

Unofficial Translation by FAS/Beijing:

**General Administration of Quality Supervision, Inspection and Quarantine of People's
Republic of China (AQSIQ)**

NOAA/DOC of USA

Dear Mr. Timothy Hansen,

Re: Reply to Issues Related to PSP in Geoduck Originated from the United States

Thank you for your letter related to the investigation results PSP in geoduck originated from the United States. This is to reply to you on the relevant issues:

1. China's PSP maximum residue standard

China adopts the international standard on PSP in bivalve mollusks. As for PSP, the maximum level is 400 MU/100g (80µg/100g). The notified geoduck originated from the USA showed PSP residue level at 3024MU/100g by laboratory test, which is 8 times high than the China's standard.

2. China's PSP test methodology

2-1. Based on China's testing methodology, the edible part of the geoduck is used by the laboratory for testing. According to the test standard, the test sample is 2 kg minimum. In general, 1 or 2 geoducks are used as samples for testing depending on the weight of the geoducks.

2-2. AQSIQ conducted tests of 350 samples of geoducks originating from the USA in 2013 based on AQSIQ's safety and hygienic monitoring plan.

2-3. China adopts mouse bioassay and conducts test based on Test in Shellfish-GB/T 5009.231-2008 PSP. This test methodology is equivalent to AOAC in effectiveness. The sample-smashed geoduck tissue is treated with mol L⁻¹HCl at density of 0.18, and boiled for 5 minutes, then the PH value is adjusted to 2.0-4.0, centrifuged for 15 minutes with 18,0000 r/min, then collect the upper liquid for mouse bioassay.

3. Regarding the US Investigation Results

Thanks for your feedback on the PSP and inorganic arsenic investigation results and the relevant technical documents. These large English documents are studied and evaluated by our experts. As we are not familiar with the US safety and hygienic regulatory system on live aquatic animals for human consumption for export to China, and have never done an evaluation before, in an effort to facilitate the evaluation, please clarify and provide information on the following issues:

3-1. PSP issue

Your report indicated that you traced back the origin of the geoduck with high PSP which is "middle Gravina Island". Prior to beginning of catch, based on the Alaska Shellfish Hygienic Program, 3 geoducks were selected for mouse bioassay test for PSP which showed PSP level at 66µg/100g. Meanwhile, your report also indicated that 5 samples from "Redondo Tract #10380"

in Washington State were tested from mid-September to mid-October with PSP test results all lower than 80µg/100g. We have the following questions:

3-1-1. Your report mentioned the US government has “National Shellfish Sanitary Program” (NSSP), we would like to know whether each state has a shellfish sanitary program based on the NSSP and enforce it mandatory? What safety and hygienic items are covered by the NSSP? Are all bivalve mollusks including geoduck from all US ocean for export to China covered by this Program?

3-1-2. Have your monitoring test results showed any PSP exceeding the standard when you conducted PSP monitoring on geoduck caught in Alaska and Washington State in 2013? As for the geoducks caught from the “middle Gravina Island (ADF&G#101-29-002)”, have you test records in recent 3 years showed any PSP results exceeding the standard?

3-1-3. Your report indicated that both Alaska and Washington States tested PSP with mouse bioassay methodology. However, based on the test results, the mouse bioassay shall not able to obtain test result as indicated in your report. PSP is a sum of all contents of paralytic shellfish poisoning, what test methodology is used for “PSP result” in the Washington state report? Whether this test data refers to STX single component or its equivalent value?

3-1-4. The PSP content in geoduck is related to the intake volume of algae which contains PSP. The algae volume and reproducing speed are highly related to season change, water temperature and water nutrition level, however, prior to beginning of catch, only 3 geoduck samples were used for test, do you think this is representative and sufficient to ensure the safety of geoduck during the catch season for the whole catch sea region?

3-1-5. As for geoduck for export to China, in addition to routine monitoring, do you conduct PSP test based on a certain percentage of export shipments? If yes, please share with us your percentage, the procedure and the test results for 2013.

We will continue our risk evaluation after receipt of your answers on the above questions.

3-2 Inorganic arsenic issue

Your investigation report indicated the USA does not enforce a residue limit for heavy metal arsenic in bivalve mollusks, and no US government agency conducts monitoring and test on heavy metal- arsenic for geoducks for export to China. Although the Washington State Health Department conducted an urgent sample test for the relevant sea region, obviously, the US system shows defects on regulating and monitoring the safety and hygiene for geoduck export to China. Therefore, the geoduck originating from the USA poses high safety risk in terms of heavy metal arsenic.

4. Suggestions on work next

We don't not have a full understanding of the US regulatory system including the definition of sea region and management, the official monitoring on PSP and heavy metals and the responsibility among the relevant government agencies, and we have not conducted an on-site

evaluation neither. Additionally, the Chinese consumers eat the geoduck meat and skin, and sometimes the digestive gland too. Therefore, for the sake of the consumers' health, we will continue to maintain the suspension on import approval for inspection and quarantine for geoduck originated from the relevant US sea region. We would like to propose the following for next steps:

4-1. We hope to have the detailed feedback on the questions raised above by Chinese side and the US monitoring system on Geoduck Safety, so that we can do further evaluation. Upon receipt of the US relevant information and completion of evaluation, based on the evaluation results and under precondition of safety, we will consider possibility on regionalization of the suspension to a minimized sea region.

4-2. The US side shall begin to monitor and test on inorganic arsenic for geoduck exports to China according to China's relevant standard, and formulate corresponding action plan and notify China for evaluation.

4-3. In view of increasing export volume of US live aquatic animals to China, we hope to send an expert team to the USA to conduct on-site evaluation on regulatory system on edible live aquatic animals at appropriate time this year. Based on the evaluation results, we would suggest that both sides negotiate for a cooperation document on inspection and quarantine of live aquatic animals and cooperative mechanism, enhance the cooperation on information exchange, non-compliance investigation and treatments, thus ensuring the safety of US live aquatic animals for human consumption to China and facilitating smooth trade.

With best regards and looking forward to your feedback,

Signed by WANG Xinwu

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