

**NOAA Seafood Inspection Program's  
Proposed Changes to the United States Certification of Geoduck Clams for  
Shipment to the People's Republic of China  
April 2014**

**US Regulation of Live Product for Export**

The safety assessment and certification of live product from the United States (US) to the People's Republic of China (PRC) is a collaborative effort between state authorities and the federal competent authorities, including the U.S. Food and Drug Administration and the National Oceanographic and Atmospheric Administration (NOAA) Seafood Inspection Program (SIP).

NOAA's SIP is the certifying authority in the US for all exported seafood products and serves as the lead agency for communication with trade partners on these issues. For geoducks, the states of Alaska and Washington, other federal partners, and tribal co-managers are also involved.

**Purpose**

Recently, an issue with geoducks exported from the US to PRC revealed that the US and PRC have differing interpretations of health risks associated with inorganic arsenic. Inorganic arsenic is not routinely monitored in the US because it is not considered a public health concern for US consumers. This approach is based on these facts:

- Inorganic arsenic is generally rare in the marine environment in the US;
- Exposure to inorganic arsenic in the US is typically low; and
- Inorganic arsenic accumulates in the skin and gut ball of geoduck. However, consumption patterns of geoducks are different in the US than they are in other countries, including the PRC, and these specific portions of the animal are generally not consumed in the US.

The US has learned that inorganic arsenic is of specific concern to the PRC because of exposure to inorganic arsenic to consumers within PRC and because the whole animal, including the skin and gut ball (areas of the animal where inorganic arsenic may accumulate), is commonly consumed.

The US approach to assessment and certification is guided by laws and regulations to ensure the health and safety of US consumers. These laws and regulations also ensure the health and safety of consumers in foreign countries through the US export certification process. Although the US does not currently have laws or regulations addressing levels of inorganic arsenic in geoduck and does not routinely monitor for inorganic arsenic, because of PRC's concerns, the US is proposing changes to its export certification process to ensure that arsenic levels in geoducks shipped to the PRC are acceptable.

This document outlines the US approach to evaluate arsenic levels in geoducks to resume issuing export certificates for the shipment of live geoducks to PRC. This approach consists of:

1. Review of existing data and other information to assign level of concern designations to harvest locations;
2. Collection of new or additional data to confirm initial level of concern designation of harvest locations;
3. Issuance of export certificates for shipment to PRC only if live geoducks have been harvested from areas identified as having inorganic arsenic levels acceptable to PRC; and
4. Enhanced collaboration between US and PRC regarding certification of US geoduck exports to the PRC.

### **Harvest Location Designation**

The US will evaluate and assign initial designations to harvest locations as "Low Concern" or "Elevated Concern" as follows:

- "Low Concern" means that levels of inorganic arsenic in a harvest location are unlikely to exceed PRC levels of concern;
- "Elevated Concern" means that levels of inorganic arsenic in a harvest location are more likely to exceed the PRC standard for inorganic arsenic.

The initial designation will be based on evaluation of existing available data and known environmental influences. The US will update harvest location designations as additional data is collected, taking into consideration existing data, scientific literature, environmental influences, and other information that may impact the designation of the harvest location.

### **Data Collection to Confirm Harvest Location Designation**

After assigning initial harvest location designations, the US will implement the following sampling and testing to confirm the initial designation of harvest locations.

Both Washington and Alaska have numerous harvest locations for geoducks, but only a few locations are open for harvesting at any one time. Locations that will be harvested in 2014 and 2015 will have the highest priority for collecting additional data.

### *Sample Collection Sites per Harvest Location*

Samples will be obtained from each harvest location based upon assigned concern designation as follows:

- Each “Low Concern” location will require 3 collection sites.
- Each “Elevated Concern” location will require 5 collection sites.

Collection sites within a harvest location will be determined based on relevant factors including, but not limited to, harvest activity and access to the site. Collection sites and samples will be identified by Global Positioning Satellite coordinates.

### *Number of Geoducks per Collection Site*

A sample will consist of 3 whole geoducks, including skin, gut ball, and meat. The 3 whole geoducks will be composited for testing.

- For each “Low Concern” location, the US will analyze 3 samples, a total of 9 geoducks.
- For each “Elevated Concern” location, the US will analyze 5 samples, a total of 15 geoducks.

### *Analyses*

The US will initially analyze samples for total arsenic and apply the premise that inorganic arsenic is a fraction of total arsenic values. Based on the total arsenic results, the US will determine whether additional testing will be conducted to determine actual levels of inorganic arsenic. If the total arsenic level is

- less than or equal to 3 ppm, it is probable that the sample contains an inorganic arsenic level less than or equal to 0.5 ppm and no additional testing is required.
- greater than 3 ppm, the sample will be further tested to determine actual levels of inorganic arsenic.

### **US Export Certification**

Geoducks harvested from a harvest location with inorganic arsenic levels greater than the PRC standard of 0.5 ppm, will not be eligible for export certification to the PRC.

### *Designation of Harvest Location on Export Certificates*

The US appreciates PRC’s proposal to provide more specific harvest area information on export certificates for seafood to allow PRC to restrict imports from a specific harvest area rather than all of FAO Area 67 if PRC determines a restriction is necessary. SIP proposes to add the state and harvest location in the section of the Live Aquatic Animal Health Certificate titled “Catch Area”. For example for wild caught geoducks: “FAO Area 67, Washington State, Dumas Bay harvest area”. Aquaculture geoducks will name the farm. For example: “Great Bay Clam Farm, registration number 12345.” There are two example certificates attached for your information.

### **Collaboration between Countries**

The US anticipates that the Border Inspection Posts in China will continue to take samples of geoducks upon entry and analyze them for inorganic arsenic. Any surveillance system, no matter how robust, will still have the possibility of having a sample with elevated levels of inorganic arsenic in a shipment. Geoducks may have varying level of contaminants due to differences in uptake and exposure.

An open dialogue between the US and PRC will keep the shipments of compliant geoduck clams moving in trade. As such, the US requests that the officials of the PRC, upon finding an elevated level of inorganic arsenic in an import shipment:

1. contact SIP immediately,
2. provide SIP with shipment documents; and
3. permit SIP to investigate and communicate its findings to PRC.

SIP will quickly work with the affected state, identify the specific harvest location, provide a plan of action to deal with the issue, and assist in providing any data to support PRC decisions and proposed actions.