



**UNITED STATES FOOD AND DRUG ADMINISTRATION  
U.S. PUBLIC HEALTH SERVICE  
CENTRAL REGION**

**FY 2009**

**ANNUAL PROGRAM EVALUATION REPORT  
OF STATE OF NEW JERSEY SHELLFISH PROGRAM**

**ADMINISTERED BY**

**THE NEW JERSEY DEPARTMENT OF ENVIRONMENTAL  
PROTECTION  
DIVISION OF LAND USE MANAGEMENT, BUREAU OF MARINE  
WATER MONITORING  
AND  
DIVISION OF FISH AND WILDLIFE, MARINE ENFORCEMENT  
SECTION**

**AND**

**THE NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR  
SERVICES  
CONSUMER AND ENVIRONMENTAL HEALTH SERVICES  
FOOD AND DRUG SAFETY PROGRAM**

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**FDA ANNUAL PROGRAM EVALUATION REPORT**  
**State of New Jersey**  
**FY 2009**

**A. Overall Program Status**

The National Shellfish Sanitation Program (NSSP) is a 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 State of New Jersey participates in the NSSP/ISSC as a shellfish producing, receiving, and shipping state. New Jersey has four program elements that must conform to the minimum requirements set forth in the *NSSP Guide for the Control of Molluscan Shellfish* in order for its dealers to ship to other participating states. This report summarizes FDA's Annual Program Evaluations of the Elements for the Fiscal Year 2009. The evaluation assessed the overall effectiveness of the program as measured by the criteria set forth under the NSSP. Detailed Program Element Evaluation Reports (PEERs) for each evaluated element have been reviewed by the division or agency responsible for administering the programs. The following portion of this reports the findings for each element evaluation in FY 2009.

**1. Growing Area Classification Element**

**Status:** The New Jersey Department of Environmental Protection (NJDEP), Bureau of Marine Water Monitoring (BMWM) is responsible for the Growing Area Classification Element. This element was found to meet and in some cases exceed the requirements of the NSSP Model Ordinance (MO). No program deficiencies were cited. The program is well managed by knowledgeable, experienced staff. Classifications of shellfish growing areas are currently supported by appropriate field work, reviews, and applications of NSSP standards. This program element will be evaluated again in FY 2010.

**2. Processing and Shipping Element and Standardization**

**Status:** The New Jersey Department of Health and Senior Services (NJDHSS), Food and Drug Safety Program administers the Processing and Shipping Element which includes shellfish dealer certification and plant inspections, illness outbreak and product recall coordination.

**The Processing and Shipping Element did not meet all of the program requirements established by the ISSC under the NSSP during the last complete evaluation in 2008. An Action Plan was requested by FDA at that time to address inspection frequency problems.** Specifically NJDHSS did not comply with the inspection frequency requirements for Certified Shellfish Dealers. In addition during the 2008 summer oyster harvest under the State's *Vibrio parahaemolyticus* (Vp) Control Plan there was inadequate enforcement staffing available at Shellfish Dealers that purchase oysters directly from harvesters to verify that they were

meeting the 2008 Vp Control Plan including HACCP time-temperature requirements from harvest to refrigeration. A review of the NJDHSS files and records revealed that official inspections or investigations were not conducted at each Certified Shellfish Dealer receiving oysters from harvesters during the period of the 2008 New Jersey Vp Control Plan to determine if the firms were complying with the New Jersey Vp CP.

**As of 2009 the NJDHSS has not yet come into compliance with the NSSP MO Shellfish Plant inspection frequency based on this progress report which included a review of inspections conducted in FY 2009.** This assessment did include New Jersey Certified Shellfish Dealer Inspections performed by FDA Shellfish Standardizing Officer (SSO).

### **3. Control of Harvest (Patrol) Element**

The Control of Harvest (Patrol) Element is administered by the NJDEP, Division of Fish and Wildlife (DFW), Marine Enforcement Section. Their mission is to assure that illegal harvesting of shellfish from waters classified as Prohibited, Restricted or in a Closed status are not harvested in order to protect the health of the public.

**The FY 2009 evaluation found New Jersey's Shellfish Patrol element was not conforming to the requirements as stipulated in the NSSP MO.** Patrol Areas were evaluated by the FDA Regional Shellfish Specialist including site visits by boat with NJDEP Fish and Wildlife Officers or BMWM staff. Where an evaluation by NJDEP vessel could not be made Patrol Areas were evaluated by land and records were reviewed. The entire 2009 Patrol Policy Document was reviewed and discussed with the Marine Enforcement Captain Mark Chicketano.

**The FY 2009 evaluation found that the Shellfish Patrol element was not conforming to the requirements of the NSSP MO. The Overall Patrol Frequency levels did not meet minimum NSSP guidance for the number of Patrols in Prohibited, Restricted or Closed status areas. The FDA requests that the DFW develop an action plan to address this deficiency.**

## **B. Status of Deficiencies (If Any) Identified during Evaluation**

### **1. Growing Area Classification Element**

**Present Status:** Thirteen (13) growing areas were randomly selected for the FY 2009 FDA evaluation. New Jersey has a total of 34 Growing Areas. A comprehensive review of the Sanitary Survey, Triennial Reevaluation, and Annual Update Reports was conducted. Field visits to these thirteen growing areas were conducted to verify sanitary survey report classifications, sample station locations, and identified pollution sources. New Jersey performs a very thorough review of growing areas when classifying or annually re-evaluating them. As previously stated, no program deficiencies were cited.

**FDA follow-up:** No corrective Action Plan was required.

Based on the Evaluation the FDA recommends that BMWM provide a written summary of changes to the annual Growing Area classifications to the NJDEP Marine Enforcement Unit prior to publishing it in the State Register as a regulatory proposal. This was not evident in 2009 when one area was upgraded to Restricted from Prohibited which requires adjustments in the NJDEP Marine Enforcement Unit's Patrol frequency and strategy.

There is no regulation in place to require Marine Sanitation Devices (MSD) or other waste containment systems on harvest vessels to prevent overboard discharge of human bodily wastes and prevent the public health risk related to overboard discharge of such waste. The FDA recommends that the New Jersey Shellfish Program have a formal harvester and shellfish dealer education program which includes written material describing the public health risks associated with overboard discharge of human waste to ensure that the industry understands and is aware of risks.

**Note:** Additional information regarding the Growing Area Classification Element evaluation may be found in the FDA FY 2009 Growing Area Classification PEER.

## **2. Processing and Shipping Element and Standardization**

**Present Status:** The NJDHSS was asked by FDA for an ACTION PLAN following the FY 2008 FDA Processing and Shipping Evaluation. As of 2009 the NJDHSS has not yet come into compliance with the NSSP MO Shellfish Plant Inspection Frequency Based on this Progress Report which included a review of the 2009 Inspections Conducted. (Note: See the PEER for the basis for this conclusion.)

**NJDHSS Response:** The NJDHSS has brought additional field staff during late 2009 and early 2010 into the shellfish inspection cadre that were undergoing NSSP required field and classroom training. It has been indicated to FDA by the NJDHSS that this additional staff should be providing the required inspections of New Jersey Certified Shellfish firms during 2010 as well as verifying the implementation of the 2010 Vp oyster Control Plan. A complete NSSP Plant Evaluation will be conducted by the FDA Regional Shellfish Specialist in 2010 and NJDHSS is confident that frequency of inspection issues will be improved and in conformance with NSSP MO requirements.

**FDA Recommendation:** The FDA requests that NJDHSS develop an Action Plan to address its failure to meet inspection frequency requirements. The FDA is prepared to assist NJDHSS in the development of the plan and in assisting NJDHSS in meeting inspection frequency requirements.

### 3. Control of Harvest (Patrol) Element

**Present Status:** The FDA requested an Action Plan in 2009 based on the FY 2008 evaluation that the NJDEP communicate a timetable and corrective action for the areas not in compliance with the NSSP MO, particularly the inability of NJDEP to meet frequency of patrol requirements. The Overall Patrol Frequency levels did not meet minimum NSSP requirements for the number of Patrols in Prohibited, Restricted or Closed status areas. Out of thirty (30) New Jersey designated Patrol Areas 21 (70 percent) were not in compliance during one or more thirty day Patrol periods for FY 2009.

At this time FDA finds the Marine Enforcement Section has insufficient staffing to meet the patrol frequency requirements. There are increased demands placed on this Marine Enforcement Section from non-commercial shellfish oyster gardening requests in "Closed" harvest areas and from additional growing areas downgraded by the NJDEP BMWM. This deficiency could negatively impact the public health as well as New Jersey's large shellfish industry. In addition during the summer 2010 oyster harvest the New Jersey Vp Control Plan will expand to include all oysters harvested throughout the state not just sections of Delaware Bay and will include both sub-tidal and inter-tidal harvest methods. This 2010 Vp Control Plan will run from June through early September. The Vp Control Plan will require that there be adequate enforcement through the Patrol staff within the DFW Marine Enforcement Section.

**FDA Recommendations:** It is again recommended (2008 and 2009 Evaluations) that the DFW Marine Enforcement Unit consider the purchase a larger more sea-worthy patrol vessel to cover the expansive oyster harvest areas in Delaware Bay under most weather conditions. In addition it is recommended that this vessel be equipped with GPS that has radar interface. The FDA requests that NJDHSS develop an Action Plan to address its failure to meet patrol frequency requirements. The FDA is prepared to assist the DFW Marine Enforcement Unit in the development of the plan.

**DFW Response:** The NJDEP which responsible for the shellfish Control of Harvest (Patrol) has agreed to provide an Action Plan to the FDA to address the deficiencies and recommendations that are noted in this Report. To date the FDA has not received an Action Plan, however it was indicated that there are plans to purchase an additional larger appropriately equipped vessel to patrol the waters of Delaware Bay. However this vessel will not be available for the summer 2010 oyster season during the implementation dates for the New Jersey Vp Control Plan dates from June through early September. During this time the requirements of the Vp Control Plan will necessitate that Patrol of the waters include the enforcement of limited oyster harvest hours, the proper use of shade covers over oysters on-board the vessels and the off-loading and transport conditions from the docks to the shellfish dealers for refrigeration. NJDEP is committed to doing all it can within its resources to meet the NSSP MO frequency of patrol requirements.

### **C. Information on Illnesses Cases/Outbreaks and/or Recalls**

During the 2009 summer season the NJDHSS reported a number of sporadic *Vibrio parahaemolyticus* (Vp) cases that were confirmed by the NJDHSS Epidemiology Division that implicated molluscan shellfish (see details in the PEER Report). In several instances it could not be determined if the implicated product was raw clams or raw oysters although there were cases that only involved raw clams harvested in New Jersey Open Shellfish Growing areas. The NJDHSS made a determination that the Vp cases were sporadic in nature given the dates of illness onset and the lack of a common shellfish Growing Area. Therefore the State of New Jersey did not declare a Vp outbreak. At the same time the New York Department of Environmental Control (NYDEC) Shellfish Program reported and linked through epidemiological data several cases of confirmed sporadic Vp illnesses originating from clams or oysters from approved New York shellfish Growing Areas. New York State did not declare a Vp illness outbreak and reported the cases to the FDA. (For details refer to the Plant Sanitation PEER.)

### **Vp Control Plan Implementation 2009**

In 2009 NJDEP and NJDHSS met with the Delaware Bay Shellfisheries Council and Rutgers University's Haskin Shellfish Research Facility to develop a new Vp Control Plan. As a result of discussions at several meetings and subcommittees between the Council, the NJDEP and NJDHSS, and the FDA and other technical experts, the State of New Jersey implemented a revised Vp Control Plan in 2009 that requires pre-chilling of the oysters to a product temperature of 50°F within twelve (12) hours of harvest and prior to placement onto refrigerated trucks/trailers for interstate transport.

The implementation included FDA and State Shellfish Dealer refrigeration capability pre-approval. Once approved, the facilities were visited to determine if they developed the appropriate HACCP Plans to implement this Vp Control Plan. During the Vp Control Plan season evaluations of the "Approved" facilities were conducted frequently to verify compliance with the provisions of the Vp Control Plan.

A FDA Shellfish Specialist New Jersey assisted in this process since the NJDHSS had lost all but two of their trained and standardized Shellfish staff.

### **D. State Program Accomplishments**

- The FDA Basic Shellfish Plant Sanitation Course was presented in November 2009 to two (2) NJDHSS Sanitarians. During 2010 those staff will be completing field training in Shellfish Plant inspections through the State Standardization Officer (SSO) in New Jersey and if successful become State Standardized Shellfish Inspectors (SSI's) for New Jersey. In addition the NJDHSS has hired two additional staff during early 2010 that took the FDA Basic Shellfish Plant Sanitation Course in March. Upon completing the class and successfully completing their field training and SSI Standardization they will also be able to conduct NSSP inspections at Certified

Shellfish Dealers. This should help bring the NJDHSS into compliance in 2010 regarding inspection frequency of their Certified Shellfish Dealers.

- The NJDEP and NJDHSS Shellfish Agencies worked with the FDA and the New Jersey oyster industry and were proactive in developing the 2009 Vp CP which included the provisions that would require the Certified Shellfish Dealers that purchase oysters during the summer months to pre-chill within 12 hours the oysters to a product temperature of 50°degrees F prior to shipment. New Jersey was one of the first states to require oyster rapid chilling before transport to reduce Vp levels nationally. There were no Vp illnesses associated with the growing areas covered by the Vp control Plan in 2009.
- On balance, water quality continues to improve in NJ. Based on analysis by the staff, the BMWM is currently proposing a net upgrade of over 1,000 acres of shellfish growing waters. One of those areas (Sunset Lake) was the result of BMWMs use of source tracking to determine precise pollutant sources impacting the waters. This source tracking led to the discovery of a broken forced main beneath the bay which was responsible for upgrade classification recommendations to Seasonal.
- A Senior Laboratory Technician attended training that was funded by the FDA Central Region provided at the FDA Research Lab in Dauphin Island, Alabama.
- New Jersey continues to take significant steps to improve its monitoring of toxic pollutants in shellfish. The BMWM secured funding to expand its toxics monitoring in the shellfish growing waters. This included equipment such as an Atomic Absorption (AA) unit to analyze for metals and other chemical toxins. A compilation of toxic data from various sources is being developed by the BMWM. Data from the monitoring efforts described above as well as from National Coastal Assessment, and NOAA's Mussel Watch are being compiled into one database. Once completed, the data from this data base should be used to enhance the growing area reports.
- The BMWM continues to improve the public's access to information. Classifications, Regulations, updated Permit applications, and Growing Area reports, when completed, are now posted on the internet.

#### **E. Emerging Issues**

We understand that a state budgeted line item is no longer provided to be utilized to help pay for the Patrol of Areas # 2 and #3 due to the large clam populations in the "Restricted" waters for Depuration harvest. The ability to sustain additional patrols in these two areas will be critical to ensure that NSSP patrol frequencies are met.

The NJDEP BMWM continues to maintain an appropriate focus on the public health aspects of oyster/shellfish gardening. However the NJDEP continue to have need of a Department-wide approach to shellfish gardening and restoration based on requests in non-Approved waters. New Jersey has regulated this activity through the issuance of a

"Scientific Collecting Permit" which allows the activity, but prohibits use of the oysters from oyster gardening for human consumption. The activity cannot be conducted in Restricted or Prohibited areas and not until approval is received from NJDEP. However, the key to public health protection with regard to shellfish gardening remains accountability and enforcement. The NJDEP BMWWM is working closely with the NYDEC Shellfish Program to coordinate efforts and responses to the shellfish gardening issue since there are common waters in the New York/New Jersey Harbor Estuary. There have been meetings with both agencies and the interested parties. The FDA has provided information on the NSSP and stressed the importance of the public health issues relating to raw molluscan shellfish and the relationship to the pollution sources and the Growing Area Classifications and Patrol.

As New Jersey attempts to adjust to the impacts of the economic downturn, it is important for the Department to consider that further cuts in these field functions will likely result in NJ's inability to maintain compliance with the NSSP without the closure of a significant portion of New Jersey's coastal waters to shellfish harvest.

The BMWWM continues to look for options to address its roughly 30% shortfall in sampling that resulted from the loss in 2008 of one of its three staff assigned to collecting samples for NSSP compliance. Actions taken to date include use of hourly employees where possible and use of overtime to allow multiple sampling runs to be collected in one day. This latter option has been severely limited recently due to policies relating to Temporary Layoff or Furlough days.

There remain waters in New Jersey that are clearly impacted by non-point source pollution such as the upper Navesink River, Sandy Hook Bay and the Shrewsbury River. Use of microbial source tracking will be needed to continue to improve New Jersey's coastal waters and to make additional waters available for shellfish harvest.

**NJDEP and NJDHSS need to coordinate the implementation and enforcement of the 2010 Vp Control Plan to discuss the planned extension of the New Jersey Plan to all oyster growing areas of the state.** This will include the Cape-Shore oyster aquaculture in Cape May County and the Mullica River oyster harvest areas in Atlantic County. This is in addition to the normal daily oyster dredging in the Delaware Bay Cumberland County. Also the Proposed 2010 Vp Control Plan will add an additional two (2) weeks to the approved harvest during June which was traditionally closed voluntarily by the industry to move seed. All of this will create additional demands on the Control of Harvest (Patrol) element under the NJDEP DFW which already had deficiencies cited in the 2009 FDA Evaluation Report. (See 2009 PEER Report issued to NJDEP in March.)

## **F. Unresolved Issues**

Areas Not-in-Compliance are being addressed and monitored through the Action Plans and Follow-up status reports as part of the FDA Evaluation process. At this time progress will be reported via the FDA NSSP Evaluation process during 2010.



It appears that the NJDHSS is continuing to work on Plans to increase its staffing to conduct NSSP MO required inspections and compliance follow-up for the New Jersey Shellfish Program in 2010. The FDA Regional Shellfish Specialist will conduct a complete Plant Sanitation Element Evaluation in 2010.

#### **G. Acknowledgements**

The FDA would like to thank the management and staff of the NJDEP especially the BMWM and the Marine Enforcement Section of the DFW as well as the NJDHSS, Food and Drug Safety Program for their time and assistance in allowing the completion of the State Shellfish Program Evaluation.