DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District
State Programs Branch

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MEMORANDUM

To: Amy Fitzpatrick, Director
Public Health Division
Department of Marine Resources

From: Peter Koufopoulos
Regional Shellfish Specialist
USFDA

Date: January 25, 2002

Re: Conditional area verification studies

The 1999 version of the NSSP Model Ordinance references verification studies that are needed to demonstrate that "…sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels." When a conditional area management plan is violated, this study may be used to establish criteria for reopening based on coliform levels in the water. I would like to review the study plans you have generated to address these concerns during the Growing Area program evaluation, which will be scheduled for sometime later this year.

If you have not completed a particular study in a conditional area that is based on non-point source pollution and the area is opening in less than 14 days after closure; please refer to Chapter IV.@.03.C.(2)(c) regarding Management plan requirements and Chapter V.@.02.B regarding the reduction of contamination within shellstock. The contaminant reduction section speaks directly to relayed shellstock; however, it is the guidance for assessing conditional area closures based on non-point source pollution.

The definition of 'study' is open to discussion. It has been recommended that a cross section of samples would be necessary in each of the individual conditional areas (those based on non-point sources of pollution). Due to the uniqueness of any particular conditional area, the parameters of the study will need to be determined on a case-by-case basis.

I would be happy to speak to you, and your staff if necessary, to answer any further questions or review any possible study plans at your request.