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Alaska Marine Biotoxin Monitoring Plan for Bivalve Shellfish Other than Geoducks

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**State of Alaska
Department of Environmental Conservation
Environmental Health – Food Safety & Sanitation**

Marine Biotoxin Monitoring Plan for Bivalve Shellfish other than Geoduck Clams

Purpose & Scope

It is the purpose of this document to identify procedures to be followed for preventing the dangers to public health that arise as a result of marine bio-toxins in bivalve shellfish in the state of Alaska.

The scope of this plan covers the commercial harvest of all bivalve shellfish, wild or farmed, sub-tidally or inter-tidally grown in Alaska. The department does not monitor marine toxins in shellfish harvested from recreational beaches or for personal use.

The Uniform Shellfish Sampling Plan for Paralytic Shellfish Poison (PSP) will be used to monitor PSP in all shellfish other than geoduck clams.

Biotoxins levels in molluscan shellfish are monitored year round. Biotoxins such as Paralytic Shellfish Poison (PSP) and Amnesic Shellfish Poison (ASP) also known as Domoic Acid are known to be present in the marine waters of Alaska. While PSP is known to be found in unsafe concentrations in shellfish, Domoic Acid is present in levels well below the regulatory limit set by FDA. PSP and ASP are tested routinely.

Diarrhetic Shellfish poison (DSP) and Neurotoxic Shellfish Poison (NSP) are not routinely monitored but may be tested on an as needed basis.

When toxins are detected at dangerous levels, the harvest area is closed. The area will only be opened to harvesting if the lab confirms that biotoxin concentrations have dropped again to safe levels.

All bivalve shellfish harvested to be placed into commerce and intended for human consumption must come from an approved growing area in the open status that was properly classified by the Department of Environmental Conservation (DEC).

Introduction

The uniform shellfish sampling plan for Paralytic Shellfish Poison (PSP) testing is revised to address the seasonal nature of toxicity within shellfish growing/harvesting areas. Sampling protocols and product holding requirements are different for summer and winter, and are required to ensure product safety while providing historical and predictive data. This sampling plan covers only clams, mussels, and oysters. **Geoducks, snails, and whole scallops are not covered by this plan.** Species must be sampled and tested as specified in the plan. Samples must be submitted during all months of anticipated harvest and sales.

The plan has four levels. Level One, Two and Three are species specific. Level Four is non-species specific for individual growing areas and entire classified areas. A growing/harvesting area may not move to Level Four until criteria for all species can be met.

A recall plan must be in place prior to moving into Level Three or Level Four.

SAMPLING PROGRAM

“Lot” is defined as the number of shellfish harvested from a classified area in one day.

“Lot” size is defined as number of animals.

A month is defined as a calendar month.

Each sample must contain at least 150 grams of drained weight, and must include a minimum of twelve animals. An eight-ounce cup of drained product is equivalent to 150 grams. All products submitted for testing must be shucked and drained according to the lab sampling protocol.

The department may deviate from this uniform shellfish sampling plan and impose a different PSP sampling program for a classified area. A review of environmental factors, epidemiology and all PSP data will be used in formulating any changes to a sampling program. Affected growers, harvesters and shellstock shippers will be notified, if a different sampling program is implemented.

I. SPECIES SPECIFIC SAMPLING PLAN FOR INDIVIDUAL GROWING AREAS.

LEVEL ONE (Years One and Two):

Summer

Sampling Period: May 1 through October 31.

- Sampling Frequency: **Each lot per species harvested.**
- Number of Samples: One (1) per species.
- Harvesting & Holding Conditions: In accordance with the National Shellfish Sanitation Program (NSSP) the entire lot must be harvested, held out of water under refrigeration, protected from contamination at the facility, and not placed into commerce until satisfactory PSP test results are received from the department. The lot must not be put back into the water pending distribution.
- Test Results and Distribution: Shellfish lots with <80 micrograms of toxin per 100 grams of tissue will be released for commerce. Lots with 80 micrograms of toxin per 100 grams of tissue or greater are rejected for commerce. The lot may be returned to the approved growing area. If returned, the lot identity must be maintained for subsequent testing prior to marketing.

Winter

Sampling Period: November 1 through April 30.

- Sampling Frequency: **Once per month per each species harvested.**
- Number of Samples: One (1) per species.
- Harvesting & Holding Conditions: In accordance with the NSSP the entire lot must be harvested, held out of water under refrigeration, protected from contamination at the facility, and not placed into commerce until satisfactory PSP test results are received from the department. The lot must not be put back into the water pending distribution.
- Test Results and Distribution: Shellfish lots with <80 micrograms of toxin per 100 grams of tissue will be released for commerce. Lots with 80 micrograms of toxin per 100 grams of tissue or greater are rejected for commerce. The lot may be returned to the approved growing area. If returned, the lot identity must be maintained for subsequent testing prior to marketing.
- Switching Procedures: See criteria for progressing to next level on page 6.

To advance to the next level at least one sample per month must be submitted during anticipated harvest period.

LEVEL TWO (Years Three):

Summer

Sampling Period: May 1 through October 31.

- Sampling Frequency: **Once per week per species harvested.**
- Number of Samples: One (1) per species.
- Harvesting & Holding Conditions: In accordance with the NSSP the entire lot must be harvested, held out of water under refrigeration, protected from contamination at the facility, and not placed into commerce until satisfactory PSP test results are received from the department. The lot must not be put back into the water pending distribution.
- Test Results and Distribution: Shellfish lots with <80 micrograms of toxin per 100 grams of tissue will be released for commerce. Lots with 80 micrograms of toxin per 100 grams of tissue or greater are rejected for commerce. The lot may be returned to the approved growing area. If returned, the lot identity must be maintained for subsequent testing prior to marketing.

Winter

Sampling Period: November 1 through April 30.

- Sampling Frequency: **Once per month per species harvested.**
- Number of Samples: One (1) per species.
- Harvesting & Holding Conditions: In accordance with the NSSP the entire lot must be harvested, held out of water under refrigeration, protected from contamination at the facility, and not placed into commerce until satisfactory PSP test results are

received from the department. The lot must not be put back into the water pending distribution.

- Test Results and Distribution: Shellfish lots with <80 micrograms of toxin per 100 grams of tissue will be released for commerce. Lots with 80 micrograms of toxin per 100 grams of tissue or greater are rejected for commerce. The lot may be returned to the approved growing area. If returned, the lot identity must be maintained for subsequent testing prior to marketing.
- Switching Procedures: See criteria for progressing to next level on page 6.

To advance to the next level at least one sample per month must be submitted during anticipated harvest period.

LEVEL THREE (Years Four and After):

Summer

Sampling Period: May 1 through October 31.

- Sampling Frequency: **Once per week per species harvested.**
- Number of Samples: One (1) per species.
- Harvesting & Holding Conditions: In accordance with the NSSP the entire lot must be harvested, held out of water under refrigeration, and protected from contamination at the facility. The lot may be placed into commerce before the PSP results are received from the department.
- Test Results and Distribution: Shellfish lots with 80 micrograms of toxin per 100 grams of tissue or greater are rejected and all product must be recalled from commerce. All products from that lot must be destroyed or returned to the approved growing area. If returned, the lot identity must be maintained for subsequent testing prior to marketing.
- Rejected lot Procedures: See page 6.

Winter

Sampling Period: November 1 through April 30.

- Sampling Frequency: **Once per month per species harvested.**
- Number of Samples: One (1) per species.
- Harvesting & Holding Conditions: In accordance with the NSSP the entire lot must be harvested, held out of water under refrigeration, protected from contamination at the facility. The lot may be placed into commerce before the PSP results are received from the department. Once the minimum sample frequency has been met in a given month with satisfactory results, no additional sampling is required for that month.
- Test Results and Distribution: Shellfish lots with 80 micrograms of toxin per 100 grams of tissue or greater are rejected and all product must be recalled from commerce. All products from that lot must be destroyed or returned to the approved growing area. If returned, the lot identity must be maintained for subsequent testing prior to marketing.

- Switching Procedures: See criteria for progressing to next level.

To advance to the next level at least one sample per month must be submitted during anticipated harvest period.

II. NON-SPECIES SPECIFIC SAMPLING PLAN FOR INDIVIDUAL GROWING AREAS OR ENTIRE CLASSIFIED AREAS. At the time of initial evaluation, the individual growing area or all growing areas within the classified area must have a three year history of acceptable sample results per species.

LEVEL FOUR:

Summer

Sampling Period: May 1 through October 31.

- Sampling Frequency: **Once per week.**
- Number of Samples: One (1), alternate species of oysters or mussels from alternating growing areas within the classified area. Clams may be submitted if that is the only species being harvested that week.
- Harvesting & Holding Conditions: In accordance with the NSSP the entire lot must be harvested, held out of water under refrigeration, and protected from contamination at the facility. The lot may be placed into commerce before the PSP results are received from the department.
- Test Results and Distribution: Shellfish lots with 80 micrograms of toxin per 100 grams of tissue or greater are rejected and all product must be recalled from commerce. All products from that lot must be destroyed or returned to the approved growing area. If returned, the lot identity must be maintained for subsequent testing prior to marketing.
- Rejected Lot Procedure.

Winter

Sampling Period: November 1 through April 30.

- Sampling Frequency: **Once per month.**
- Number of Samples: One (1), alternate species of oysters or mussels from alternating growing areas within the classified area. Clams may be submitted if that is the only species being harvested that week.
- Harvesting & Holding Conditions: In accordance with the NSSP the entire lot must be harvested, held out of water under refrigeration, and protected from contamination at the facility. The lot may be placed into commerce before the PSP results are received from the department. Once the minimum sample frequency has been met in a given month with satisfactory results, no additional sampling is required for that month.
- Test Results and Distribution: Shellfish lots with 80 micrograms of toxin per 100 grams of tissue or greater are rejected and all product must be recalled from commerce. All products from that lot must be destroyed or returned to the approved

growing area. If returned, the lot identity must be maintained for subsequent testing prior to marketing.

III. RECALLED OR REJECTED LOT PROCEDURES

In the event of a recall due to high levels of paralytic shellfish toxins in shellfish, the area will be closed for all species. The area must have at least three (3) consecutive acceptable samples from the same site, per species, taken not less than four (4) days apart over a minimum of a 14 day period, to reopen. The area may reopen by individual species. All samples must test at <80 micrograms of toxin per 100 grams of tissue before area is re-opened. **Lot sampling may be used during a closure, however, this must be coordinated with the Anchorage office and the lab prior to harvest.**

IV. SWITCHING PROCEDURES

Levels One, Two and Three of the sampling plan are species specific. There is no requirement that all species achieve the next sampling level in unison. The following criteria must be met to move to the corresponding levels below:

To move from Level One to Level Two: (Species Specific)

1. All samples must have been submitted as required for the anticipated harvest months and species, over a twenty-four month period.
2. If any sample submitted during the anticipated harvest months was not acceptable, sampling starts over for that year, for that species.

To move from Level Two to Level Three: (Species Specific - Individual Growing Area)

1. All samples must have been submitted as required for the anticipated harvest months for that species.
2. At the time of initial evaluation, a growing area must have a consecutive three year history of acceptable sample results for that species.
3. Individual growing areas will be approved for harvest of individual species only during the months samples were submitted and released for sale, during the preceding twelve month period.

If samples are not submitted as required for a period of one or more years, the area will revert back one level, on a year for year basis.

To move from Level Two or Three to Level Four: (Non-Species Specific – Individual Growing Area or Entire Classified Area)

Individual Growing Area

- At the time of initial evaluation, the area must have a consecutive three year history of acceptable sample results for the anticipated harvest months, for all species to be harvested.

Entire Classified Area

- At the time of initial evaluation, each individual growing area in the entire classified area must have a consecutive three year history of acceptable sample results for the anticipated harvest months for all species to be harvested.
- Samples must be submitted for all anticipated harvest months for each species to be harvested each year, to remain at this level.

If samples are not submitted as required for a period of one or more years, the area will revert back one level, on a year for year basis.

V. SAMPLE SUBSTITUTION

The use of non-target shellfish species for PSP monitoring may be an alternative for new aquaculture farms that may not have harvestable product for three years. This could allow the operator to be at a higher level of the plan when ready to harvest to substitute for oysters; both mussels and butter clams will be required as monitoring species. Each species must be submitted at the appropriate frequency to be considered equivalent. PSP results must be < 80 micrograms of toxin per 100 grams of tissue for both species, in order for the sample to be considered acceptable.

Requests to use substitute species must be made:

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