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MARINE BIOTOXIN CONTROL

2019 NSSP GUIDE

Implementation of:

19-149

Marine Biotoxin Control

Submitted by the ISSC Biotoxin Committee

Adopted at the 2019 ISSC Biennial Meeting

Drivers for Proposal Submission

2015 ISSC Biennial Meeting highlighted the need for broad understanding of State biotoxin management

ISSC Biotoxin Workshop in March 2017

Lessons learned

Varied monitoring approaches	Biotoxin content was outdated	Increase in toxins	→	Need for options in control strategies

Biotoxin Workshop → Proposals

Proposal 17-122 Section II. Model Ordinance

- Included mention of other toxins beyond PSP toxins
- Distinguished management from contingency plans
- Required reopening criteria in plans
- Established detailed requirements for routine monitoring

Biotoxin Workshop → Proposals

Proposal 17-123

Section IV. Guidance Documents

- Updated Introduction section
- Included mention of other toxins beyond PSP toxins
- Distinguished management from contingency plans

Additional Background Proposal

Proposal 13-116

Section II. Model Ordinance
Section IV. Guidance Documents

- Aimed to establish protocol for quarantine harvest due to *Karenia brevis* closure
- 2015: Adopted language in MO to allow harvest from closed state waters
- 2017: Requested Biotoxin Committee develop guidance

Outstanding Factors to Consider

- Optics of harvesting in closed waters
- Onboard screening dockside testing frequency for federal waters
- End product testing
- Practicality and public health significance of cell count thresholds

Proposal 19-149

Section II. Model Ordinance

Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification

@.04 Marine Biotoxin Control

Section IV. Guidance Documents

Chapter II. Growing Areas

.02 Guidance for Developing Marine Biotoxin Plans

Section II. Model Ordinance
Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification

Controlled Access Status

- New status
- Only for marine biotoxins
- No longer harvesting from ‘closed’ waters
- Where routine monitoring doesn’t occur

Controlled Access Status

Applied to allow harvesting in areas with biotoxin concerns where routine monitoring or pre-harvest testing is not practical

Section II. Model Ordinance
Chapter IV. Shellstock Growing Areas

@.04 Marine Biotoxin Control

B. Marine Biotoxin Management Plan

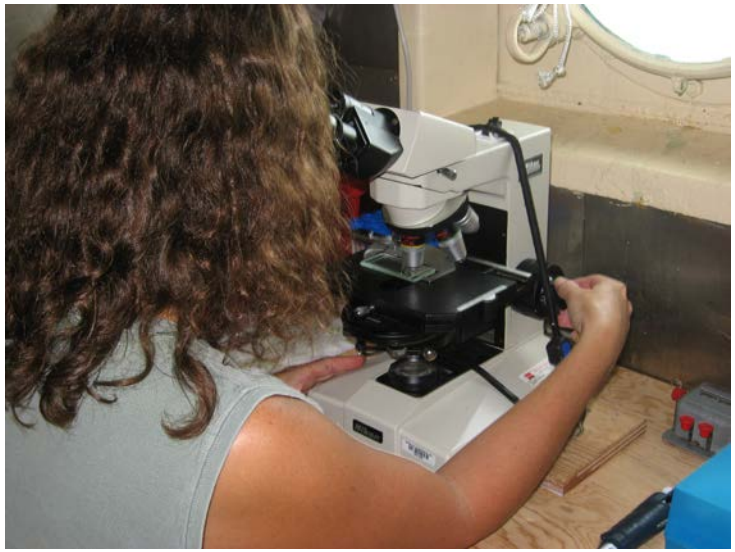
- Management strategy
- 5 Options
- Connects to Guidance
- Links Controlled Access Status
- Removes onboard screening dockside testing details

Management Strategy

…in accordance with one or a combination of the marine biotoxin management strategies listed in 4. and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

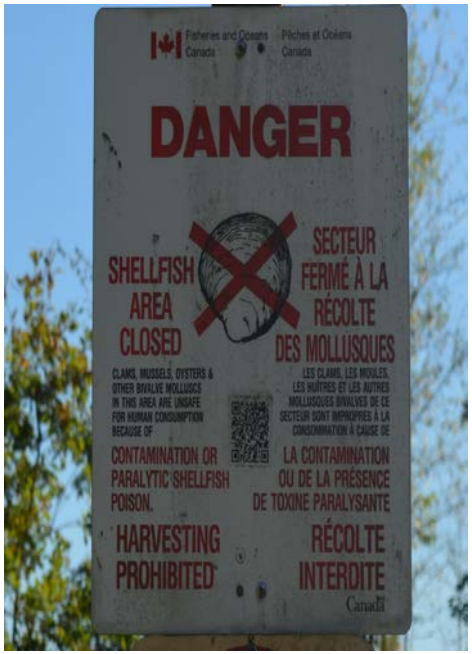
Phytoplankton Monitoring – Option #1

- Routine Sampling
- Must be used in combination with another strategy



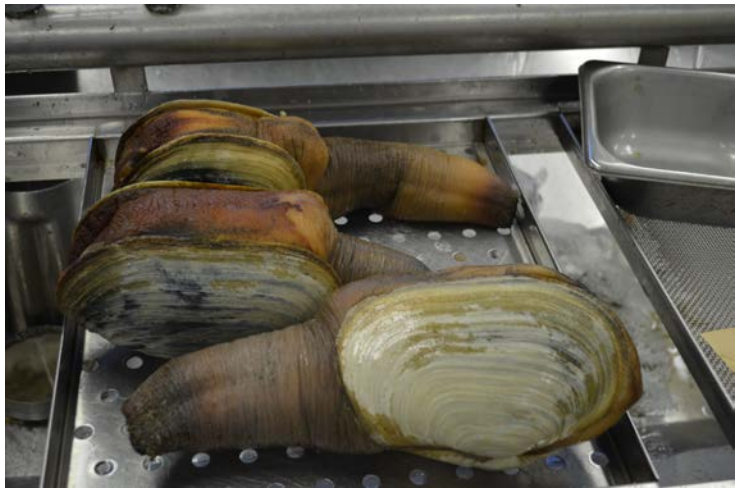
Shellfish Toxicity Monitoring – Option #2

- Routine Sampling
- Shellfish meat testing
- Species-specific or highest risk species



Pre-Harvest Shellfish Toxicity Testing – Option #3

- Shellfish meat testing
- Intended harvest area
- Advance of harvest
- Allows harvest for short period of time

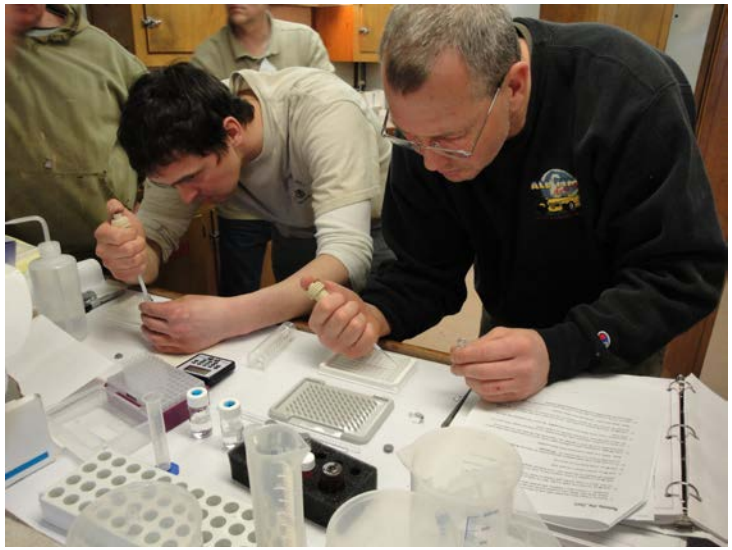


Shellfish Lot Testing – Option #4

- Shellfish meat testing
- Lot testing
- After harvest

Pre-Harvest Screening + Lot Testing – Option #5

- Formerly ObSDT
- Pre-harvest shellfish screening
  - Intended harvest area
- Lot testing
  - Upon landing



Additional Management Requirements

Controlled Access Status

Restriction conditions

✓*Sampling, testing, holding*

Agreements or MoU

Removal of ObSDT Details

To be consistent in granularity and prescriptive requirements in the Model Ordinance

Appropriate for Agreements, MoU, and permit conditions

Refer to pre-harvest screening + lot testing

Section II. Model Ordinance
Chapter IV. Shellstock Growing Areas

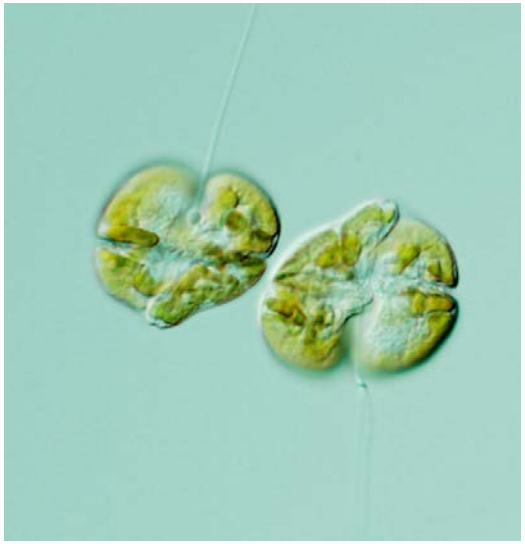
@.04 Marine Biotoxin Control

C. Closed or Controlled Access Status

- Removes *K. brevis* cell counts
- Describes Controlled Access Status
- Permit conditions
- Restricted Shellstock tags

Karenia brevis Cell Counts

- Removal of cell counts from threshold criteria
- Cell counts ≠ shellfish toxicity



Controlled Access Status

- Authority determines additional requirements
- Include in permit conditions
- Restricted Shellstock tags

Restricted Shellstock

Restricted shellstock is identified with a tag indicating that the shellstock has restrictions requiring further processing or testing prior to distribution.

Section IV. Guidance Documents
Chapter II. Growing Areas

.02 Guidance for Developing Marine Biotoxin Plans

Management Strategies

- Sets minimum samples
- Describes strategies
  - Pre-harvest testing
  - Lot testing
- Links to methods
- Removes ObSDT details

Minimum Baseline:

36:3

36 samples over at least 3 years

Per growing area or hydrographically linked waterbodies

Phytoplankton Monitoring

Routine monitoring	As traditionally utilized
Frequency based on historic database	Or 36 samples over 3 years
Must be used with another strategy	Trigger shellfish toxicity testing
Potential scenarios	Traditional monitoring programs used by states Aquaculture sites in nearby federal waters

Phytoplankton Monitoring

Strategy must establish:

- Appropriate screening levels (trigger)
- Appropriate methods (no NSSP methods for cells)
- Appropriate laboratory/analyst
- Appropriate sampling plan
- Appropriate sample stations
- Appropriate sampling frequency
- Sufficient dataset to support management decisions

Phytoplankton Monitoring

- Trigger
  - Establish cell count thresholds
    - 5,000 *Karenia brevis* cells/L
  - If little or no data are available, make thresholds low
- Initiate shellfish toxicity testing
- Use of precautionary closures
  - Find no toxin issue: Reopen
  - If toxins were above level: follow reopening criteria and use Approved Method

Shellfish Toxicity Monitoring

Routine monitoring	As traditionally utilized
Frequency based on historic database	Or 36 samples over 3 years
Species-Specific	Or use highest risk species
Potential scenarios	Traditional monitoring programs used by states Aquaculture sites in nearby federal waters

Shellfish Toxicity Monitoring

Strategy must establish:

- Appropriate screening levels
- Appropriate methods
- Appropriate laboratory/analyst
- Appropriate sampling plan
- Appropriate sample stations
- Appropriate sampling frequency
- Sufficient dataset to support management decisions

Pre-Harvest Shellfish 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

Pre-Harvest Shellfish Testing

Strategy must establish:

- Appropriate screening levels
- Appropriate methods (Approved Method)
- Appropriate laboratory/analyst
- Appropriate sampling plan
- Appropriate sampling frequency
- A defined harvest area
- Appropriate duration for permitted harvest after sampling

Shellfish Lot Testing

Testing	Post-harvest
Lot	Specific to harvest area/lot
Controlled	Controlled Access Status
Tags	Restricted Shellstock tags

Shellfish Lot Testing

Strategy must establish:

- Appropriate screening levels
- Appropriate methods (Approved Method)
- Appropriate laboratory/analyst
- Appropriate sampling plan
- Appropriate sampling frequency
- Representative number of samples per lot

Pre-Harvest Screening + Lot Testing

Pre-Harvest	Screening
Lot	Testing
Controlled	Controlled Access Status
Tags	Restricted Shellstock tags

Pre-Harvest Screening + Lot Testing

Strategy must establish:

- Appropriate screening levels
- Appropriate methods
- Appropriate laboratory/analyst
- Appropriate sampling plan
- Appropriate sampling frequency
- A defined harvest area
- Representative number of samples per lot

Removal of ObSDT Details

To be consistent in granularity and prescriptive requirements in the NSSP Guide

Appropriate for Agreements, MoU, and permit conditions

Refer to pre-harvest screening + lot testing

2019 Revision Implementation

ISSC Constitution, Bylaws, and Procedures

Procedure X, Section 2

NSSP changes will be effective posting on the FDA website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