



Alaska Department of Environmental Conservation (DEC)

Shellfish Sanitation Program Briefing on Geoduck Shipment Linked to China Shellfish Import Ban – February 10, 2014

Issue

In early December 2013, China banned the import of shellfish originating from west coast states. China claimed that sampling conducted on product that arrived in China indicated high levels of paralytic shellfish toxin (PST) in geoducks from Middle Gravina Island in Alaska and arsenic in geoducks from a site in Washington.

We take the safety of Alaska's shellfish very seriously and whenever shellfish of any type exceed safe testing levels, we do not open growing areas until tests show the shellfish are again safe to eat. We're working hard with our partners to find out more about the situation and it's our goal to resolve this issue quickly.

Overview of Alaska's Geoduck Fishery

- There are 49 approved geoduck harvest areas in Southeast Alaska.
 - Of these 49 areas, there are four geoduck aquaculture sites that are not subject to the same Alaska Department of Fish and Game (ADFG) harvest management rules applied to the wild harvest sites and four approved areas located at Annette Island that are managed by the Metlakatla Indian Community, rather than ADFG.
 - The four aquaculture and four tribal-managed sites not under ADFG management are open to harvest (subject to acceptable pre-harvest test results) as the owner or tribe determines appropriate.
- Annually, in accordance with their fishery management plan, ADFG announces which of the 41 growing areas under their management will be available for harvest.
- For the 2013/2014 commercial geoduck season in Southeast Alaska, ADFG announced 19 approved growing areas available for harvest (subject to acceptable pre-harvest test results) and set a harvest limit of 583,000 pounds. The 2013/2014 season began October 3, 2013 and will end when the harvest limit is reached or at the direction of ADFG.
- All approved geoduck harvest areas are only open for harvest in accordance with the Alaska Geoduck Clam Biotxin Monitoring Plan. The plan specifies that an area is only open for harvest after testing of geoduck tissue shows Paralytic Shellfish Toxin (PST) levels that are less than 80 micrograms (μ)/100 grams (g). The harvest must occur within 5 days of the sample collection and is usually opened by ADF&G for 3-6 hours.
- The harvest areas are not continuously open for harvest after an acceptable pre-harvest result and must be retested before the next opening.

DEC's Role in Shellfish Sanitation and Safety

- Alaska participates in the National Shellfish Sanitation Program (NSSP) and Alaska's regulations adopt the NSSP Model Ordinance by reference.

- We monitor the safety and sanitation of molluscan shellfish commercially harvested from Alaska waters and entered into commerce for human consumption.
- We perform water and shellfish analyses and manage harvest from shellfish growing areas when pollution, biotoxins, or other factors indicate a potential safety problem.
- We investigate illnesses that may be linked to eating shellfish and close areas to shellfish harvest or impose conditions on harvest to make it safer for consumers.
- We inspect shellfish harvesters and dealers.
- We (or National Oceanic and Atmospheric Administration (NOAA)) issue certificates to shellfish shippers for export (called “Certificate of Origin and Permit Verification”). The certificate is not a health certificate; rather, it is a document that verifies that the shipper has a valid permit and has undergone inspection by Alaska’s program. For the shipment questioned by China, NOAA issued the certificate, number CN.4023.134871-13 HA.

Explanation of NSSP

- The NSSP is the federal/state cooperative program recognized by the U.S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption.
- The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of state shellfish programs.
- Participants in the NSSP include agencies from shellfish producing and non-producing states, FDA, Environmental Protection Agency (EPA), NOAA, and the shellfish industry.
- Under international agreements with FDA, foreign governments also participate in the NSSP.
- Other components of the NSSP include program guidelines, state growing area classification and dealer certification programs, and FDA evaluation of state program elements.
- Alaska’s Shellfish Sanitation Program undergoes regular audits, conducted by FDA, to ensure conformance to the requirements of the NSSP. These audits include review of the Alaska Geoduck Clam Biotoxin Monitoring Plan and the Environmental Health Laboratory’s (EHL) testing activities for PST. Recent audits show Alaska conforms to these national standards.

Alaska Geoduck Clam Biotoxin Monitoring Plan

In accordance with the requirements of the NSSP, Alaska has implemented a Geoduck Clam Biotoxin Monitoring Plan to ensure that dangers to public health that arise as a result of marine biotoxins in commercially-harvested geoduck clams are prevented.

- To determine whether an area may be open for harvest, three geoducks are collected from each approved geoduck growing area and sent to the EHL for analyses. The harvesters collecting the required samples have transponders onboard their vessel that DEC tracks to verify sampling from a particular area.
- The laboratory removes and composites the three visceral balls* (also referred to as digestive gland) for PST analyses.
- The EHL analyzes the viscera of the three composited geoducks from each area using the *PSP in Shellfish Mouse Bioassay Method*.

- Test results represent only the specific growing area from which the three geoducks were sampled and determine whether that specific growing area is open for harvest during a limited time period.
- Acceptable results needed to open an approved growing area for harvest are $<80\mu/100$ g of tissue.
- If results are unacceptable, the approved growing area remains closed for harvest. The area may be sampled again during the season, and a decision will be based at that time on the new sampling results.
- The EHL notifies ADFG of results and ADFG opens a classified growing area based on acceptable results.
- Harvest may occur two to five days after sampling, but not before receiving EHL results of analyses.
- Each area is resampled prior to subsequent openings.

*The states of Alaska and Washington, as well as the province of British Columbia, analyze the composited viscera of three geoducks to determine PST levels in a specific harvest area.

China's Suspension of Molluscan Shellfish Imports

- NOAA notified DEC on December 6, 2013 that China suspended all imports of molluscan shellfish from the North American west coast because they detected PST and arsenic in two shipments of geoduck (one from Alaska and one from Washington State).
 - The affected area is known as "Area 67," a Food and Agriculture Organization of the United Nations (FAO) designation for California, Oregon, Washington, British Columbia, and Alaska.
- On December 13, 2013, NOAA sent a letter to China
 - NOAA advised that Alaska and Washington were preparing their investigation reports.
 - NOAA asked questions for clarification from China regarding whether they were using other sample results or sources to extend the ban to all bivalve mollusks and sampling and analyses methods for PST testing.
- On December 19, 2013, NOAA sent a response to China
 - NOAA explained the purpose of the NSSP as well as Alaska and Washington's rigorous PST testing protocols.
 - NOAA requested that China limit its suspension to live geoduck clams (rather than all bivalve molluscan shellfish) because that species was the only one implicated.
 - NOAA explained that the US does not monitor for arsenic.
 - NOAA stated that they and FDA believe geoduck clams and mollusks in FAO Area 67 are safe for consumption, meet China's safety requirements, and should be allowed for import into China.
- On January 23, 2014, China sent a letter to NOAA
 - China provided some information regarding their sampling and analyses methods.
 - China requested additional information. Specifically,
 - regarding analyses results of all geoduck harvest areas within the last year
 - whether "geoducks caught from the Middle Gravina Island" area have shown PST levels that exceeded $80\mu/100$ g within the last three years

- whether analyses of three geoducks were representative of a given area and sufficient to ensure the safety of geoduck
- specifics on testing methodologies for PST
- whether the US conducts PST analyses of a certain number of shipments for export
- China stated that the US system “shows defects on regulating and monitoring the safety and hygiene for geoduck export to China” because it does not require testing for arsenic.
- China stated that, because Chinese consumers eat the geoduck meat, skin, and digestive gland (viscera), they will continue to maintain the suspension.
- China expressed interest in sending a team to the US to conduct on-site evaluations of the US regulatory system regarding edible, live aquatic animals.
- China expressed interest in developing a cooperative document regarding inspection and information exchange.

What DEC has Done

- DEC traced the shipment from Alaska associated with the health certificate to geoducks harvested from Middle Gravina Island (ADFG 101-29-002), an approved growing area that was open October 10, 2013 for harvest based on an acceptable PST result of 66µ/100 g, results that were below the US regulatory limit of 80µ/100 g. DEC determined that geoducks were legally harvested and the shellfish dealer/shipper records appeared to be properly maintained.
- Like NOAA and Washington State, Alaska immediately stopped issuing health certificates for exports bound for China.
- December 14, 2013, DEC provided its investigation findings to FDA and NOAA. NOAA forwarded those findings to China.
- DEC provided responses February 7, 2014 to NOAA so that NOAA could respond to China’s January 23, 2014 letter requesting additional information.
- Although FDA has reviewed Alaska’s program and finds that the program complies with the requirements of the NSSP, Alaska regularly reviews all elements of its program and is currently reviewing its biotoxin monitoring plans.
- DEC continues to work closely with other western states, NOAA, and FDA to obtain more details of China’s decision and respond to inquiries for additional information.

PST Levels for All Approved Growing Areas 2013/2014

- For the 2013/2014 commercial geoduck season in Southeast Alaska, a total of 27 approved growing areas were open for possible harvest.
- To date, of 188 samples submitted to the EHL for analyses, 16 samples showed levels of PST less than 80µ/100 g and two samples were rejected by the EHL because they did not meet receiving criteria.
- Based on these acceptable results, the commercial geoduck fisheries in specific harvest areas have been open 16 times during the 2013/2014 season and areas were not open when the PST levels exceeded 80µ/100 g.

Middle Gravina Island PST Levels 2011 – 2014

- Middle Gravina Island has been sampled 12 times during the 2013/2014 season.

- Results of these tests range from 66µ/100 g to 784µ/100 g.
- Middle Gravina Island harvest area was open one time after testing showed PST results of 66µ/100 g, a value below the regulatory limit of 80µ/100 g.
- As part of the ADFG fishery management plan, Middle Gravina Island was not open for harvest for the 2011/2012 or 2012/2013 seasons and no samples were collected for these time periods, so no data is available.

Inorganic Arsenic

- China reported that the levels of inorganic arsenic in one shipment of geoducks from Washington State measured above their limit, which is 0.5 mg/kg.
- Alaska does not test for arsenic and there are no US guidelines for arsenic in shellfish.
- Historically, research testing for arsenic in shellfish in other areas have shown levels below human health concern.
- The Chinese requested in their January 23, 2014 letter to NOAA that the US begin to monitor geoduck for inorganic arsenic according to China's standard.

Roles of Partner Agencies

- *FDA*: Oversees the NSSP and provides technical support to member states to ensure molluscan shellfish safety. FDA audits all state shellfish control authorities to ensure compliance with the Model Ordinance.
- *NOAA*: Oversees the National Seafood Inspection Program. Issues certificates for export as do many state shellfish control authorities.
- *Alaska State Troopers (AST)*: Our enforcement partner; while DEC conducts civil enforcement, AST does criminal enforcement. They conduct emphasis patrols to prevent poaching and other illegal activity to prevent unsafe shellfish from entering the market.
- *Department of Natural Resources – Aquatic Farming Program*: Owns state lands where much of the geoduck resource exists. They are responsible for ensuring the overall process that allows companies to lease and have access to harvest on state lands.
- *ADFG – Division of Commercial Fisheries Mariculture Program*: Issues permits for construction and operation of aquatic farms and hatcheries.
- *ADFG – Commercial Fisheries*: Manages fishery openings and closures. DEC notifies ADFG of pre-harvest analyses results and ADFG opens fisheries when results in an area are acceptable.