



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Northeast Region

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February 16, 2012

Mr. Paul Diodati, Director
Division of Marine Fisheries
251 Causeway Street, Suite 400
Boston, Massachusetts 02114-2119

Dear Mr. Diodati,

Enclosed are two copies of the Program Element Evaluation Report (PEER) covering the U.S Food and Drug Administration's (FDA's) 2011 review of the Massachusetts Vibrio Management program with respect to the requirements of the National Shellfish Sanitation Program (NSSP). The Shellfish Section of the Division of Marine Fisheries reviewed a draft of this report and their comments and suggestions were incorporated where appropriate.

FDA's Northeast Region recommends that Massachusetts complete a *Vibrio parahaemolyticus* (Vp) risk evaluation per NSSP Model Ordinance criteria prior to March 20, 2012, and then implement any needed control plan measures prior to the 2012 Massachusetts Vp season.

If you have any questions or wish to discuss the enclosed reports please do not hesitate to contact me at the phone number above or Martin Dowgert, Regional Shellfish Specialist, at (781)587-7441. Thank you for your continued cooperation in this important public health program.

Yours truly,

for Elizabeth O'Malley
Director – State Programs Branch
U.S. FDA – Northeast Region

Enclosures

cc: w/enclosure

- ✓ Mr. J. Michael Hickey, DMF/New Bedford
- Mr. Jeff Kennedy, DMF/Gloucester
- Mr. Thomas Shields, DMF/New Bedford
- Mr. Martin Dowgert, FDA/NER/SPB

Vibrio Evaluation Report

FY 2011

State of Massachusetts

**Department of Public Health
and
Division of Marine Fisheries**

PROGRAM ELEMENT EVALUATION REPORT

STATE: Massachusetts DATES OF EVALUATION: March - September 2011

PROGRAM ELEMENT EVALUATED: Vibrio Management Program

1. Background Information & Status of Previous Vibrio Program Evaluation

The commercial harvest of oysters in Massachusetts has traditionally occurred from October 1 through May 1 each year. All oyster harvesting is conducted in intertidal and sub-tidal areas of the classified growing waters. Massachusetts summer-harvest oysters are almost exclusively cultured, private-lease oysters.

During 2010 Massachusetts did not report any Vibrio illnesses due to the consumption of oysters harvested in state waters.

During 2011 Massachusetts reported two Vibrio parahaemolyticus (Vp) illnesses traced to oyster consumption and linked the cases in time and to a region of Cape Cod Bay (CCB) with similar tidal characteristics, i.e. growing areas which experience tides that expose oysters to sun and air temperatures for several hours around the time of low tide.

This report represents the first Vibrio Management Program Element Evaluation for Massachusetts.

2. Status of Current Vibrio Evaluation

- A. Does the state *Vibrio* Management Plan meet NSSP-MO requirements? *At the beginning of the 2011 summer harvesting season, the State of Massachusetts was not required to have a Vibrio Management Plan in effect based upon MO criteria described in Chapter II@.04 and II@.05.*
- B. Is there evidence that the state is conducting proper illness investigations and procedures as stipulated by the NSSP-MO Chapter II@.01 Section C and J? *Yes. The MA Department of Public Health (MADPH) tracks reported foodborne illnesses. Field investigation of any restaurants and retail outlets involved are most often performed by inspectors representing the local Boards of Health. MADPH officials review illness information, conduct any needed additional investigations and conduct inspections of certified dealers if they are identified in the traceback.*
- C. Have changes/modifications been made to the State's *Vibrio* Risk Management Plan? What precipitated the changes? (Please cite appropriate changes to the state law or health code in applicable.) *For*

the 2011 summer season the State of Massachusetts was not required to have a Vibrio Risk Management Plan in effect based upon MO criteria described in Chapter II@.04 and II@.05. MADPH and the MA Division of Marine Fisheries (MADMF) actively promoted a voluntary harvester/dealer program that encouraged refrigeration/cooling and/or delivery to final retail customer within 6 hours of harvest during warm weather periods. Compliance with this voluntary program varied since it depended upon the cooperation of individual harvester/growers who operated during the warm weather months.

- D. In field industry compliance review -
- i. Were points of landing randomly or selectively visited to verify compliance with required harvester records and time-temperature requirements? Where applicable, were internal oyster temperatures measured? Results? *Not applicable during 2011. However, the FDA reviewer has visited shellfish growing areas on an ongoing basis and is experienced with the placement of leases as well as tidal and hydrographic conditions throughout the region. Also, a shellfish constable working in an active summer oyster harvest region was interviewed and he stated that in his experience most commercial harvesters gathered only the product that they needed for that day's delivery- whether it was to a retail outlet or to a wholesale dealer and that those activities were accomplished within a 6 to 8 hour period. However, he was also aware of growers/harvesters who held on to product for longer periods of time prior to delivery to a wholesale dealer.*
 - ii. Were processing plants, including PHP plants, visited? Were records and labeling reviewed for verification and compliance with HACCP plans and NSSP-MO? Results of internal product temperature checks for compliance with HACCP/NSSP-MO? *Not applicable since this question refers to Vibrio vulnificus control plans.*
- E. General description of State Vibrio Management Plan. *Not applicable. At the time of this review the State of Massachusetts was not required to have a Vibrio Management Plan in effect based upon MO criteria described in Chapter II@.04 and II@.05.*
- F. If Gulf State, is state in compliance with illness rate reduction goal? What control or combination of controls are used to achieve goal (e.g. time-temperature, harvest closures, PHP, labeling for shucking, etc.) *Not applicable. Massachusetts is not a Gulf State and this question refers to states with Vibrio vulnificus control plans.*
- G. Vibrio illnesses/outbreaks for 2011
- i. Incidence of illnesses or outbreaks for most recent calendar year. *No Vibrio vulnificus (Vv) cases were reported during 2011. One Vibrio parahaemolyticus (Vp) case was reported to MADPH during July 2011 and a second case was reported*

during August 2011. Follow-up investigation by MADPH revealed that the 2nd case that was reported in August was actually related in time to the 1st case that was reported in July, i.e. both illnesses had an onset dates within a few days of one another. The source of the oysters was found to have been from one or both of two Massachusetts growing areas – both of which are located in the eastern/southeastern portion of Cape Cod Bay (CCB).

- ii. Information regarding increases or decreases from previous year(s). Explain? If increase is state planning modification of *Vibrio* Management Plan? *The two illnesses represent an increase from the previous year during which no Vp illnesses were reported. Massachusetts will be working on the annual risk evaluation. Upon review of the risk evaluation, the state shellfish authorities will enter a discussion phase of development of a vibrio control plan with input from all stakeholders including FDA, state agencies, and industry. Implementation of control steps to reduce the occurrence of vibrio illnesses will be part of these discussions.*
 - iii. If outbreak was recall initiated? Performance of recall in accordance with NSSP-MO? *Not applicable. The second Vp case was not reported until August 2011 - a month after the 1st case – and only then were both cases linked to consumption dates that occurred back in early July. There were no additional cases reported during or after the early July period. The DPH has treated these as two individual confirmed cases of Vp linked in time, with isolates of different pulse field gel electrophoresis patterns.*
 - iv. Is CDC notified of illnesses/outbreaks as they occur? *Yes.*
 - v. How does the occurrence of continuing sporadic illnesses effect changes to the state's *Vibrio* Management Plan? *Not applicable since the two illnesses only occurred in 2011. Massachusetts shellfish authorities are currently working on their annual risk evaluation and plan to take appropriate action per MO Chapter II@.05.*
- H. Exemptions to state *Vibrio* Management Plan. Explain. Compliance with exemption requirements? *Not applicable because this question refers to Vibrio vulnificus control plans.*
- I. Time temperature controls. *Temperature checks of shellstock storage are routinely made during MADPH inspections at certified dealers. MADPH also promotes the importance of reviewing shellstock handling practices and conducting temperature checks at local restaurants and retailers by the local Board of Health inspectors.*
- J. State *Vibrio* Education Program details. *Massachusetts does not have a formal, ongoing Vibrio Education Program. (Refer to item K.)*

- K. State program accomplishments and future goals. *Both MADPH and MADMF participated in a June 2010 Vibrio Workshop in order to help harvesters, growers and dealers become familiar with Vibrio issues and to emphasize the importance of getting shellstock under rapid temperature control. Both agencies together are considered to be the official MA Shellfish Sanitation Control Authority (SSCA) and will be working on completion of the MA Vp Risk Evaluation report.*
- L. New or emerging issues associated with *Vibrio*. *The immediate need to complete a Vp Risk Evaluation is a significant and challenging new issue for the MADPH and MADMF.*
- M. Technical Assistance or Training Requested by the State. *No formal requests at this time. However, the outcome of the risk evaluation will determine if FDA assistance is needed during 2012.*
- N. Summary of the States Responses to FDA Evaluation including corrective actions taken. *The State response to a draft of this report was reviewed and in a number of instances those comments were incorporated into the final report.*
- O. Conclusions – *Massachusetts is currently considered to be in compliance pending timely receipt of a Vibrio risk evaluation per Chapter II @.05 of the NSSP Model Ordinance.*
- P. Recommendations and/or Request for Action Plan. *The FDA recommends that MA SSCA, i.e. MADMF and MADPH, complete a Vibrio Risk Evaluation by March 20, 2012. Any recommended control measures should be implemented for the affected species and geographic regions prior to the 2012 Vp season.*
- Q. Attachments:
Attachment #1 - Example of a Vp Risk Evaluation
Attachment #2 –Vp Control Plan Criteria per Model Ordinance Chapter II@.05B

Attachment #1 – Example of a Vp Risk Evaluation

Reference: 2009 Revision of the Model Ordinance Chapter II@.05A Risk Evaluation

The 2011 MA Vp Risk Evaluation that will be developed by the MA SSCA may – but is not required to - utilize this outline.

A. Risk Evaluation.

Every State from which oysters are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur. For the purposes of this section, “reasonably likely to occur” shall mean that the risk constitutes an annual occurrence.

- (1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State.; and
- (2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and
- (3) The water temperatures in the area; and
- (4) The air temperatures in the area; and
- (5) Salinity in the area; and
- (6) Harvesting techniques in the area; and
- (7) The quantity of harvest from the area and its uses i.e. shucking, halfshell, PHP.

Evaluation of seven (7) factors:

(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State.
There were two Vp illnesses related to the consumption of oysters harvested in MA waters during 2011. These two cases were related in terms of time of onset (illness onset for both cases were within a few days of one another) and because the oysters likely came from one or both of two growing areas in Cape Cod Bay that share similar tidal characteristics. In the prior 8 years there have been several individual Vp illnesses reported for MA. In those cases it was typical that multiple growing areas in different states and/or countries were mentioned in the traceback report as possible sources. Therefore no one state or country could be definitively implicated. However, it was not uncommon for a CCB area to be listed in those reports as one of the possible sources.

(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists.
No significant data exists in regards to Vp levels in MA shellfish growing area waters to accurately assess the potential risk. (If the MA SSCA has updated data then it can be summarized and discussed under this section.)

(3) The water temperatures in the area.

Water temperatures do exceed 81⁰F in several shellfish harvesting areas and was determined to constitute a "reasonably likely" risk. The months of July, and August were identified as having average temperatures above 81⁰ F in a limited number of growing areas. (This is a general example. Updated temperature data can be discussed under this section along with specific growing areas that share temperature characteristics. Also the SSCA may wish to discuss the tidal regime that groups of Massachusetts growing areas share, e.g. growing areas with ~10 tidal ranges which leave shellstock exposed to the air for extended periods of time around the time of low tide.)

(4) The air temperatures in the area.

Air temperatures are intermittently high in the summer months and may contribute to increased risk when growers/harvesters do not minimize the time between the exposure of the oysters to the air and the time the oysters are placed on ice or into refrigerated storage. (Again, the SSCA may wish to discuss specific average monthly maximum air temperatures for regions of potential concern.)

(5) Salinity in the area.

Salinity is high in many of MA shellfish growing areas and this was not associated with a particular risk of Vp that was "reasonably likely" to occur.

(6) Harvesting techniques in the area.

During the summer, oysters in MA are harvested in sub-tidal areas normally by boat or by walking and/or wading into the harvest site at low-tide. Summer harvesters are generally in their own leased area for relatively short periods of time in order to harvest what they need for deliveries that day. However, some growers/harvesters may take longer to harvest product from their lease, and may also hold product in their vehicles for longer periods of time prior to delivery to the cooler storage of the first wholesale dealer. Other growers/harvesters plan their orders carefully and make an effort to only harvest what they need that day and to promptly deliver that product to their dealer's refrigeration facility within shorter time periods. There are a few growers/harvesters who also use ice while harvesting, packing and transporting their product.

Conclusion: During the hot weather months, the handling and storage practices of some growers/harvesters may create a conducive environment for increased Vp growth because of extended harvest times and extended storage and transport times prior to shellstock delivery into refrigerated storage at the first wholesale dealer.

(7) The quantity of harvest from the area and its uses.

Oysters harvested in MA shellfish harvesting areas are generally sold to certified wholesale dealers for interstate distribution or to intrastate wholesale dealers for local in-state distribution to local restaurants and retail outlets.

Attachment #2 - *Vp* Control Plan Criteria per Model Ordinance Chapter II

B. Control Plan

(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or

(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:

(a) Waters bordering the Pacific Ocean - 60°F.

(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south) - 81°F.

(c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in §A., that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.

(i) In conducting the evaluation, the State shall evaluate the factors listed in §A. for the area during periods when the temperatures exceed those listed in this section;

(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in §A differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

(3) If a State has a shellfish growing area that was the source of oysters that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in § B. (2) where they apply, or other triggers as determined by the risk evaluation.

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include:

(i) Post harvest processing using a process that has been validated to achieve a 2 log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a 3 log reduction for the Pacific Coast oysters;

(ii) Closing the area to oyster harvest;

(iii) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(iv) Limiting time from harvest to refrigeration to no more than five hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;

(v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60 °F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *Vp* illness is no longer reasonably likely to occur, as approved by the Authority.

(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within 10 hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within 10 hours or less as

determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled "*for shucking only*", or other means to allow the hazard to be addressed by further processing.

(d) Evaluate the effectiveness of the Plan.

(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.

(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.

C. The Time When Harvest Begins

For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.