



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Northeast Region

Office of the Regional Director

158-15 Liberty Avenue
Jamaica, New York 11433
(718) 662-5621
(718) 662-5434 Fax

November 4, 2008

Amy M. Fitzpatrick, Director
Public Health Division
Department of Marine Resources
Post Office Box 8
West Boothbay Harbor, Maine 04575

Re: Growing Area Element

Dear Ms. Fitzpatrick,

The Food and Drug Administration (FDA) has completed its evaluation of the Maine Shellfish Sanitation Program, Growing Area Element, administered by the Maine Department of Marine Resources (DMR), Public Health Division. The FDA Program Element Evaluation Report (PEER) describing the findings of this evaluation is enclosed, including deficiencies and recommendations as determined from file reviews and field observations.

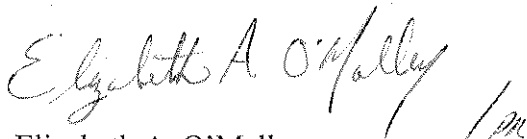
The Growing Area Element currently does not meet all of the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). Five program wide deficiencies have been cited, all of which must be addressed through action plans describing in detail how the DMR will remedy the deficiencies. It is requested that the action plans be completed and submitted to the Regional Shellfish Specialist, Peter Koufopoulos, within thirty (30) days of receipt of this letter. In addition to the program deficiencies, two recommendations are included within the PEER. The recommendations have been included to further strengthen the Shellfish Classification Program.

As stated, the recent evaluation completed by Mr. Koufopoulos found a number of aspects of the program in need of immediate attention. A number of these issues are a direct result of inadequate staffing levels within the Public Health Division-Growing Area Classification Section, a concern previously noted in the FY 2004 Growing Area PEER and each of the subsequent annual evaluations. In order to comply with the requirements of Chapter IV of the MO, the DMR must have all the necessary resources available so that all required work (report writing, sampling, pollution assessment, etc) can be completed in the appropriate time frames.

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I wish to thank you and your staff for the continued hard work, professionalism and courtesy, shown both during this evaluation and throughout the year. If you should have any questions for me, please contact me at the number above. If you should have any questions regarding the evaluation itself, please do not hesitate to contact Mr. Koufopoulos directly at (781) 596-7780. I look forward to continuing the close cooperative relationship between FDA and the Maine Department of Marine Resources.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth A. O'Malley". To the right of the signature, there is a small, stylized mark that appears to be "EAO".

Elizabeth A. O'Malley
Director, State Programs Branch
Northeast Region
US Food & Drug Administration

cc(w/encl): Maj. John Fetterman, DMR
F. Raymond Burditt, FDA
Peter Koufopoulos,
File

EAO/pnk