary authority.
- ❖ Definition of shellfish:
 - “means all species of:
 - Oysters, clams, mussels, or cockles whether:
 - Shucked or in the shell;
 - Raw, including post-harvest processed;
 - Frozen or unfrozen
 - Whole or in part; and
 - Scallops in any form, except when the final product form is the adductor muscle only.”



NSSP in Federal Waters



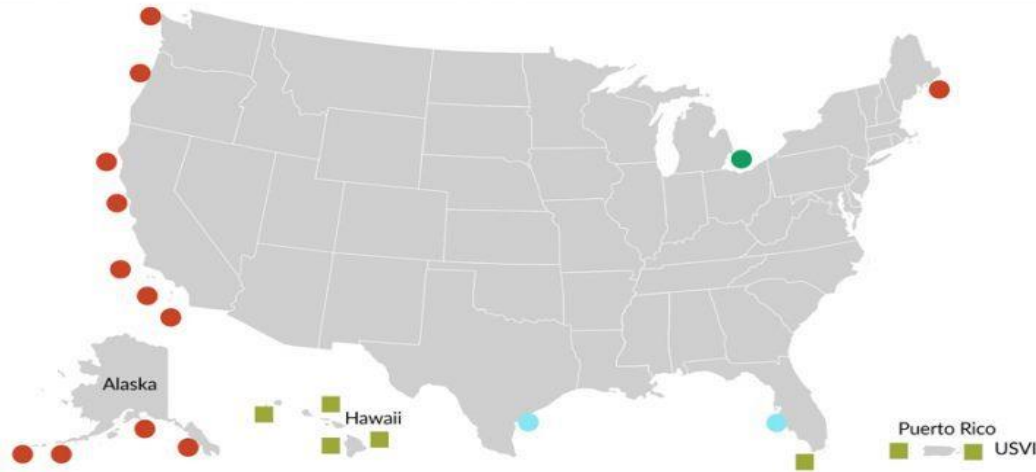
Present



US HABs
Pre-1972
VS
2019

- ◆ *Karlodinium* ● NSP ● PSP ▼ DSP ■ Ciguatera ▲ Brown tide ▲ ASP ● CyanoHABs
- ⚠ Occasional anoxia, marine mammal mortalities (whales, manatees, sea lions, dolphins), noxious blooms (aesthetics), macroalgal blooms

Pre-1972



- ◆ *Karlodinium* ● NSP ● PSP ▼ DSP ■ Ciguatera ▲ Brown tide ▲ ASP ● CyanoHABs
- ⚠ Occasional anoxia, marine mammal mortalities (whales, manatees, sea lions, dolphins), noxious blooms (aesthetics), macroalgal blooms

Credit: U.S. National
Office for Harmful
Algal Blooms

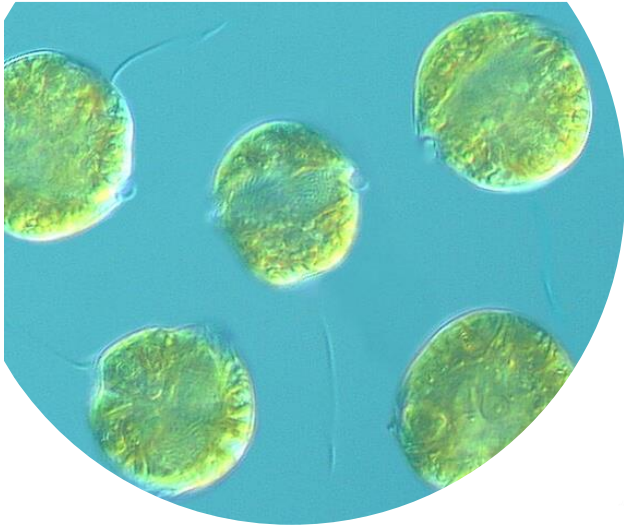


NSSP Model Ordinance

Five Types of Shellfish Poisonings

- ❖ **PSP** - Paralytic Shellfish Poisoning
- ❖ **NSP** - Neurotoxic Shellfish Poisoning
- ❖ **ASP** - Amnesic Shellfish Poisoning (also known as Domoic Acid poisoning)
- ❖ **DSP** - Diarrhetic Shellfish Poisoning
- ❖ **AZP** - Azaspiracid Shellfish Poisoning

Paralytic Shellfish Poisoning (PSP) Toxins



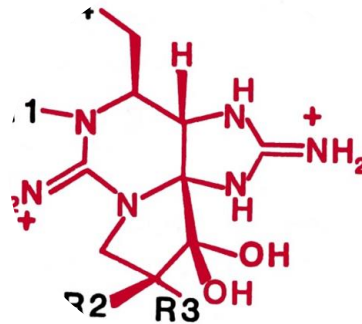
Saxitoxins (STXs)

Dinoflagellates

Alexandrium spp.

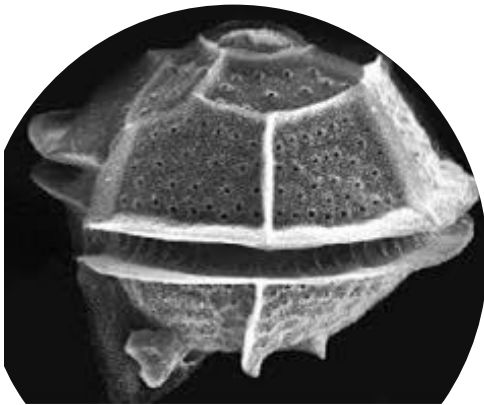
Gymnodinium catenatum

Pyrodinium bahamense



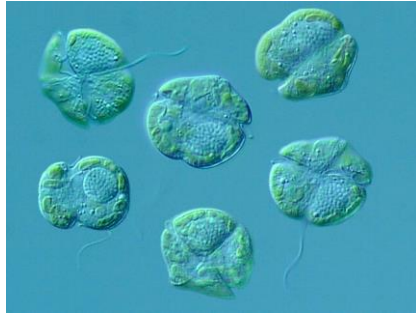
Guidance Level

80 $\mu\text{g}/100\text{ g}$



Credit: Stacey Wiggins, PhD, US FDA CFSAN

Neurotoxic Shellfish Poisoning (NSP) Toxins



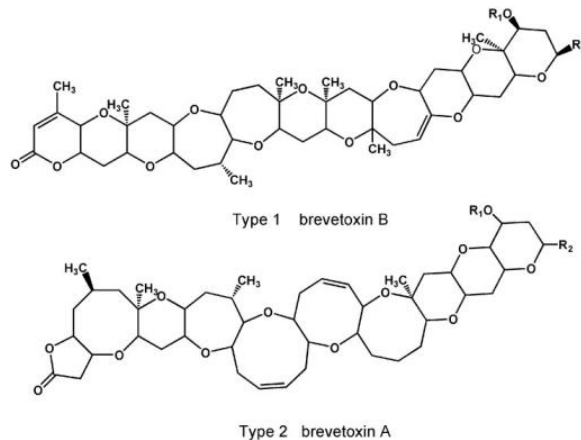
Brevetoxins (BTXs)

Dinoflagellate

Karenia brevis

Guidance Level

20 MU/100 g



Credit: Stacey Wiggins, PhD, US FDA CFSAN

Azaspiracid Shellfish Poisoning (AZP) toxins

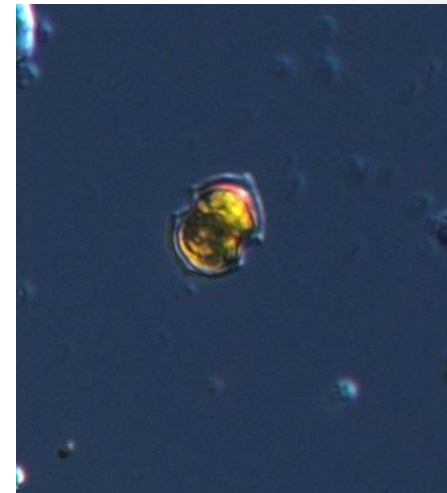
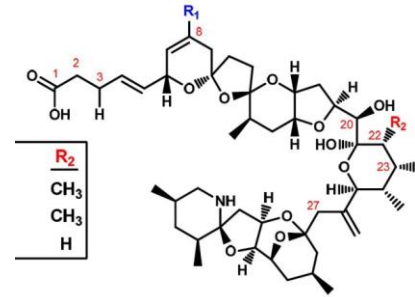
Azaspiracids (AZAs)

Dinoflagellates

Azadinium spp.

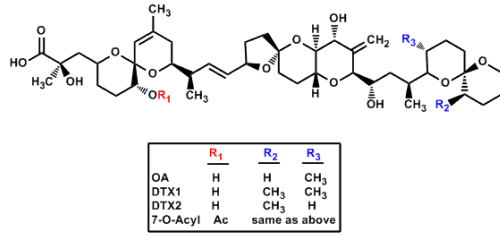
Guidance Level

0.16 mg/kg



Credit: Stacey Wiggins, PhD, US FDA CFSAN

Diarrhetic Shellfish Poisoning (DSP) Toxins



Okadaic Acid & Dinophysis Toxins (OA & DTXs)

Dinoflagellates

Dinophysis spp.

Prorocentrum spp.



Guidance Level

0.16 mg/kg

Credit: Stacey Wiggins, PhD, US FDA CFSAN



Amnesic Shellfish Poisoning (ASP) Toxins

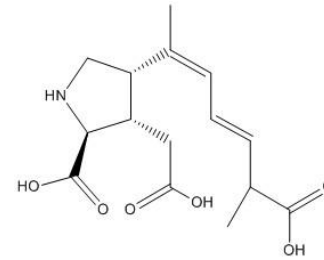
Domoic Acid (DA)

Diatoms

Pseudo-nitzschia spp.

Guidance Level

20 mg/kg



Credit: Stacey Wiggins, PhD, US FDA
CFSAN

Controlling Marine Biotoxin in Shellfish

Contingency Plan

- ❖ **Emergence** of toxin-producing phytoplankton that has historically occurred
- ❖ **New** illness outbreak
- ❖ Reactive management

Management Plan

- ❖ **History of biotoxin closures**
- ❖ **Toxin**-producing phytoplankton
- ❖ Reasonable likelihood that biotoxin closures could occur

Section II. Model Ordinance
Chapter IV. Shellstock Growing Areas
B. Marine Biotoxin Management Plan and
@.04 Marine Biotoxin control

- ❖ Management Plan
- ❖ **5 Management Strategies - Options**
- ❖ Model Ordinance guidance/strategy
- ❖ New “Controlled Access Status”



Federal Waters Molluscan Shellfish Harvest

Marine Biotoxin

Management Strategies:

1. Phytoplankton monitoring
2. Routine shellfish toxicity monitoring
3. Pre-harvest shellfish toxicity testing
4. Shellfish lot testing
5. Pre-harvest shellfish toxicity screening and lot testing



Phytoplankton Monitoring

- ❖ Routine monitoring
- ❖ Frequency based on historic database
 - Or, 36 samples over 3 years – from representative environmental conditions
- ❖ Must be used with another strategy
 - Trigger shellfish toxicity testing
- ❖ Potential scenarios
 - Traditional monitoring programs used by states
 - Aquaculture sites in nearby federal waters



Credit: Stacey Wiggins, PhD, US FDA CFSAN

Shellfish Toxicity Monitoring

- ❖ Routine Sampling
- ❖ Frequency based on historic database
 - Or, 36 samples over 3 years – from representative environmental conditions
- ❖ Species-Specific
 - Or use highest risk species
- ❖ Potential scenarios
 - Traditional monitoring programs used by states
 - Aquaculture sites in nearby federal waters



Credit: Stacey Wiggins, PhD, US FDA CFSAN

Pre-Harvest Shellfish Toxicity Testing

- ❖ Testing – Pre-harvest
- ❖ Harvest Area – Specific to intended harvest area
- ❖ Advance – Short duration (3 days)
- ❖ Potential scenarios
 - Easily accessible and remote
 - Wild harvest and aquaculture
- ❖ Frequency: 36 samples/3 years

Credit: Stacey Wiggins, PhD, US FDA CFSAN



Photo credit: NOAA Fisheries - Julie Rose

Shellfish Lot Testing

- ❖ Testing – post-harvest
- ❖ Lot – specific to harvest area/lot
- ❖ Controlled – controlled access status
- ❖ Tags – restricted shellstock tags/require holding shellstock until lots tests are available
- ❖ Potential scenarios
 - Easily accessible and remote
 - Wild harvest and aquaculture
- ❖ Frequency: 36 samples/3 years



Credit: Stacey Wiggins, PhD, US FDA CFSAN

Pre-Harvest Screening + Lot Testing

- ❖ Pre-harvest Shellfish Screening/intended harvest area coupled with:
- ❖ Lot – Testing Upon Landing/initial Dealer
- ❖ Controlled – Controlled Access Status
- ❖ Tags – Restricted Shellstock tags/require holding shellstock until lots tests are available
- ❖ Potential scenarios
 - Easily accessible and remote
 - Wild harvest and aquaculture
- ❖ Frequency: 36 samples/3 years



Credit: Stacey Wiggins, PhD, US FDA CFSAN

Challenges and the Future

Emerging technology models

- ❖ Machine learning forecasting with toxin data
- ❖ Biological/Physical model using oceanographic, weather, and ship-based survey of cysts
- ❖ Drone sampling, Imaging FlowCytobot, Environmental Sample Processor - imaging real-time, Other?



Thank You!

Questions?

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