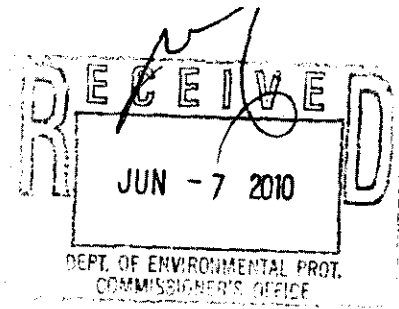


June 2, 2010

Robert Martin, Commissioner
New Jersey Department of Environmental Protection
401 E. State Street, 7th Floor
P.O. Box 402
Trenton, NJ 08625



Dear Commissioner Martin:

I am writing to provide you with the findings of the Food and Drug Administration (FDA) Annual State Shellfish Program Evaluation. Enclosed is our 2009 Evaluation for the State of New Jersey as required by the National Shellfish Sanitation Program (NSSP).

As you know, the New Jersey Department of Environmental Protection (NJDEP) is responsible for the administration of the Shellfish Growing Area Classification and Control of Harvest (Patrol) programs. The Shellfish Processing and Shipping Certification program activities are the responsibility of the New Jersey Department of Health and Human Services (NJDHSS) and a similar letter has been sent to Acting NJDHSS Commissioner Poonam Alaigh.

I am pleased to report the Growing Area water classification element was found in conformance with the NSSP requirements. The NJDEP has been in the forefront of utilizing the newest technologies to analyze water samples and determine sources and extent of pollution that could impact the safety of shellfish harvested in New Jersey.

I regret to report that the New Jersey Shellfish Program was found in nonconformance with the NSSP Control of Harvest (Patrol) Program requirements. The State of New Jersey has been a partner in the NSSP and a member of the Interstate Shellfish Sanitation Conference (ISSC) for many years. As a member of the ISSC, New Jersey has agreed to enforce the provisions of the NSSP Model Ordinance (NSSP MO) by conducting patrol of shellfish harvesting areas at prescribed frequencies to ensure that shellfish are not being illegally harvested from waters that are unsafe because of pollution, high numbers of bacteria or for other reasons. However, the Department's Control of Harvest (Patrol) element was not in compliance with the NSSP requirements for patrol frequency of patrols and in providing a vessel in Delaware Bay that is adequate to assure the public that shellfish are only harvested from open and approved waters. We further believe the Division of Fish and Wildlife, Marine Enforcement Unit is in need of a larger vessel so that it can adequately patrol portions of the Delaware Bay during harvesting seasons. Resolution of this deficiency by increasing patrol to the NSSP minimum requirements and adequately patrolling all New Jersey waters of the Delaware Bay are necessary to ensure adequate protection of public health.

Finally, New Jersey still has not fully addressed the issue of regulatory authority regarding the overboard discharge of human waste from harvest vessels as required by the NSSP. Human waste discharge from shellfish harvest vessels has led to serious illness outbreaks in the past and the ISSC has resolved to solve this important public health problem by requiring harvest have onboard human waste containment systems. I request that the NJDEP work to develop, issue and enforce these important public health regulations.

I understand that state agencies, including the NJDEP, face challenges in light of the current budgetary situation in New Jersey. However, New Jersey has one of the largest shellfish industries in the nation and if program improvements do not bring the Patrol Element into compliance with the NSSP requirements, the FDA is prepared to take the issue before the Interstate Shellfish Sanitation Conference as an unresolved issue. The ISSC may determine that shellfish from New Jersey should no longer be accepted in interstate commerce, which would have a detrimental impact on New Jersey's large shellfish industry.

I am requesting that you reply to this letter with a plan to address the deficiencies outlined above within sixty (60) days. Specifically, I request that NJDEP develop a plan for increasing patrol frequency of shellfish growing waters and develop regulations based on the NSSP MO concerning containment of human waste onboard shellfish harvest vessels with the intent of having these regulations move forward through the state rulemaking process. If you require assistance in developing a plan for increasing patrol of harvest areas, developing regulations or during the rule-making process, the FDA would be happy to assist you. Failure to move forward with specific regulations concerning the shellfish industry will result in the FDA taking this issue before the ISSC as an unresolved issue. Please direct your response and action plan to me at the address on the letterhead above.

I would like to thank members of your staff who worked cooperatively with our Regional Shellfish Specialist, Gary Wolf, to complete the 2009 evaluation. Specifically, I would like to recognize the time and effort of Mr. Robert Connell and Captain Mark Chicetano who provided information to Mr. Wolf and who assisted Mr. Wolf in observing and visiting New Jersey Shellfish Growing Areas. Should there be any questions, please contact Larry Stringer, Director of State Programs or Mr. Wolf. We look forward to continuing the close cooperation between the NJDEP and the FDA.

Sincerely,



Melinda K. Plaisier
Regional Food and Drug Director
Central Region