MARYLAND DEPARTMENT OF THE ENVIRONMENT
SCIENCE SERVICES ADMINISTRATION

MEMORANDUM

To: Ken Moore, Executive Director, ISSC

From: Kathy Brohawn, Environmental Program Manager, MDE

RE: ISSC Constitution, Bylaws and Procedures – Procedure IX Subdivision e.

Date: April 30, 2015

Maryland Department of Environment (MDE) was found to be in compliance with deficiencies in the 2014 Growing Area Element report and MDE is in disagreement with these findings. MDE does not agree that the program is not meeting all the requirements of the NSSP. MDE does not agree that the items identified by FDA in 2014 represent NSSP deficiencies. MDE took corrective action immediately when the 2014 draft report was provided to staff. We were under the impression that by satisfying these concerns, the final report would have MDE in full compliance. MDE would like to submit our disagreement to the ISSC as an unresolved issue as outlined in Procedure IX. Section 2. Subdivision e. MDE requests the following:

1. Clarity on the 30-day review period for the final report and how that requirement could have changed the outcome of the 2014 Program Element Evaluation Report (PEER) and Annual Program Evaluation Report (APER).
2. What steps are needed to achieve full compliance prior to the next PEER. It is my understanding that there is a period of time for discussions to achieve full compliance before the final report when appropriate. This did not occur for Maryland this year.
3. ISSC review of Chapter IV. @.01 D. (1) (a) to determine whether the following findings constitute a program deficiency.

   While most Sanitary Surveys reviewed were found to be in conformance with the NSSP Model Ordinance, issues were identified in Sanitary Surveys of two of the growing areas assessed. According to MDE, one Growing Area (03-04) has been in the "Closed" status for at least five years and was not identified in its June 2014 Sanitary Survey as being in the "Closed" status. While use of the regulatory authority of the MD Department of Natural Resources to limit harvest for resource management purposes also achieves public health protection by precluding harvest from waters that have not been classified with an adequate Sanitary Survey, the authority for the implementation of the requirements of Chapter IV. of the Model Ordinance in Maryland rests with the MDE. Additionally, it is unlikely that MDE intends all of MD's Growing areas to be in the "Closed" status if they contain an oyster sanctuary. Therefore, MDE must clearly identify where the "Closed" status is in effect. Therefore, the MDE must document in some manner that it has made the decision to place a growing area into the "Closed" status. The

Sanitary Survey would seem to be an appropriate place to document that.

In the Sanitary Survey for another Growing Area (03-03) the Shoreline Survey for a portion of the area that was recently upgraded (Fishing Creek) was not included or referenced in the report. Another portion of this Growing Area that is adjacent to harvestable waters has not had a Shoreline Survey in more than 12 years. Growing Area 03-03 is adjacent to Growing Area 03-06 which was similarly found to be missing a Shoreline Survey in FDA's 2012 Evaluation of the MD Growing Area Classification element. As a result of the FDA evaluation in 2012, MDE reactivated the missing Shoreline Survey Area (#286) and discovered a marina and 12 homes that had never been connected to the sewage collection system.

Completion of Shoreline Survey for all areas (whether sewered or not) is a key component of the NSSP and a requirement of the Model Ordinance. Since FDA can only assess a subset of the State's Growing Area, it is conceivable that there may be additional locations where Shoreline Survey information is not available to support classification decisions. Therefore, it is important that MDE complete the actions described under "Corrective Actions" in the FY 2012 MD Growing Area PEER report of "reviewing MD's other growing areas to assure that all other Shoreline Survey areas are being assessed within the time frames required by the NSSP."

Action Plan
No action plan was deemed necessary given the actions that MDE is taking already.

I have included a timeline to explain the events which have led to the MDE disagreement with FDA findings.

Timeline:

1. FDA spent at least 10 days with field staff in June 2014
2. FDA spent June 9-10, 2014 in central office for file review
3. Between June 2014 and November 12, 2014- FDA never mentioned that MDE was in non-compliance or in compliance with deficiencies.
4. November 13, 2014- MDE received draft PEER- Growing Area Element stating that MDE was in non-compliance with the NSSP and were notified that we had until November 19, 2015 to respond.
5. MDE contacted FDA immediately with concerns about the findings and seeking remedy before the report was final. FDA agreed to a meeting at MDE November 18, 2015.
6. At the November 18 meeting, MDE agreed to address the issue of sewered areas due to the serious nature of finding our program deficient. MDE demonstrated to FDA that all corrections would be made quickly and by the end of January at the latest. The

corrections were to incorporate some sewered areas into existing surveys or create new survey areas and have them routinely scheduled.

7. No Action Plan required.
8. No NSSP MO references were provided for the deficiencies.
9. January 21, 2015- MDE provided FDA with all "corrections" and actions taken to mitigate all deficiencies noted in the 2014 PEER for growing areas (attached). Not only were corrections made, but all new shoreline surveys were completed.
10. February 2, 2015 – letter sent by MDE to FDA requesting that the report be changed.
11. March 12, 2015 letter received by MDE from FDA refusing to change report or acknowledge that all corrective actions have been completed. FDA referenced sections of the NSSP MO as deficient in this letter, suggesting that Sanitary Surveys were incomplete. MDE disagrees with this response from FDA.

After receiving the 2012 final report in November of 2014, MDE noticed that our responses to concerns about sewered areas were not acknowledged in the final 2012 PEER. In 2012, FDA recommended MDE create new boundaries and schedules for additional shoreline surveys in areas served by public sewer. At that time, MDE responded verbally and/or modified the draft report that the majority of sewered areas were already included in the existing boundaries of named shoreline survey areas. In addition, the few areas served by public sewer and not incorporated in existing shoreline survey boundaries are adequately addressed as follows:

- Monthly observations of areas during routine monitoring activities by boat
- There is detailed information about these areas in the Sanitary Survey
- Maryland has a State mandated regulation that requires reporting of any type of sewage spill or by-pass within 24-hours to MDE Compliance Division and the local health department.
- A written follow-up within 5 days of the incident is also required by regulation.

These State requirements in addition to MDE's relationship with our own Compliance Division, local environmental health agencies, and monthly observations via monitoring vessels more than adequately address the concerns first noted in the 2012 PEER. These concerns were never discussed in 2013 and after spending many hours with staff in 2014; our FDA Regional Specialist never indicated that MDE was deficient in meeting MO requirements until MDE received the draft 2014 PEER. Since 2012, no specific NSSP Model Ordinance reference for a deficiency has been included in the PEER.

During the November 18, 2014, meeting to discuss program deficiencies, FDA did not question Maryland's current growing area classifications in these areas nor did FDA cite Model Ordinance requirements associated with the FDA identified deficiencies. Model Ordinance references were not provided until MDE received the March 12, 2015, letter from FDA which was a response to the February 2, 2015, letter to FDA from MDE. At this meeting, FDA agreed with MDE's proposed corrective actions and no action plan was required. FDA never suggested that drive through surveys or boat surveys had to be completed to address the deficiency only that new lines be drawn and that the areas be incorporated into our routine shoreline survey schedule. Before the draft report was final MDE requested that the 2014 PEER reflect that MDE was in full compliance since all corrections could be made in a timely fashion. Our Regional Shellfish Specialist indicated that only the Regional State Cooperative Program Manager could make that decision.

MDE sent a letter to Joann Givens, Acting Regional Food & Drug Director dated February 2, 2015 (attached) to request that Maryland's 2014 Shellfish Program Element Evaluation Report for the growing area classification element of Maryland's State shellfish program be changed. FDA responded on March 12, 2015, refusing to remove the corrected deficiencies from the PEER report and refusing to acknowledge all corrective actions had been completed.