



Seafood Inspection Program
U.S. Department of Commerce
National Oceanic & Atmospheric Administration
1315 East West Highway
Silver Spring, MD 20910



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MEMORANDUM To: Seafood Inspection Program Participants

FROM:

Steven Wilson
Deputy Director
Office of International Affairs and Seafood Inspection

SUBJECT: Role of Analytical Testing with Approved Establishments

Any audit function of a food quality and safety system must consider three pillars to be effective: documentation, observation, and verifiable evidence. Any system audit process will include evaluation of the processes within that system and evaluation of the product produced from that system. The Seafood Inspection Program (SIP) is well known internationally for its auditing integrity and has often been requested to train other government personnel. However there has always been criticism of our minimal analytical testing from buyers and other countries to fully accept our system. It is understood that most processors perform their own analysis and this information is available to our auditors when evaluating the system. However, this information is still generated by the firm being audited and does not go far enough for the full evaluation of the firm's adherence to their planned food quality and safety management system.

For many years the approved establishment process of the SIP included a provision for our auditors to pull samples and have them tested for various for applicable food safety concerns. These samples were taken as a means to address criticisms of the Seafood Inspection Program and its lack of analytical testing. It was, and continues today, to be the belief of Program management that testing seafood after production is ineffective and does not provide the same level of acceptability as surveillance of the system and process that produces the product. However, performing no testing is problematic in that you have no final evidence the process is properly implemented and works as designed. Therefore, the SIP implemented a broad sampling and testing process where samples were pulled from our participating processors at a rate of 2 samples per year for firms producing high risk products and 1 sample for all others. The data collected was used to illustrate the totality of the actions of the SIP and not the acceptability of the firm. This protocol existed for over ten years with only a few samples yielding a detected concern.

The Seafood Inspection Program has been taking steps to update and improve their processes and work to find means that will make the Program and its results of better use to our trading partners, buyers, and the public. When the sampling and testing protocol was evaluated, we found that for all the samples pulled under our surveillance protocol, very little could be stated as to the work of the firm, nor could any connection be made between the data collected to the

results of audits performed. It was clear our sampling protocol had to be updated in a manner where the data was more useful and was not over burdensome to the industry.

During this time some firms desired to utilize their own sampling and testing process to meet the Program's need. A provision was placed in the annual SIP fees memo describing the means by which the firm must provide the results of this internal testing. An evaluation of this process revealed that the background documentation required to accept these results had not routinely been provided, thereby making the test results received unusable by the Seafood Inspection Program. Further, these samples still were not considered official as they were not pulled by SIP personnel and a chain of custody was not present.

Based on the information above, it has been determined that periodic official samples were necessary to support the efforts of the Seafood Inspection Program and its participants. The method to be used will be to periodically pull samples during audits conducted at the firm. These samples will be pulled by Seafood Inspection Program personnel and sent to the National Seafood Inspection Laboratory for analysis. Samples will be pulled relative to the system audit that day, and therefore will be focused on product being produced while the audit is being conducted or in recent storage. Product to be sampled will be directed by Program management based on risk. Sampling will be conducted quarterly as part of the audit, but will not be compliance based. In other words, only enough samples (and replicates) will be taken to perform the tests and these results cannot be used to determine lot acceptability. The results are only an indicator of the process controls in place.

It is known that some firms have been holding shipments of product where SIP has taken samples until the results have been received by NSIL. This is a business decision however the samples pulled are not compliance-based with only sufficient material being taken to conduct the analyses and these results cannot be used to determine lot acceptability. NSIL will provide the results to our headquarters office who will have them available to regional personnel. In this way if a firm decides to hold product waiting for results, they should be able to release soon after the tests are completed. At this time, we are being informed by NSIL that a short turnaround is expected for delivery of the results.

Finally, this activity will be part of the overhead costs of the Seafood Inspection Program. As such, and due to the changes noted above, the annual fees memo has been modified to eliminate any details of analytical testing as it is not germane. Those firms which have been sending their results in lieu of official testing may continue to do so until October 1, 2016 at which time this process will become the only sampling process for the Seafood Inspection program.