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June 7, 2012

W. Charles Becoat
Acting Regional Food and Drug Director
U.S. FDA – Northeast Region
158-15 Liberty Avenue
Jamaica, NY 11433

Dear Mr. Becoat,

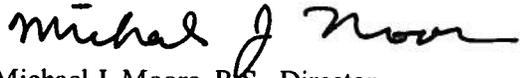
On March 5, 2012, the Northeast Region of the U.S. Food and Drug Administration (FDA-NER) sent the Massachusetts Department of Public Health (MDPH) a Program Element Evaluation Report (PEER) which reviewed *Vibrio* Management in Massachusetts from October 1, 2010 to September 30, 2011. The purpose of this PEER report was to advise Massachusetts shellfish program officials, the Interstate Shellfish Sanitation Conference (ISSC) and the Commissioner of FDA as to whether the Massachusetts Shellfish Sanitation Program conforms with requirements of the National Shellfish Sanitation Program (NSSP).

In this report, FDA-NER identified an emerging public health issue involving the occurrence of *Vibrio parahaemolyticus* in Cape Cod Bay, and recommended that enhanced *Vibrio* control measures be developed and implemented prior to the 2012 *Vibrio* season so that harvesters and dealers are fully aware of shellstock handling requirements well before the conditions conducive to *Vibrio* growth arrive.

In response to this request, MDPH is submitting the enclosed document entitled "Massachusetts 2012 *Vp* Control Plan". Please note that Appendix a of the Control Plan contains a risk evaluation for 2012 that was prepared by the Massachusetts Division of Marine Fisheries.

If you have any questions concerning this letter, please feel free to contact me at (617) 983-6754.

Sincerely,

A handwritten signature in black ink that reads "Michael J. Moore". The signature is written in a cursive style with a large, stylized initial "M".

Michael J. Moore, R.S., Director
MDPH/BEH Food Protection Program

Cc: John Auerbach, MDPH Commissioner
Suzanne Condon, Associate Commissioner, MDPH/BEH
Elizabeth O'Malley, Director, State Programs Branch, NER/FDA
Martin Dowgert, FDA/NER/SPB
Paul Diodati, Director DMF
Michael Hickey, DMF

Massachusetts 2012 *Vp* Control Plan

Public Health Warm Weather Commercial Harvest Restrictions for Oysters:

A. Harvesters:

1. No provision of this plan shall apply to seed oysters.
2. The requirements of this plan shall apply to both wild oysters from the public fishery and privately cultured oysters harvested for commercial purposes.
3. The requirements of this plan shall apply to oysters harvested in Eastern Cape Cod Bay (ECCB) from June 17th through September 8th. For the purposes of this plan the ECCB consists of the waters and flats of Cape Cod Bay within the towns of Barnstable, Yarmouth, Dennis, Brewster, Orleans, Eastham, Wellfleet, Truro and Provincetown.
4. All oysters harvested from June 17th through September 8th shall be **adequately shaded** during transport from harvest area to original dealer.
5. All shellfish tags shall include the **time of harvest** in addition to harvest date, harvest area, identification of harvester, type of shellstock and quantity. Time of harvest shall be placed on the harvester tag in indelible ink at the actual beginning of harvest.
6. All oysters shall be refrigerated or **adequately iced** within five hours of time of harvest.
7. Shellfish handling by harvesters:
 - a. Oysters may be bagged during low tide one or two days prior to actual harvest or removal from the culture site (“grant”) to allow the grower more time to meet the five hours from harvest to refrigeration requirement.
 - b. If oysters are to be bagged prior to actual harvest, the containers need to be tagged with water proof tags stating “ Precollected for later harvest” with the date and time bagged or placed in a container.
 - c. In this case, the harvest date and time shall be the date and time the bags/containers are finally removed from the water or are exposed to the air prior to being brought to the first wholesale/original dealer.
 - d. Each harvester will keep a bound harvest log book that records the date, time of harvest and amount harvested (bushels, or count bags, etc)

recorded in indelible ink. Books will be filled out before the days harvest leaves the harvest area.

- e. If shellfish are precollected prior to final harvest (per b. above) the date, time bagged and the quantity shall be entered into the log book on the same day.
 - f. No market size oysters (either legal size or “petites”) maybe removed from the grant for offsite culling and subsequently be placed in commerce.
8. The Division of Marine Fisheries shall, pursuant to 322 CMR 7.01: (7) Form ,Use and Contents of Permits condition all Commercial Permits endorsed for shellfish in the nine ECCB area towns to include the provisions governing commercial harvest of oysters in this *Vibrio parahaemolyticus* Control Plan.

B. Dealers:

- 1. All oysters received by the original shipper between June 17th through September 8th shall be cooled to 50°F within 10 hours of placement into refrigeration or ice.
- 2. All dealers who receive oysters harvested from ECCB between June 17th and September 8th inclusive shall implement a HACCP plan that indicates pathogen growth of naturally occurring *Vibrio parahaemolyticus* as a significant hazard that is reasonably likely to occur and includes:
 - a. Control measures 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 after being placed under temperature control; and
 - b. Corrective action to ensure that oysters that are not cooled to an **internal temperature** of 50°F (10°C) within 10 hours are not directed to the raw shellfish market.
- 3. To comply with dealer requirements of the plan, a dealer shall ensure that a temperature control mechanism for cooling and storing of oysters:
 - a. Cools oysters to an internal temperature of 50°F (10°C) in 10 hours or less after placement under temperature control; and
 - b. Maintains an ambient temperature of 45°F.
- 4. Each dealers receiving records shall include the following minimum information:
 - a. Identification of harvester;
 - b. Harvest date and area;
 - c. Time of harvest;
 - d. Time of temperature control;
 - e. Time oysters were cooled to ≤50°F with actual internal temperature.

5. In addition, dealers shall comply with all relevant requirements of 105 CMR 533.007 Fish and Fishery Products
6. The Division of Marine Fisheries shall,, pursuant to #22 CMR 7.01.(7) : Form, Use and Contents of Permits, condition all Wholesale Dealer Permits, endorsed for shellfish to include the provisions governing the receiving, handling and record keeping related to oysters in this *Vibrio parahaemolyticus* Control plan.

C. Corrective Action:

1. Dealers shall reject any lots of oysters that are not properly tagged as harvested by a licensed harvester and/or do not indicate time of harvest.
2. Dealers shall reject any lots of oysters that are not compliant with the time/temperature requirements of Section B of this Plan.
3. Dealers who receive lots of oysters that are not compliant with the requirements of this plan shall conduct one of the following actions;
 - a. Place lot on internal hold and immediately notify the local shellfish authority to evaluate oysters for possible return to lease site or harvest area.
 - b. Dispose of non-compliant lots, document the deviation in a Notice of Unusual Occurrence and Corrective Action (NUOCA) and notify the Food Protection Program (FPP) as soon as possible.

D. Enforcement:

1. Representatives of state and local regulatory agencies (DMF, DPH, OLE, etc.) shall conduct periodic unannounced inspections at harvest sites, common landings and wholesale dealer facilities to determine compliance with the requirements of this Plan.
2. All shellfish harvested under this plan shall be subject to embargo and/or disposal if found to be significantly time/temperature abuse or non-compliant with requirements of this Plan.
3. Local Shellfish Constables and their deputies will conduct spot checks at harvest sites to verify harvest times on harvester tags and other controls such as shading and icing.
4. Inability or refusal of harvesters and/or dealers to maintain compliance with the requirements of this plan may result in enforcement up to and including suspension and revocation of harvester and/or dealer permits in accordance with Chapter 130, section 2, of Massachusetts General Laws.

Definitions

Adequately Iced means the containers holding the shellfish have enough ice on the shellfish to provide cooling to achieve required internal temperatures.

Adequately Shaded means that measures be taken to prevent oysters from direct exposure to sunlight that might cause a significant increase in pathogenic growth due to an increase in temperature.

Internal Temperature means the external temperature of the shell of the animal, at the center of a packaged mass of shellstock (box, sack, bag, etc.).

Time of Harvest means the time when the first shellstock in a lot is taken from the water or, in the case of intertidal harvest, the time of first exposure. Should the harvesting technique used involve re-submerging, the Authority must approve the harvesting technique to assure that the harvest method does not promote post harvest growth of *Vibrio parahaemolyticus* associated with oysters.

The MA Department of Public Health's Food Protection and the MA Division of Marine Fisheries will review this Plan on an annual basis and revise it as needed to maintain compliance with the National Shellfish Sanitation Program's Model Ordinance.

Appendix A

MASSACHUSETTS *Vibrio Parahaemolyticus* Risk Evaluation - 2012

MASSACHUSETTS DIVISION OF MARINE FISHERIES

Every state from which oysters are harvested commercially shall conduct a *Vibrio parahaemolyticus* (*Vp*) risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in factors, in determining whether the risk of *Vp* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur. For this risk assessment, “reasonably likely to occur” shall mean that the risk constitutes an annual occurrence. (NSSP Guide, Sec.II, Chapt. II, @.05, A, 2009).

1) Number of Cases

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

An illness outbreak (2 or more illnesses) epidemiologically linked to oysters from an area triggers a Control Plan for the area. In previous years, there have been sporadic *Vp* illnesses involving shellfish from a combination of in state and out of state sources. This is the first time two illnesses have been associated with a strictly Massachusetts source.

2) Levels of *Vp* in Water and Shellfish

Marine Fisheries does not test for levels of either total or pathogenic strains of *Vp* in water or shellfish. *Vp* has been known to occur in Massachusetts waters since the early 1960’s especially in waters around Cape Cod and the Islands.

Over the past five years, one out of state oyster buyer has found low numbers of *Vp* in Cape Cod Bay oysters during the summer months as a result of their own quality assurance testing. Since this company has a zero tolerance for *Vp*, they do not buy Cape Cod Bay oysters during the summer.

3) Water Temperatures

It appears that excessive water temperature that would trigger a *Vp* Control Plan (*above an average monthly daytime temperature of 81° F*) under the NSSP is not a problem in any area. There are six identified areas that approach but do not reach or exceed 81° F in either July and/or August. These are shallow water, enclosed ponds or embayments with low flushing, and 2 to 4 foot tidal amplitudes, located in Buzzards Bay or on the south side of Cape Cod and account for minimal oyster production.

Marine Fisheries has three years (2009 -2011) of data at 9 sites and will be adding 7 more sites in 2012 to acquire additional water temperature data for annual risk evaluations and to track the trend of increasing water temperatures due to climate change. The original sites were selected because they were deemed to represent “worse case” situations.

4) Air Temperatures

Air temperature data has been collected for three years (2009 -2011) from NOAA at 5 locations: Chatham, Hyannis, Nantucket, New Bedford and Plymouth. These sites are not on the water and also reflect warmer temperatures than would be seen at the oyster culture/harvest sites. From a public health perspective this is conservative. DMF intends to expand air temperature monitors in 2012 to actual culture /harvest sites. Air temperatures can intermittently reach daytime highs above 90 degrees F; however this is not the norm along the shore on Cape Cod or the Islands.

5) Salinity

Vp bacteria survive in salinities ranging from 5 to 30 ppt (parts per thousand) while an optimum salinity of 23 ppt has been reported for *Vp* (Zimmerman 2007). This is considered high by other researchers. Massachusetts coastalwaters supporting oysters are within that range. Optimum salinities for oysters are 10 to 28 ppt (Loosanoff, 1965). However, oysters will survive at low salinities of 5 to 7.5 ppt and in more Open Ocean like salinities of 32 to 33 ppt, the later generally being the case in Cape Cod Bay. Salinity is high in most culture sites throughout the state (25 to 32 ppt in summer). The only wild commercial oyster harvest in the summer months occurs in Wellfleet Harbor where summer salinities range from 29 to 33 ppt. at oyster sites.

6) Harvesting Techniques

Oyster harvesting techniques in Massachusetts fall into two categories depending almost entirely on tidal amplitude at the harvest location. Cape Cod Bay has tidal amplitudes with a mean range varying from 10 feet in Wellfleet to 9.5 feet at Beach Point, Barnstable Harbor and 9.1 feet at Provincetown. On extreme minus or moon tides, the tides can be 1 to 2 feet lower than average. As a result, most oyster culture and harvest in Eastern Cape Cod Bay is conducted in the intertidal zone where oysters are exposed to ambient air temperatures and sunlight in some cases for over four hours around the time of low tide. There is very little subtidal harvest of oysters in Cape Cod Bay except for about six commercial wild harvest draggers in Wellfleet Harbor.

All other summertime commercial oyster harvest in Massachusetts is conducted by private growers on their own licensed sites. Almost all of these are subtidal harvest situations because of the limited intertidal area available for oyster culture due to significantly smaller mean tidal amplitude. Throughout Buzzards Bay the mean amplitude is 3.1 to 4.0 feet; on the south side of Cape Cod and on Martha's Vineyard it is between 1 and 2 feet at oyster sites; and about 3 feet at a maximum on Nantucket.

With the exception of the Wellfleet wild fishery, summer harvesters are on their own licensed sites for relatively short periods of time harvesting what they need for that day and promptly delivering the oysters to their dealer where it can be placed in refrigeration. Some growers use ice and/or shading or evaporative cooling while harvesting, handling and transporting to the first wholesale dealer.

The greatest potential for a problem seems to be exposure to high ambient air temperature and sunlight in intertidal culture and harvest situations rather than harvest from subtidal situations.

7) Quantity of Harvest and Use.

Almost all of the oysters produced by private growers in Massachusetts and a high percentage of summer wild caught Wellfleet oysters are consumed in the raw half shell market in both intrastate and interstate commerce. Those not used for raw consumption are shucked and cooked locally, mostly as fried oysters.

Total oyster production reported by private growers for all of Massachusetts in 2010 was 71,831 bushels with a landed value of \$8,619,720.00. In Eastern Cape Cod Bay there are 9 towns. Oysters are harvested commercially in 8 of towns with the exception being Yarmouth that has no commercial production in Cape Cod Bay. The eight towns produce about 37,188 bushels with a landed value of \$4,422,045.00.

RECOMMENDED ACTION

During 2011, two *Vp* illnesses were traced to consumption of commercially harvested oysters. These cases were linked in time and to the same region of Eastern Cape Cod Bay. This geographic area has similar tidal characteristics and culture techniques that expose most oysters to sun and ambient air temperatures for several hours around low tide. Such exposure in warm weather can cause vibrio bacteria to thrive and multiply at alarming rates. At 80 degrees F, vibrio levels can double every hour.

Based on the exposure times around low tide, it reasonable to conclude that without time to temperature controls, illnesses are reasonably likely to occur on an annual basis. Also, the two illnesses automatically trigger the need for a *Vp* Control Plan under provisions of the NSSP.

Since other oyster producing areas in Massachusetts do not experience significant tidal amplitude and exposure of the oysters at low tide the risk of vibrio growth prior to actual harvest is considerably less. Also, average monthly daytime water temperatures have not reached 81 degrees F in any of these areas which would automatically trigger the need for a Control Plan.

Therefore, the following is recommended:

- 1) A *Vp* Control Plan be developed and implemented for Eastern Cape Cod Bay that requires stringent time to temperature controls consistent with the NSSP and other controls such as shading of oysters during harvest and transport.
- 2) At this time, a Control Plan for the remainder of the oyster industry in Massachusetts does not appear to be necessary since the risk factors for illness do not seem “reasonably likely to occur” annually. However, consistent with recent changes to the NSSP, every effort should be made to encourage the shellfish industry to comply with the new time to temperature requirements in order to minimize the risk of *Vp* illnesses from areas not under the *Vp* Control Plan.