



**FY 2009**  
**PROGRAM ELEMENT EVALUATION REPORT**  
  
**OF THE**  
  
**PLANT SANITATION PROGRAM ELEMENT**  
**SHELLFISH SANITATION PROGRAM**  
**DEPARTMENT OF MARINE RESOURCES**  
**STATE OF MAINE**

**PREPARED BY**

**PETER N. KOUFOPOULOS**  
**REGIONAL SHELLFISH SPECIALIST**  
**NORTHEAST REGION FIELD OFFICE**  
**FOOD AND DRUG ADMINISTRATION**

**ON**

**March 23, 2009**

## PROGRAM ELEMENT EVALUATION REPORT

STATE: Maine

DATES OF EVALUATION: December 15 - 19, 2008 & February 6, 2009

PROGRAM ELEMENT EVALUATED: Plant Sanitation

### A. Status of Previous Program Evaluation

The FY 2007 evaluation of the Maine Department of Marine Resources (DMR) Plant Sanitation Program found that the DMR was in full compliance with the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). No administrative deficiencies were cited during the FY 2007 program evaluation per Chapter I of the NSSP MO. Certified dealers were found to be inspected per the minimum requirements in Chapters X thru XV.

### B. Status of Current Evaluation

#### 1. Total Number of Plants Evaluated

The number of certified firms listed in the December 1, 2008 ICSSL was utilized in determining the number of firms selected for FY 2009 evaluation activities. The December 1, 2008 ICSSL indicated that Maine had 116 shellfish plants certified, to include: 1 Depuration Processor, 31 Shucker-Packers, 78 Shellstock Shippers and 6 Reshippers. Thirteen firms were selected for the joint FDA/DMR evaluation inspections as required by Attachment D in the FY 2009 FDA Molluscan Shellfish Compliance Program (CP). A majority of the firms selected to be visited during this evaluation had not been inspected as part of the joint evaluation inspection process in the past five years.

The selection of plants was conducted jointly by the DMR Shellfish Plant Inspection Staff and the FDA. Plant selection was performed daily as the evaluation proceeded. Final selections were based on geographic location and availability. Field evaluations of the selected firms were conducted December 15 - 19, 2008 and February 6, 2009. A file review of the 13 facilities evaluated was conducted at the Central Office in Hallowell, ME on December 19, 2008. Maine does not have any certified firms conducting post harvest processing activities for the purpose of reducing vibrios.

Certified firm name, certification number and date of inspection are listed in the table below. The actual inspection reports completed by the FDA are included as Attachment A of this report.

Certified Firm Name	Certification #	Date of Inspection
Bayley's Lobster Pound	ME-140-SS	12/15/2008
Nova Seafood, LTD	ME-297-SS	12/15/2008
Fisherman's Catch Seafood Market	ME-172-SS	12/16/2008
Associated Sea Farms	ME-22-SS	12/16/2008
Seaside Seafood	ME-194-SP	12/16/2008
Muscongus Bay Aquaculture, Inc.	ME-46-SS	12/16/2008
Ocean Harvest	ME-8-SS	12/17/2008
Phinney Fisheries	ME-190-SS	12/17/2008
Maine Shellfish Co., Inc.	ME-100-SP	12/18/2008
Grant's Seafood	ME-177-SP	12/18/2008
Harbor Fish Market, Inc.	ME-233-SS	02/06/2009
Maine Oyster, Inc.	ME-210-SS	02/06/2009
S & S Seafood	ME-91-SS	02/06/2009

2. Program Areas in Compliance

a) Program Administration

**Legal Authority**

In 2004, the Maine Department of Marine Resources adopted the recently released 2003 NSSP Model Ordinance portion of the Guide for the Control of Molluscan Shellfish, with only minor exceptions. The DMR now has the legal authority to enforce the NSSP HACCP requirements and all of the general sanitation items. The DMR also created a specific harvester chapter to help specify what rules the harvesters must follow in their attempts to protect the shellstock from contamination after leaving the harvest area. This new chapter (Chapter 9) also describes the recording keeping requirements necessary to facilitate a timely traceback in the event of shellfish associated illnesses. Their legal authority can be found in the Code of Maine Rules (CMR), Chapter 13-188 (DMR), sub-Chapters 15 through 20 (plant sanitation).

Shellfish related illnesses are investigated by the DMR as the lead agency with support from the Maine Department of Agriculture and the Maine Centers for Disease Control when necessary. The DMR will also coordinate efforts with local town health departments depending on illness location and jurisdictional concerns.

The DMR has established a statewide commingling plan and therefore does permit the commingling of shellfish at the dealer level as long as the dealer is adhering to the details of the plan to ensure the proper traceback of shellfish anywhere within the distribution chain. As part of the administrative requirements, the DMR maintains various types of records to help demonstrate the effective administration of their statewide shellfish safety and sanitation program. Records are maintained in centralized files in the cities of Hallowell, West Boothbay Harbor and Lamoine.

### **Dealer Certification**

The DMR certifies shellfish facilities per the requirements of Chapter I@.02(A) (B)(C). Shellfish dealers are required to complete an application to remain on-file with DMR. The facilities are inspected within the 120 day period immediately prior to certification issuance or renewal of the certification. A certification is only granted to those facilities who meet the established requirements. A unique certification number is issued to individual firms and the certification expires May 31 each year. Records are maintained for each facility which document: inspection reports, notification letters and enforcement actions, shellfish sample results and follow-up actions taken, records of complaints or inquiries and follow-up actions taken, and administrative hearing transcripts and records.

The DMR follows the MO requirements which list the maximum number of deficiencies allowed for both initial certification and certification renewal. Upon certification the DMR does notify the FDA for the purpose of having the dealer listed in the Interstate Certified Shellfish Shippers List (ICSSL) by using the electronic version of FDA form 3038. The DMR will notify the FDA to remove a dealer from the ICSSL in the event of a suspension or revocation.

The DMR follows the MO requirement to inspect firms at a specific frequency based on the firm's level of certification (i.e. quarterly for shucker-packer, semiannually for shellstock shipper). The inspection reports on file revealed that correction dates were established after each inspection. Where compliance schedules were extended a reason was offered as to why the dealer needed more time to complete the repair. In most cases the required parts or labor by a certified individual justified the time extension.

#### b) Field Verification

##### **General**

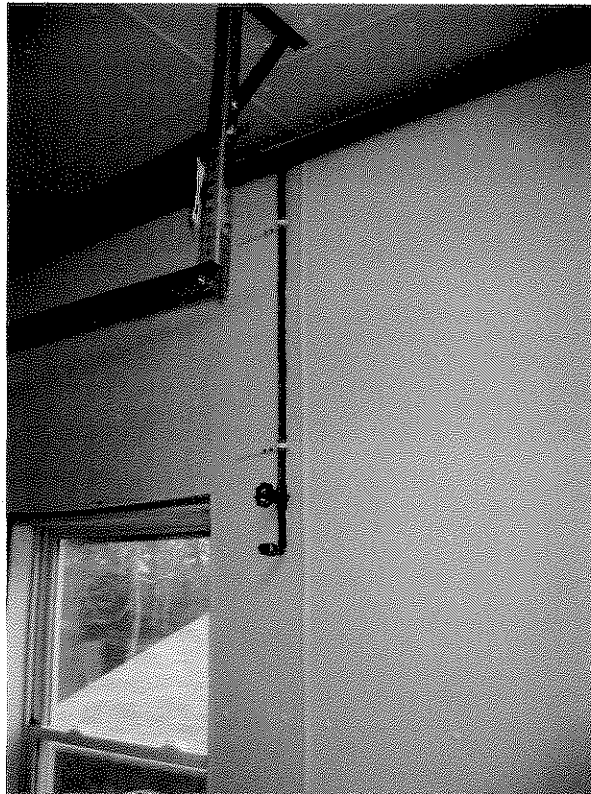
The SSO, Bruce Chamberlain, and Shellfish Inspectors Jeffrey Armstrong and Arthur Rowe III continue to work with certified firms to fully implement the Seafood HACCP regulations. They have distributed HACCP notebooks with examples of HACCP plans, SSOPs, monitoring forms and daily sanitation records. The notebooks are provided to the firm's management/staff during in-plant HACCP training sessions

at the firms when needed or requested. The certified dealers were mailed updated “notebooks” on CD in 2007 and the document in addition to all the necessary forms was added to the DMR Plant Sanitation website in 2007.

[http://www.maine.gov/dmr/rm/public\\_health/haccpmanual/index.htm](http://www.maine.gov/dmr/rm/public_health/haccpmanual/index.htm)

There were two critical deficiencies identified at one certified facility during this evaluation. The critical deficiencies noted at Seaside Seafood (ME-194-SP) are listed below:

- ✘ A dead leg in the plumbing system was noted along the wall adjacent to the loading area. It appears that an ice machine was removed leaving the old piping in place. The termination in the pipe resulted in a dead leg where bacteria could grow in the stagnant water. (Chapter XI.02.A.4.a.i)



- ✘ While inspecting the grounds of the firm a broken waste pipe was noted outside on the ground behind the facility. Outside of the rear exit door of the firm a sewage pipe which drains waste from a neighboring home was found running on top of the ground across the property of the firm. Immediately adjacent to the back door and next to the break in the pipe female toiletry items and toilet tissue

were found on the ground. This raw sewage was in the direct foot path leading into the facility from the rear entrance. (Chapter XI.03.A.3)



All 'Key' and 'Other' deficiencies noted at the plants visited during this evaluation were either corrected during the inspection or are being corrected as part of a compliance schedule developed by the DMR and plant management.

### **HACCP Implementation**

Eleven of the 13 certified shellfish plants evaluated in Maine were all in possession of a properly formatted and complete HACCP Plan. Fisherman's Catch Seafood Market (ME-172-SS) and Muscongus Bay Aquaculture, Inc. (ME-46-SS) were unable to provide a copy of their HACCP Plan at the time of inspection. The state authority provided a generic plan to the firm until the original could be located. Since the last evaluation the level of HACCP compliance (monitoring and verification) within the certified facilities has slipped. The DMR conducts mandatory workshops for the managers of the shellfish facilities. The facility managers are also encouraged to have their employees attend these information training sessions. During the workshop, the DMR staff presents the HACCP notebook which contains customized HACCP plans, standardized forms and other related information to aid in HACCP education. The notebooks contain all of the information needed to comply with the NSSP MO HACCP requirements. The inspection staff also provide detailed in-plant training in hopes of achieving a higher level of compliance in regards to the actual

implementation of the plan's monitoring and record keeping sections. As new firms request certification, or when there is staff turnover within the facility, the SSO and/or other standardized inspectors provide the notebooks and training as needed. Despite the level of effort listed above, 54% of the facilities (7 of 13) were unable to properly verify their receiving records for accuracy and completeness once every seven days. It was also noted that 46% (6 of 13) of all firms evaluated did not review their HACCP Plan annually and sign and date the plan indicating they had done so and 6 of the 13 firms did not possess properly formatted receiving records and/or were not completing the records properly. Refer to Attachment B for specific numbers found in this section.

### **General Sanitation**

The inspection form consists of two additional sections: the Key Sanitation items (8 through 16) and the Other Model Ordinance Requirements (17 through 30) which deal with the general facility conditions, management and sales records. It was noted during the field evaluations that Key Sanitation Item #12 - "Protection from Adulterants" and Item #16 - "Sanitation Monitoring and Records" were debited at 4 of the 13 firms (31% overall non-compliance). This is a significant improvement over the last evaluation.

The general facility requirements (17 thru 30) experienced the most debits under two distinct items. Item #17 - "Plants and Grounds" was debited at 7 of the 13 firms (54%) and Item #18 - "Plumbing and related facilities" was debited at 5 of the 13 firms evaluated (38%). This is a slight improvement in both items since the last evaluation.

#### **c) Standardization/Maintenance**

The Maine DMR Shellfish Standardization Officer (SSO) Bruce Chamberlain and back-up Shellfish Standardization Officer (SSO) Amy Fitzpatrick conducted standardization inspections with the FDA in December 2008. Mr. Chamberlain's and Ms. Fitzpatrick's standardization are now current through February 2014. Mr. Chamberlain's and Ms. Fitzpatrick's average composite score based on the five formal standardization inspections are within the acceptable average score required to achieve standardization. The firms inspected and the disagreement results of these standardization inspections can be found in the table below (additional paperwork can be found in Attachment C).

The DMR Plant Inspection Program has two plant inspectors who report directly to Mr. Chamberlain. Mr. Chamberlain utilizes the NSSP Plant Standardization Procedures guidelines to standardize the two state shellfish plant inspectors.

Composite Performance Chart for Bruce Chamberlain

FIRM NAME	HACCP	SANITATION ITEMS	ADDITIONAL MO REQUIREMENTS
Bayley's Lobster Pound - ME-140-SS December 15, 2008	0	2	1
Fisherman's Catch Seafood Mkt.- ME-172-SS December 16, 2008	1	0	0
Associated Sea Farms - ME-22-SS December 16, 2008	2	0	0
Seaside Seafood - ME-194-SP December 16, 2008	0	0	0
Muscongus Bay Aquaculture, Inc. - ME-46-SS December 16, 2008	2	0	1
TOTAL	5	2	2
	/5	/5	/5
*Average Score	1.0	0.4	0.4
Acceptable Avg. Score	3	3	4

INSPECTIONAL EQUIPMENT	SATISFACTORY	NEEDS IMPROVEMENT
COMMUNICATION	SATISFACTORY	NEEDS IMPROVEMENT

Composite Performance Chart for Amy Fitzpatrick

FIRM NAME	HACCP	SANITATION ITEMS	ADDITIONAL MO REQUIREMENTS
Bayley's Lobster Pound - ME-140-SS December 15, 2008	0	1	1
Fisherman's Catch Seafood Mkt.- ME-172-SS December 16, 2008	1	0	1
Associated Sea Farms - ME-22-SS December 16, 2008	2	1	0
Seaside Seafood - ME-194-SP December 16, 2008	0	2	2
Muscongus Bay Aquaculture, Inc. - ME-46-SS December 16, 2008	1	0	1
TOTAL	4	4	5
	/5	/5	/5
*Average Score	0.8	0.8	1.0
Acceptable Avg. Score	3	3	4

INSPECTIONAL EQUIPMENT	SATISFACTORY	NEEDS IMPROVEMENT
COMMUNICATION	SATISFACTORY	NEEDS IMPROVEMENT

d) Illnesses Reported

The State of Maine has not been the original source of shellfish associated with any *Vibrio vulnificus* (*V.v.*) illness in the past three years. Maine was the possible source of one *Vibrio parahaemolyticus* (*V.p.*) illness in the past three years.

- A 21 year old male, consumed lobster along with steamed mussels and clams on July 29, 2006 at two different restaurants (lunch and dinner) with illness onset the next day. Six different shellfish dealers provided the clams and mussels within two days prior to consumption to the two dealers. All shellfish tags reviewed showed the product was harvested only from Maine state waters.

No additional *V.p.* illnesses have been reported since the July 29, 2006 illness. The illness above was an isolated case with no other individuals becoming ill. The DMR recently updated their state regulations and require harvesters to deliver shellstock to dealers within 16 hours of harvest. This is currently more restrictive than the previous requirement which allowed harvesters to follow Time-Temperature Matrix Option 3 - Level 2.

Time-Temperature Matrix Option 3

<b>ACTION LEVEL</b>	<b>AVERAGE MONTHLY MAXIMUM AIR TEMPERATURE</b>	<b>MAXIMUM HOURS FROM HARVEST TO TEMPERATURE CONTROL</b>
LEVEL 1	<66 °F (18 °C)	36 hours
LEVEL 2	66 °F - 80 °F (19 °C - 27 °C)	24 hours
LEVEL 3	> 81 °F (> 27 °C)	20 hours

Because there have been no *V.p.* illnesses epidemiologically linked to the consumption of oysters harvested in the state, and because water temperatures do not exceed 81 degrees Fahrenheit, a *Vp* control plan for Maine is not required by the NSSP. Despite not being required to perform the risk assessment, the DMR did complete the FDA *V.p.* risk assessment worksheet. Under state regulation European oysters can not be harvested June 15 to September 15. Currently American oysters and all oysters harvested by aquaculturists are exempt from the harvesting date restrictions.

The DMR was alerted to a possible *Vibrio fluvialis* (*V.f.*) illness from mahogany clams harvested from Area 2 in Addison, Maine. A 56 year old white male, and resident of Delaware, consumed both raw oysters (harvested in Delaware) and raw clams (harvested in Maine) at a restaurant in Maryland in July 2007. No other illnesses were reported associated with this shellfish and no other individuals became ill with *V.f.* who ate at the Maryland restaurant in July 2007.

The state of Maine experienced their first paralytic shellfish poisoning case in nearly 30 years on August 1, 2007. A lobsterman from the Downeast area of the state found a floating 55-gallon poly drum offshore while tending to his lobster pots. The drum was covered with blue mussels of varying sizes. The lobsterman retrieved the drum from the open ocean and took it home that same day. He proceeded to remove the mussels, cook them and serve them to three of his family members in addition to himself. The mussels contained high levels of saxitoxin which resulted in immediate respiratory distress among the family members. Three of the four individuals were admitted to the hospital with symptoms ranging from tingling and numbness to complete paralysis. All four individuals fully recovered. A sample of the remaining cooked mussels revealed toxin levels greater than 16,000 ug/100 g of shellfish tissue (closure threshold is 80 ug/100 g).

A second documented PSP intoxication occurred July 4, 2008. A local family from Washington County was aware of the existing PSP closure in the area; however did not heed the warnings. A family member harvested blue mussels in Cutler Harbor from abandoned fish pens for personal consumption. Three family members consumed the shellfish that same day and were subsequently hospitalized for PSP related symptoms. All three individuals were released from the hospital the following day. Mussels were collected from the fish pens and analyzed by the DMR. The PSP scores were greater than 6,000 ug/100 g of shellfish tissue (closure threshold is 80 ug/100 g).

### 3. Current Findings

Observed nonconformities with NSSP requirements for certified firms are indicated on the NSSP Standardized Shellfish Processing Plant Inspection Form (93-01(A)) completed by FDA Northeast Regional Shellfish Specialist Peter N. Koufopoulos for each firm evaluated during FY 2009. The table below is a breakdown of the firms evaluated during this visit; along with the number of debits noted on the first page of the inspection form. The "Total Page 2" column shows the actual total number of various debits listed on the narrative page of the inspection form. This column was added to show the total number of deficiencies noted since the first page could have multiple deficiencies under a single item number. Certified firm deficiencies are summarized by code in the table below and are listed by checklist deficiency and firm classification in Attachment B. A copy of the inspection form completed by the FDA for each of the 13 certified dealers is included as Attachment A.

Certified Firm Name		Number of Violations				
		Critical	Key	Other	Total	Total Page 2
Bayley's Lobster Pound	ME-140-SS	0	5	6	11	12
Nova Seafood, LTD	ME-297-SS	0	1	1	2	2
Fisherman's Catch Seafood Mkt	ME-172-SS	0	5	4	9	10
Associated Sea Farms	ME-22-SS	0	3	4	7	8
Seaside Seafood	ME-194-SP	2	3	3	8	11
Muscongus Bay Aquaculture, Inc.	ME-46-SS	0	4	5	9	9
Ocean Harvest	ME-8-SS	0	4	3	7	8
Phinney Fisheries	ME-190-SS	0	4	5	9	16
Maine Shellfish Co., Inc.	ME-100-SP	0	4	1	5	8
Grant's Seafood	ME-177-SP	0	2	2	4	4
Harbor Fish Market, Inc.	ME-233-SS	0	5	2	7	7
Maine Oyster, Inc.	ME-210-SS	0	0	0	0	0
S & S Seafood	ME-91-SS	0	0	0	0	0

a) Inspection Program Evaluation Criteria

As part of the FY 2009 FDA evaluation of molluscan shellfish programs, the FDA has been tasked to test the following compliance criteria. These criteria are designed to rate the Plant & Shipping Element of state and foreign shellfish programs in order to determine overall compliance of the program element. None of the criteria can be exceeded for the program element to be considered in compliance with the NSSP MO.

- i. All dealers are required to be properly certified in accordance with the Guide for the Control of Molluscan Shellfish.

The DMR requires all firms to apply for initial certification and recertification in accordance with NSSP MO Chapter I.@.02. All firms must meet the standards for certification and/or recertification and also demonstrate their ability to properly implement their HACCP program. The state of Maine exceeds the certification requirements by not allowing any carry over deficiencies from the previous certification period. The Maine Plant & Shipping Element is in compliance with this criterion.

- ii. 95% of the certified dealers must be evaluated with an inspection frequency, which is compliant with the current Guide for the Control of Molluscan Shellfish.

All 13 certified dealers which had file reviews completed as part of the FY 2009 Program Evaluation were inspected by the DMR staff at the minimum rate specified in Chapter I@.02.F. The Maine Plant & Shipping Element is in compliance with this criterion.

- iii. Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.

All 13 certified dealers which had file reviews completed as part of the FY 2009 Program Evaluation had an established compliance schedule as specified in Chapter I@.02.H.2.d. The Maine Plant & Shipping Element is in compliance with this criterion.

- iv. States must demonstrate that they have performed proper follow-up for compliance schedules for 90% of the dealers evaluated and if the compliance schedules were not met that administrative action was taken.

All 13 certified dealers which had file reviews completed as part of the FY 2009 Program Evaluation revealed that all 13 firms had documented deficiencies on the inspection reports on file which revealed that correction dates were established after each inspection. Where compliance schedules were extended a reason was offered as to why the dealer needed more time to complete the repair as required in Chapter I@.02.H.1. The Maine Plant & Shipping Element is in compliance with this criterion.

- v. All critical deficiencies have been addressed in accordance with the Guide for the Control of Molluscan Shellfish.

The file review of certified dealers in Hallowell revealed that any critical deficiencies noted were addressed immediately per the Guide for the Control of Molluscan Shellfish. The Maine Plant & Shipping Element is in compliance with this criterion.

The DMR is currently meeting all five Plant Evaluation Criteria items. This evaluation is based on the level of performance found during the review of the central files. The interim 2007 Plant Evaluation Criteria which is also based on observations made during field activities can be found in Attachment D.

b) Program Deficiencies

No administrative deficiencies were cited during the FY 2009 program evaluation per Chapter I of the NSSP MO. Certified dealers were found to be inspected per the minimum requirements in Chapters X thru XV.

4. Corrective Actions taken by the State

All critical violations found during the evaluation were corrected immediately. Seaside Seafood (ME-194-SP) was the only certified dealer during the evaluation found to have critical deficiencies. As a result of the findings at the firm the dealer was immediately de-certified and will remain off of the Interstate Certified Shellfish Shippers List until debits noted during the inspection are corrected. Other deficiencies found during the concurrent FDA/DMR inspections were addressed in action plans.

5. Action Plans

No Action Plans were requested as part of this evaluation.

6. Program Accomplishments

- ◆ Amy Fitzpatrick and Bruce Chamberlain attended the annual partnership meeting of the Northeast State Standardization Officers (NESSO) in Providence, RI. The annual meeting was held September 10 & 11, 2008.
- ◆ Bruce Chamberlain schedules field time to work with the other two inspectors at least twice a month therefore increasing standardization and compliance. The success of this joint field time is evidenced in the increased dealer compliance reflected in this audit.
- ◆ Bruce Chamberlain collaborated with the DMR Water Quality Laboratory Manager to develop a tracking mechanism for well water sampling to insure that each dealer that has well water is sampled at the minimum frequency. The Laboratory Manger will send Mr. Chamberlain a quarterly report of all well water samples to date so that Mr. Chamberlain can ensure compliance with the minimum sampling frequency.

7. New or Emerging Problems

There were no new or emerging trends identified as a result of this evaluation.

8. Technical Assistance and/or Training Requested by the State

The Maine DMR Plant Sanitation Program has requested additional assistance and training from the FDA to help certified dealers with proper record keeping. A training schedule and educational material will be developed over the summer of 2009.

9. Summary of the State's response to FDA evaluation

*"We concur with all of the findings in this report. We continue to aggressively implement existing policies and procedures set in place to address the requirements of the NSSP"*

*MO. We are pleased that there has been significant improvement over the last evaluation in the areas of Key Sanitation items, Other Model Ordinance Requirement and General Facility Requirements. We continue to be dismayed that despite our attempts to provide education and materials regarding HACCP plans, HACCP and SSOP documentation and shipping and receiving records the level of compliance has slipped and that ~50% of dealers evaluated are not keeping records properly. The DMR appreciates all the effort and cooperation that Specialist Koufopoulos provides to help strengthen the program."*

#### 10. Conclusions

The State of Maine DMR Plant Sanitation Program meets all of the requirements of the NSSP Model Ordinance. The level of compliance the DMR usually obtains from the dealers has improved as compared to previous years. During the FY 2007 evaluation the FDA recommended that more training time be offered to the field inspectors to help them bring firms into compliance more quickly. It was apparent during this evaluation that the additional training helped the inspectors which in turn helped the certified dealers improve in areas of general sanitation items and other MO requirements. The FDA applauds the efforts of the three full time inspectors who must ensure that the 116 certified firms comply with all of the requirements of the NSSP-MO.