

PROGRAM ELEMENT EVALUATION REPORT

STATE: Maine

DATES OF EVALUATION: December 6 - 20, 2006

PROGRAM ELEMENT EVALUATED: Plant Sanitation

A. Status of Previous Program Evaluation

The FY 2005 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 2005 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, 2006 ICSSL was utilized in determining the number of firms selected for FY 2007 evaluation activities. The December 1, 2006 ICSSL indicated that Maine had 124 shellfish plants certified: 1 Depuration Processor, 35 Shucker-Packers, 82 Shellstock Shippers and 6 Reshippers. Thirteen firms were selected for the joint FDA/DMR evaluation inspections as required by Attachment D in the FY 2007 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 the weeks of December 4 and 11, 2006. A file review of the 13 facilities evaluated was conducted at the Central Office in Hallowell, ME on December 20, 2006. 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 B of this report.

Certified Firm Name	Certification #	Date of Inspection
Spinney Creek Shellfish	ME-271-DP	12/06/2006
J.P.'s Shellfish, Inc.	ME-352-SS	12/06/2006
Weathervane Seafoods	ME-164-SS	12/06/2006
York Lobster & Seafood	ME-138-SS	12/06/2006
Shucks Maine Lobster	ME-147-SP	12/07/2006
Plant's Seafood, Inc.	ME-99-SS	12/07/2006
Gilmores Seafood	ME-114-SS	12/07/2006
Great Eastern Mussel Farms	ME-309-SS	12/13/2006
C & S Seafood	ME-84-SP	12/13/2006
Frenchman's Bay Fisheries	ME-188-RS	12/14/2006
Erma's Seafood	ME-63-SP	12/14/2006
Sandy Cove Shellfish, Inc.	ME-148-SS	12/14/2006
DC Air & Seafood, Inc.	ME-78-SS	12/14/2006

2. Program Areas in Compliance

a) Program Administration

Legal Authority

In 2004, the Maine Department of Marine Resources adopted the recently released 2002 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 thru 20 (plant sanitation).

Shellfish related illnesses are investigated primarily by DMR in conjunction with the Maine Department of Agriculture 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). During the file review of the 13 firms it was noted that all 13 firms had documented deficiencies on at least one inspection report in the past 12 months. 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 Jerry Bishop 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 the annual HACCP training sessions which the firms are required to attend.

There were three critical deficiencies identified at three separate certified facilities during this evaluation. The critical deficiencies are listed below:

- ✘ York Lobster & Seafood (ME-138-SS) on 12/06/2006 --
Dead lobsters and loose shellstock were found sitting in the ice supply bin in the cooler. The lobsters and shellstock were discarded and the ice was deposited on the ground behind the facility. The ice bin was then cleaned and sanitized prior to the completion of the inspection. (Chapter XIII.02.E.5.b)



- ✘ Erma's Seafood (ME-63-SP) on 12/14/2006 --
A pint of unlabeled shucked clams was found in the cooler. The owner moved the clams to her personal supply within her residence located adjacent to the facility. (Chapter XI.01.A)
- ✘ DC Air & Seafood, Inc. (ME-78-SS) on 12/14/2006 --
The ice machine cover was removed from the front of the machine. The water reservoir in the ice machine was not covered or shielded. Facility management stated they would remove the cover each night in hopes of preventing the ice machine from freezing. (Chapter XIII.02.A.2.a)

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

The thirteen certified shellfish plants evaluated in Maine were all in possession of a properly formatted and complete HACCP Plan. The DMR has achieved a moderate level of HACCP compliance (monitoring and verification) within their certified facilities. The DMR conducts mandatory workshops for the managers of the shellfish facilities. The facility managers are also encouraged to have their employees attend these informative 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 high 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, 46% of the facilities are unable to properly verify their receiving records for accuracy and completeness once every seven days. Refer to Attachment A for specific numbers found in this section.

General Sanitation

The inspection form consists of two additional sections: the Key Sanitation items (8 thru 16) and the Other Model Ordinance Requirements which deal with the general facility condition, management and sales records (17 thru 30). It was noted during the field evaluations that Key Sanitation Item #13 - "Proper labeling, storage and use of toxic compounds" was debited at 10 of the 13 firms (77% overall non-compliance).

The general facility requirements (17 thru 30) experienced the most debits under two distinct items. Item #17 - "Plants and Grounds" was debited at 9 of the 13 firms (69%) and Item #18 - "Plumbing and related facilities" was debited at 7 of the 13 firms evaluated (54%).

c) Standardization/Maintenance

No formal standardization activities took place during this evaluation. The Maine DMR Shellfish Standardization Officer (SSO) Bruce Chamberlain conducted standardization inspections with the FDA in February 2004. Mr. Chamberlain's standardization is now current through 2009. Former SSO and now Director, Amy Fitzpatrick, maintains her standardization in a back-up capacity only for Mr. Chamberlain. Ms. Fitzpatrick's standardization is current through 2008.

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.

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 three *Vibrio parahaemolyticus* (V.p.) illness in the past three years.

- A 34 year old female consumed six raw oysters as part of a sample platter on June 26, 2004 with illness onset on the same day. The oysters on the sample platter were from five different locations (four different states and 1 foreign country). A portion of the suspect oysters were from the Damariscotta River in Maine.
- A 67 year old male, consumed boiled/steamed clams as a meal on August 27, 2005 with illness onset the next morning. No other seafood was reportedly consumed. The victim died on August 30, 2005. The clams were purchased by the victim from a truck located at one of the Portland, Maine fishing piers. The clams had no identification; therefore the harvest area is unknown.
- 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 three illnesses above were isolated cases with no other individuals outside their party 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

ACTION LEVEL	AVERAGE MONTHLY MAXIMUM AIR TEMPERATURE	MAXIMUM HOURS FROM HARVEST TO TEMPERATURE CONTROL
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

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 2007. 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 A. A copy of the inspection form completed by the FDA for each of the 13 certified dealers is included as Attachment B.

Certified Firm Name		Number of Violations				
		Critical	Key	Other	Total	Total Page 2
Spinney Creek Shellfish	ME-271-DP	0	2	0	2	4
J.P.’s Shellfish, Inc.	ME-352-SS	0	3	2	5	6
Weathervane Seafoods	ME-164-SS	0	6	2	8	8
York Lobster & Seafood	ME-138-SS	1	6	3	10	10
Shucks Maine Lobster	ME-147-SP	0	5	1	6	9
Plant’s Seafood, Inc.	ME-99-SS	0	4	0	4	4
Gilmores Seafood	ME-114-SS	0	7	2	9	9
Great Eastern Mussel Farms	ME-309-SS	0	9	3	12	18
C & S Seafood	ME-84-SP	0	6	2	8	8
Frenchman’s Bay Fisheries	ME-188-RS	0	3	0	3	3
Erma’s Seafood	ME-63-SP	1	4	2	7	7
Sandy Cove Shellfish, Inc.	ME-148-SS	0	1	2	3	3
DC Air & Seafood, Inc.	ME-78-SS	1	3	4	8	10

a) Inspection Program Evaluation Criteria

As part of the FY 2007 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 2007 Program Evaluation are 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 2007 Program Evaluation did have 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 2007 Program Evaluation revealed that all 13 firms had documented deficiencies on at least one inspection report in the past 12 months. 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 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 solely on the level of performance found during the review of the central files.

b) Program Deficiencies

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.

c) Recommendations

FDA recommends that the SSO work in each of the two other inspectional regions more often. This added interaction with the inspectors will ensure more consistency in the firms and between the regions.

4. Corrective Actions taken by the State

All critical violations found during the evaluation were corrected immediately. 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

Staff completed a new HACCP and Sanitation Standard Operating Procedures manual that was distributed to all current certified dealers. Copies are available from the website and via CD at the front desk in the main office in Hallowell. Additional CD's will be available at the DMR booth at the Maine Fishermen's Forum.

Michelle Mason published a Compilation of Shellfish Laws and Regulations. CDs were mailed to all current certified dealers. Copies are available from the website and via CD at the front desk in the main office in Hallowell. Additional CD's will be available at the DMR booth at the Maine Fishermen's Forum.

The SSO has been working (since December 2006) one day a week in each of the two other inspectional regions every other week. This equates to the SSO working with each inspector in their region twice a month. We agree that this added interaction with the inspectors ensures more consistency in the firms and between the regions.

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 not requested any additional assistance or training at this time.

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. 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, however the DMR usually obtains from the dealers has slipped as compared to previous years. General sanitation items as well as other MO requirements received more than their usual number of debits during this evaluation.

The FDA has recommended that more training time be offered to the base inspectors to help them bring firms into compliance more quickly. The FDA recognizes that the DMR has had an increase of certified dealers since the last evaluation. The program has only three full time inspectors who must ensure that 124 certified firms comply with all of the requirements of the NSSP-MO.



FY 2007
PROGRAM ELEMENT EVALUATION REPORT
OF THE
PLANT SANITATION PROGRAM ELEMENT
SHELLFISH SANITATION PROGRAM
DEPARTMENT OF MARINE RESOURCES
STATE OF MAINE

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ON

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ATTACHMENT A

ATTACHMENT A.

**Objectionable Conditions Cited by Plant
(Total Number of Violative Firms by Type)**

Item	Model Ordinance Reference	Description	code	#	Violative Firms			
					SP 3 Firms	SS 8 Firms	RS 1 Firms	DP 1 Firm
HACCP Plan	X.01.B	Presence of a HACCP Plan	C					
2. Plan Elements								
2(a).	X.01.C(1)	Hazards Identified and Adequate	O					
2(b).	X.01.C(6)	Records Identified and Adequate	O					
2(c).	X.01.C(3)	Critical Limits Identified and Adequate	K					
2(d).	X.01.D(2)(c)	Signed and Dated	O	5	X	XXXX		
2(e).	X.01.C(2)	Critical Control Points Identified	K					
2(f).	X.01.C(4)	Monitoring identified and Adequate	K					
2(g).	X.01.C(7)	Verification Procedures and Adequate	O					
2(h).	X.01.C(5)	Corrective Actions (if identified)	K					
3. HACCP Training (Yes/No) X.01.I			O					
4(a).	X.01.F	Receiving -Corrective Actions (c) & Records (k)	C/K					
4(a).	X.01.G	Receiving -Verification (k) & Records (k)	K	6	XX	XXX	X	
4(a).	X.01.C	Receiving -Monitoring (k) & Records (k)	K	5	X	XXX		X
4(a).	X.01.H	Receiving - Records Format/Signed/Dated/Firm name	O	3		XXX		
4(b).	X.01.F	Shellstock Storage -Corrective Actions (c) & Records (k)	C/K					
4(b).	X.01.G	Shellstock Storage -Verification (k) & Records (k)	K	2	X	X		
4(b).	X.01.C	Shellstock Storage -Monitoring (k) & Records (k)	K	2		XX		
4(b).	X.01.H	Shellstock Storage – Records Format/Signed/Dated/Firm name	O	1	X			
4(c).	X.01.F	Processing - Corrective Actions (c) & Records (k)	C/K					
4(c).	X.01.G	Processing - Verification (k) & Records (k)	K					
4(c).	X.01.C	Processing - Monitoring (k) & Records (k)	K	1	X			
4(c).	X.01.H	Processing - Records Format/Signed/Dated/Firm name	O					
4(d).	X.01.F	Shucked Meat Storage - Corrective Actions (c) & Records (k)	C/K					
4(d).	X.01.G	Shucked Meat Storage - Verification (k) & Records (k)	K	2	X	X		
4(d).	X.01.C	Shucked Meat Storage - Monitoring (k) & Records (k)	K	1		X		
4(d).	X.01.H	Shucked Meat Storage - Records Format/Signed/Dated/Firm name	O	1	X			
4(e).	X.01.F	Other Critical Limits - Corrective Actions (c) & Records (k)	C/K					
4(e).	X.01.G	Other Critical Limits - Verification (k) & Records (k)	K					
4(e).	X.01.C	Other Critical Limits - Monitoring (k) & Records (k)	K					
4(e).	X.01.H	Other Critical Limits - Records Format/Signed/Dated/Firm name	O					

ATTACHMENT A. Continued.

Item	Model Ordinance Reference	Description	code	#	Violative Firms			
					SP 3 Firms	SS 8 Firms	RS 1 Firms	DP 1 Firm
5.	XI - XIV.01.A	Approved Source Control Failure	C	1	X			
6.	XI-XIV.01.B & C	Time/Temperature Control Failure	C					
7.	NA	Other Critical Control Failure	C					
8.	.02.A	Safety of water for processing and ice production	C/K	1		X		
9.	.02.B	Condition and cleanliness of food contact surfaces	K	3	XX	X		
10.	.02.C	Prevention of cross-contamination	C/K	3	X	XX		
11.	.02.D	Maintenance of hand-washing, hand sanitizing, and toilet facilities	C/K/O	2		XX		
12.	.02.E	Protection from adulterants	C/K/O	4		XXXX		
13.	.02.F	Proper labeling, storage, and use of toxic compounds	K	10	XXX	XXXXXX	X	
14.	.02.G	Control of employees with adverse health conditions	K					
15.	.02.H	Exclusion of pests	K					
16.	.02.A.B	Sanitation Monitoring and Records	K/O	2	X		X	
Additional Model Ordinance Requirements								
17.	.03.A	Plants and Grounds	C/K/O	9	XX	XXXXXX		X
18.	.03.B	Plumbing and related facilities	C/K/O	7	X	XXXXXX		
19.	.03.C	Utilities	C/K					
20.	.03.D	Insects and vermin control	K	3		XXX		
21.	.03.E	Disposal of other waste	O					
22.	.03.F	Equipment construction (non-food contact surfaces)	O	1		X		
23.	.03.G	Cleaning non-food contact surfaces	O	1		X		
24.	.03.H	Shellfish storage and handling	K/O					
25.	.03.I	Heat shock	K					
26.	.03.J	Personnel	K/O	1		X		
27.	.03.K	Supervision	K	1		X		
28.	IX.05	Transportation (To include only the person shipping)	K/O					
29.	X.05, X.06	Labeling and Tagging (Other than receiving)	K/O	3		XXX		
30.	X.07	Shipping Documents and Records	K	3	X	XX		

SP=Shucker-Packer; SS=Shellstock Shipper; SS/WS=Shellstock Shipper with Approved Wet Storage; RS=Reshipper; DP=Depuration Processor

C=Critical; K=Key; O=Other

ATTACHMENT B